A comparative Clinical Study of Intrathecal Hyperbaric Bupivacaine 0.5% with 25 mg Pethidine Versus 25 mg Tramadol for Infraumbilical Surgeries

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ABSTRACT

Introduction: Requirement of post operative pain relief is mandated due to therapeutic reasons. It was this need of a cost effective but efficient mode of additional post operative analgesia which prompted us to study and compare the quality of analgesia and complications of intrathecal administration of Pethedine and Tramadol along with intrathecal hyperbaric Bupivacaine. Design: This was a prospective, randomised, double-blind study.

Material and methods: 60 patients of American Society of Anesthesiologists Grade I and II randomized into two groups using Envelope method. Group A:- Subarachnoid block given with [3ml 0.5% Bupivacaine heavy + 25 mg Pethedine]. Group B:- Subarachnoid block given with [3ml 0.5% Bupivacaine heavy + 25mg Tramadol]. Outcome measures: Patients were observed for any haemodynamic changes, side effects and complications viz Hypotension, Bradycardia, Pruritis, Sedation, Nausea, Vomiting, Shivering and any other side effects and managed accordingly upto a period of 8 hours post-operatively and for post operative analgesia.

Results: Mean duration of postoperative analgesia in the Pethedine and the Tramadol groups was 316.10±8.27min and 405.60±10.25min respectively (P <0.001). Haemodynamic changes along with incidence and severity of side effects for both Pethidine and Tramadol are similar when used intrathecally as adjuvant to Bupivacaine.

Conclusion: From our study we conclude that both Pethidine and Tramadol can be used intrathecally along with hyperbaric Bupivacaine to effectively prolong duration of post operative analgesia but prolongation is more with Tramadol than with Pethidine. There are similar side effects in both the groups which can be easily controlled with medications

Keywords: Spinal Anaesthesia; Intrathecal Pethedine; Intrathecal Tramadol

INTRODUCTION

Many of the patients fear operation not only because of operation itself, but also due to the pain that they have to suffer post operatively. To increase the duration of analgesia produced by local anesthetics, a number of adjuvants have been added through intrathecal route. Addition of opioids to intrathecal local anesthetics administration has been demonstrated to provide effective post operative analgesia. Tramadol and Pethedine, are two such opioids which are used as adjuvants in spinal anesthesia using 0.5% hyperbaric Bupivacaine.[1-4] The primary objective of the present study was to study and compare the quality of analgesia and complications of intrathecal administration of Pethedine and Tramadol along with intrathecal hyperbaric Bupivacaine.

MATERIAL AND METHODS

The study was conducted at the Department of Anaesthesiology, Gandhi Medical College and Hamidia Hospital, Bhopal. After study approval from Institutional Ethics Committee, written informed consent was obtained from all patients after explaining the nature of the clinical study and the drugs to be used. Patients were drawn from those scheduled for elective operations requiring subarachnoid block for infra umbilical surgery. 60 ASA grade I and II patients are randomized into two groups using Envelope method.

These groups were Group A:- Subarachnoid block to be given with [3ml 0.5% Bupivacaine heavy + 25 mg Pethidine],

Group B:- Subarachnoid block to be given with [3ml 0.5% Bupivacaine heavy + 25mg Tramadol].

Detailed pre anesthetic examination was done. In the operating room, each patient had multi parameter monitor attached. Baseline pulse rate, non invasive blood pressure, oxygen saturation and respiratory rate were obtained and recorded before induction of spinal anesthesia and subsequently during the procedure. A venous access was secured using 16 or 18 gauge cannula and the patient was preloaded with Ringer lactate (10ml/kg) before the induction of spinal anesthesia. Anaesthesiologist who was not involved in the study prepared the spinal solutions. The anaesthesiologist performing the block was blinded to the spinal solution being administered. Lumbar puncture was performed under complete aseptic precautions in sitting or lateral position using 23G lumbar puncture needle.

Time Zero was noted i.e placement of drug in the subarachnoid space. The spinal needle was removed and patient was immediately turned to supine position.

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After that following observation were taken into account for assessing sensory and motor characteristics between the groups.

