TO COMPARE THE EFFECT OF INTRATHECALLY ADMINISTERED TRAMADOL PLUS BUPIVACAINE WITH BUPIVACAINE ALONE ON THE DURATION OF POST OPERATIVE ANALGESIA

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ABSTRACT

Objective: To asses the efficacy of addition of tramadol to bupivacaine in prolonging the duration of post operative analgesia in spinal anaesthesia.

Study Design: Double blinded randomized controlled clinical trial.

Methodology: One hundred ASA I–II patients listed for urological surgery were randomized to two groups of 50 patients each. Group A (n=50) received 2 ml of 0.75% hyperbaric bupivacaine (15 mg) with 0.2 ml of normal saline and Group B (n=50) received 2 ml 0.75% hyperbaric bupivacaine and 0.2 ml (20 mg) tramadol by intrathecal route at L3-4 inter space. Standard monitoring of the vital parameters was done during the study period. Postoperatively, the pain score was recorded by using visual analog pain scale (VAS) between 0 and 10 (0 = no pain, 10 = most severe pain). The patient was medicated and the time was recorded. Duration of analgesia or pain free period was estimated from the time of completion of spinal injection to administration of rescue analgesic administered on demand or when the VAS score was greater than 4. Diclofenac 75 mg was given intramuscularly as rescue analgesia.

Results: The duration of analgesia was 216 ± 12.18 min in Group A; whereas, in Group B, it was 392 ± 11.78 min, which was found to be extremely statistically significant. P-value less than 0.0001.

Conclusion: In conclusion, this study has demonstrated that tramadol 20 mg when added to 0.75% hyperbaric bupivacaine intrathecally, significantly prolongs postoperative analgesia after major urological surgeries.

Key Words: Spinal anaesthesia, bupivacaine, intrathecal, post operative analgesia, tramadol.

INTRODUCTION

Spinal anaesthesia is one of the most versatile regional anaesthesia techniques available. Regional anaesthesia offers several advantages over general anaesthesia. It blunts stress response to surgery, decreases intraoperative blood loss, lowers the incidence of postoperative thromboembolic events, and provides analgesia in early postoperative period. Spinal anaesthesia provides adequate anaesthesia for patients undergoing infraumbilical surgery. The most important disadvantage of single injection spinal anaesthesia is the limited duration. Adjuvants have long been used along with local anesthetics to prolong the duration of post operative analgesia. Prolongation of pain relief by various adjuvants including morphine[1], fentanyl[2,3], ketamine[4], clonidine[5], neostigmine[6], midazolam[7], dexmedetomidine[8], magnesium sulphate[9] sufentanil[10] and bupenorphine[11] were investigated by various investigators. Intrathecal opioids are a popular additive to enhance the potency and duration of the neuroaxial blockade and they lengthen the postoperative pain free period.[12] But opioids are associated with side effects like pruritus. Postoperative nausea and vomiting, urinary retention and respiratory depression.[13]

Tramadol is synthetic 4-phenyl piperidine analogue of codeine without having respiratory depressant effect.[14] Tramadol is a centrally acting analgesic that has a low affinity for opioid receptors and its about 5-10 times less potent than morphine as an analgesic. Its analgesic potency is equal to pethidine. It provides effective long lasting analgesia after extradural administration in both adults[15] and children.[16-17]

Therefore, this study was undertaken, to assess the effect of intrathecally administered tramadol with bupivacaine, on the duration of post operative analgesia in patients undergoing major urological surgeries.