Along with this we also observed haemodynamic parameters, sedation score and any side effects occurred during the study. Level of sensory block was checked using pin prick test. Surgery was started when sensory block achieved upto T_6 level and this time is noted as onset of sensory block. Each patients was observed for Heart Rate, NIBP, SPO2, Respiratory Rate, ECG during intraoperative period.

Onset of motor block was also noted by noting the inability to move the lower limbs using Modified Bromage scale. To avoid any rostral spread of the drugs, head low position was avoided.

Modified Bromage scale used for Motor block

1. Complete block (unable to move feet or knees)
2. Almost complete block (able to move feet only)
3. Partial block (just able to move knees)
4. Detectable weakness of hip flexion while supine (full flexion of knees)
5. No detectable weakness of hip flexion while supine
6. Able to perform partial knee bend.

Haemodynamic characteristics like heart rate, blood pressure were monitored initially for every 2mins for 10min,there after every 10 mins until the end of surgery.

Patients were observed for any side effects and complications viz hypotension, bradycardia, pruritus, sedation, nausea, vomiting, shivering and any other side effects and managed accordingly intra-operatively and upto a period of 8 hours post-operatively. Hypotension (fall in SBP >20% from baseline), and Bradycardia (HR<60 beats/min) were treated with intravenous boluses of Mephenteramine 6 mg and Atropine 0.6 mg, respectively.

Post-operative monitoring of pain was done every 30mins for next 8 hours according to 10 points VAS score upto >3 or request of rescue analgesia by patient

Patients were also observed for sedation during the surgery with the help of following score.

Sedation Score

Every 2 min from Time Zero [placement of drug in subarachnoid space] to 10 mins and every 10 mins thereafter till completion of surgery.

0: Awake

1: Sleeping comfortably but easily arousable

2: Deep sleep but arousable.

3: Deep sleep but not arousable.

Recorded for every 5 min for 20 mins and then every 10 min till the end of surgery

STATISTICAL ANALYSIS

The qualitative data were expressed in proportion and percentages and the quantitative data expressed as mean and standard deviations. The difference in proportion was analyzed using chi square test and the difference in means were analyzed by using student T Test. Significance level for tests was determined as 95% ($P< 0.05$).

RESULTS

Demographic Data

The two groups were similar in terms of age, weight and height (Table 1) as their difference was statistically insignificant and therefore, comparable for this study.

Sensory Block characterstics

In the present study the onset of sensory blockade was tested by pin-prick method, this has been the commonest method of testing the onset of sensory blockade. The mean time of sensory blockade upto T6 level (Table 2) is 5.60±0.50 min in Group A, and 5.67±0.48 min in Group B. On comparison, $p>0.05$ for these groups which is statistically insignificant. This shows that there was no difference of mean time of onset of sensory blockade between Group A and Group B. The mean duration of sensory blockade (Table 2) was 316.10±8.27 minutes for Group A, 405.60±10.25 minutes in Group B. On intergroup comparison the difference was statistically highly significant for Group A and Group B ($p<0.001$).

Motor block characteristics

In the present study mean time for complete motor blockade**,** was 03.50±0.51 minutes for Group A, 3.60±0.50 minutes in Group B (Table 2). On intergroup comparison, $p>0.05$ for the groups which is statistically insignificant. The mean duration of motor blockade (Table 2) in the present study

variables	Group A		Group B		p value
	Mean	± SD	Mean	± SD	
Weight (kg)	50.60	4.64	51.03	4.94	0.73
Age in years	35.07	13.37	37.73	13.19	0.44
Height (in cm)	159.87	4.71	161.37	3.16	0.15

Table-1: Showing age, weight and height

Variables	Group A		Group B		p value
	Mean	± SD	Mean	± SD	
Duration of surgery (in min)	92.4	12.08	90.00	10.50	0.31
Onset Of Sensory Block (Time to T6)	5.60	0.50	5.67	0.48	0.59
Sensory Block Duration (in min)	316.10	8.27	405.60	10.25	<0.001 [significant]
Motor Block Duration (in min)	195.91	8.90	195.16	9.21	0.74

Table-2: Showing sensory and motor characteristics of both groups

was found to be 195.91±8.90 minutes for Group A and 195.16±9.21minutes in Group B.

Vital Parameters

As seen in (Table 3), both groups are comparable for initial pulse rate, systolic and diastolic blood pressure and respiratory rate**.**

i) Baseline haemodynamic characterstics for these two groups is similar. (Table 3)

The difference in mean pulse rate, mean systolic blood pressure and mean diastolic pressure in both the groups in the study is not statistically significant (p>0.05). Hypotension is an anticipated sequel after neuraxial blockade and it is quite clear that addition of either Tramadol and Pethidine has not increased the severity of hypotension.In all the patients the systolic blood pressure did not fall more than 20mmHg from the baseline value, as all the patients in the present study were of ASA grade I and II and were properly preloaded with 10ml/kg of Ringer's Lactate, no episode of moderate or severe hypotension was encountered.

ii) Respiratory Rate: The mean respiratory rate/min (Table 3) before intrathecal injection in this study were 19.47±1.22 for Group A, 19.09±00.81 for Group B. The difference between pre-injection value and after giving intrathecal injection at different time interval in both groups were statistically insignificant (p>0.05).

Side effects

In the present study incidence and frequency of side effects (Table 4) and complications were closely monitored in intraoperative as well as postoperative period. Both groups have no statistical difference in incidence of side effects

DISCUSSION

The mean duration of sensory blockade (Table 2) was 316.10±8.27 mins for Group A, 405.60±10.25mins in Group B. On intergroup comparison the difference is statistically highly significant for Group A and Group B (p<0.001). Though duration of sensory blockade is prolonged with both, it is more prolonged with Group B. Torres et al 1993[1] Jamadar N. P, Khade Ganesh, et al 2013[2], Devendra Verma, Udita Naithai 2013[3] compared the analgesic efficacy of intrathecal Tramadol and Bupivacaine in moderate to severe postoperative pain. They concluded that intrathecal administration of Bupivacaine with Tramadol prolongs the duration of sensory blockade.

S.C. Yu, W. D. Ngan Kee and A. S. K. Kwan, 2002[4], In a prospective, randomized, double-blind, placebo-controlled trial, investigated the effect of adding Pethidine 10 mg to intrathecal 0.5% hyperbaric Bupivacaine 2.0 ml on the duration of early postoperative analgesia in 40 patients having elective Caesarean section under spinal anaesthesia. Their conclusion is similar to result of our study of prolongation of postoperative analgesia of 234.10±7.27. In our study duration of sensory blockade is more due to increased dose of both Bupivacaine and Pethidine. Susmita Chakraborty, et al 2008[5], studied the effect of intrathecal Tramadol with Bupivacaine for major gynaecological surgeries.They also concluded the increase in sensory blockade after adding Tramadol which is similar to our study.

Catalay, M Aksoy, et al 2010[6], compared intrathecal hyperbaric Bupivacaine with different doses of Pethidine, administered sequentially, with regard to blood pressure stability, post-operative analgesia and incidence of side-effects in 80 parturients undergoing caesarean section. Our study shows similar results with this study for Pethidine, the only difference is that the duration of sensory blockade is more in our study which may be explained by the higher dose of intrathecal Bupivacaine 15mg which was used in our study.

Variables	Group A		Group B		p value
	Mean	± SD	Mean	± SD	
Pulse Rate	75.40	4.04	77.47	6.01	0.12
Systolic BP	121.27	10.90	119.97	6.40	0.57
Diastolic BP	81.07	8.77	77.83	6.04	0.11
Respiratoryrate	19.47	1.22	19.03	0.81	0.111

Table-3: Showing baseline data of both groups

Side effects	Group A [30]	Group B [30]	Total	P value
Hypotension	2	3	5	0.64
	6.7%	10.0%	8.3%	
Bradycardia	1	2	3	0.55
	3.3%	6.7%	5.0%	
Respiratory depression	0	0	0	NA
	0.0%	0.0%	100.0%	
Pruritis	0	0	0	NA
	0.0%	0.0%	0.0%	
N/V	2	2	4	1.00
	6.7%	6.7%	6.7%	
Shivering	0	0	0	NA
	0.0%	0.0%	0.0%	

Table-4: Showing side effects in both groups

Subedi, B.K. Biswas, M. Tripathi, B.K. Bhattarai, K. Pokharel, 2013[7], studied the effect of intrathecal Tramadol on spinal block characteristics and neonatal outcome after elective caesarean section. Median duration of postoperative analgesia in the Tramadol group was 300 [240–360] min which is less than our study as we use higher dose of Bupivacaine and Tramadol.

Torres et al (1993)[1] compared the analgesic efficacy of intrathecal Tramadol and Fentanyl with bupivacaine in moderate to severe post operative pain. There was no effect on the time of onset and duration motor blockade in any of the groups. J.A. Alhashemi et al (2003)[8] and Susmita Chakraborty et al (2008)[5] found no significant change in the onset and duration of motor block by addition of Tramadol to hyperbaric bupivacaine.

Torres et al (1993)[1], M. Ravishankar et al (2002)[9], Sushmita Chakraborty et al (2008)[5] found no significant change in pulse rate and blood pressure in their respective studies when used Tramadol intrathecally as an adjuvant. A. M. Kaki et al (2003)[10] in his study found that there was good hemodynamic stability with intrathecal Tramadol added to Bupivacaine. These observations were similar to the present study.

C Atalay, M Aksoy et al 2010[6], concluded in their study that Pethidine intrathecally provided better blood pressure stability.Similarly Imarengia, Asudo FD et al (2011)[10] found better haemodynamic stability in their study after combining Bupivacaine and Pethidine for caesarean section intra thecally.

Majority of workers who evaluated the hemodynamic effects of intrathecal Tramadol or Pethidine have found them safe.

The difference between pre injection respiratory rate and that after giving intrathecal injection in both groups were statistically insignificant ($p>0.05$). These observations were supported by various studies. Torres et al (1993)[1,] M. Ravishankaret (2002)[9], A. M. Kaki et al(2003)[8] and Susmita Chakraborty et al(2008)[5] found that intrathecal Tramadol in their respective study doses, with hyperbaric Bupivacaine does not cause respiratory depression. Similarly no respiratory depression is found by Imarengiaye et al 2011[10], C Atalay et al 2010[6], Abdolreza et al 2012[11], Hiral et al 2009[12], in their study for intrathecal Pethidine.

Side Effects

Incidence and severity of side effects were comparable in both groups which is similar to other studies. JM Afolayan, Olajumoke et al (2014)[13], Susmita Chakraborty et al (2008)[5] found minimum side effects and which are well tolerated by the patient studied for intrathecal Tramadol.

Imarengiaye CO, Asudo et al (2011)[10], C Atalay, M Aksoy et al (2010)[6] found intrathecal Pethidine safe with minimum side effect similar to this study. Iarengiaye CO, Asudo et al 2011[10] found mild nausea which is acceptable. Frikha et al 2008[13] reported higher frequency in vomiting and a high incidence of itching might be associated with high dose of Tramadol 50mg used intrathecally.

Chen et al 1993[15] and Roy JD et al 2004[16] reported that the administration of intrathecal Pethidine significantly reduced the incidence of shivering.

Nguyen Thit et al 1994[17] studied spinal anesthesia with Pethidine as the sole agent for caesarean delivery found an incidence of pruritus of 10.7 – 32% with the use of 50 mg of intrathecal Pethidine. M. Ravishankar et al 2002[9] and Susmita Chakraborty et 2008[5] recorded no itching in the group treated with Tramadol in their studies which was in agreement with the current study.

No incidence of urinary retention could be identified as all patients were catheterized intraoperatively till post-operative period.

CONCLUSION

Following conclusions are drawn from the present study**:**

The onset of analgesia and block is similar to both for Pethidine and Tramadol when used as adjuvant to intrathecal Bupivacaine. Duration of analgesia is prolonged in both Pethidine and Tramadol but it is more for Tramadol. Haemodynamic changes are similar for both Pethidine and Tramadol. Incidence and severity of side effects for both Pethidine and Tramadol are similar when used intrathecally as adjuvant to Bupivacaine.

Thus, from our study we conclude that both Pethidine and Tramadol can be used intrathecally along with hyperbaric Bupivacaine to effectively prolong duration of post operative analgesia but prolongation is more with Tramadol than with Pethidine. There are similar side effects in both the groups which can be easily controlled with medications.

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