MATERIAL AND METHODS

It was a double blind randomized clinical trial. After obtaining institutional approval and written informed consent from all patients, 100 ASA (American Society of Anesthesiologists) I and II patients, both male and female between the ages of 18-60 year who were undergoing different urological procedures under spinal

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anaesthesia were enrolled in the study. Patients with a history of allergy to the drugs used, gross spinal deformity, peripheral neuropathy or having contraindication to regional anesthesia were excluded from this study. All patients were examined preoperatively, and details regarding clinical history and general physical examination were recorded. All routine investigations were carried out and informed written consent from all the participants was obtained. During the pre-anesthetic visit, every patient was familiarized with linear visual analog scale (VAS 0 = no pain and 10 = worst imaginable pain).[18] Patients were kept fasting for 6 h and premedicated with oral alprazolam 0.25 mg at the previous night. In the operating room, after the establishment of intravenous (IV) line and attachment of standard monitors including non-invasive blood pressure (NIBP), electrocardiography (ECG), and pulse oximetry (SpO2). In the operating room, each patient received intravenous hydration with Ringer's lactate solution (10 ml/kg), before the induction of spinal anesthesia. A second anesthetist, who was otherwise uninvolved in the study, prepared the spinal injection solution. The anesthetist performing the block was blind to the solution administered and to the postoperative observations. Under all aseptic precautions, spinal anesthesia was administered in sitting position with 27 G Quencke needle at the L3-L4 interspace and the study drug injected. The patients were randomly allocated to two groups - Group A (n=50) and Group B (n=50). Group A (n=50) received 2 ml of 0.75% hyperbaric bupivacaine (15 mg) with 0.2 ml of normal saline and Group B (n=50) received 2 ml 0.75% hyperbaric bupivacaine and 0.2 ml (20 mg) tramadol by intrathecal route at L3-4 inter space. The time of the intrathecal injection was noted and the patients were put in lithotomy position. Sensory testing was assessed by loss of pinprick sensation to 25G hypodermic needle and dermatomes levels were tested every 2 min until the highest level had stabilized by consecutive tests. On achieving T-7 sensory blockade level, surgery was allowed. Oxygen (4 L/min) was administered via a mask if the pulse oximeter reading decreased below 90%. Hypotension, defined as a decrease of systolic blood pressure by more than 20% from baseline or a fall below 90 mmHg, was treated with incremental IV doses of ephedrine 5 mg and IV fluid as required. Bradycardia, defined as heart rate < 50 beats per minute, was treated with IV atropine 0.3–0.6 mg. The incidence of adverse effects, such as nausea, vomiting, shivering, pruritus, respiratory depression, sedation, and hypotension were recorded. Postoperatively, VAS score was noted every 30 minutes for six hours and the time was recorded when the VAS score was 4 or when the concerned patient demanded rescue analgesic in the form of intramuscular diclofenac sodium. Data was collected and the results were subjected to statistical analysis before making conclusions and results. Statistical analyses were performed using SPSS (Statistical Package for Social Sciences) Quantitative variables were expressed as mean + SD (standard deviation), while qualitative variables were expressed as percentage. All the parametric data were analyzed by Student's t test and nonparametric data by Chi-square test, and

Table 1: Demographic Data

Variable	Group A	Group B	P-Value	Significance
Age (years)	46.56±12.63	42.71 ± 11.75	0.1178	Not significant
Sex (M:F)	35 : 15	38 : 12	0.6529	Not significant
Weight (Kg)	73.13±05.86	72.43 ± 06.54	0.5743	Not significant

Table 2: Duration of analgesia between Group A and Group B

Variable	Group A	Group B	P-Value	Significance
Pain-free period (minutes)	46.56±12.63	42.71 ± 11.75	0.1178	Not significant
	216 ± 12.18	392 ± 11.78	< 0.0001	Extremely Significant

Table 3: Side Effects

Variable	Group A (n=50) No of Pts	Group A (n=50) No of Pts	P-Value	Significance
Nausea	1	2	1.0000	Not significant
Vomiting	0	1	1.0000	Not significant
Pruritus	0	1	1.0000	Not significant
Bradycardia	1	0	1.0000	Not significant
Hypotension	3	2	1.0000	Not significant
Resp Depression	0	0	—	—
Sedation Score	2 ± 0.5	2 ± 0.2	1.0000	Not significant

the result was considered to be significant (P <0.05).

RESULTS

There were no statistically significant differences among the groups regarding age weight and sex (Table 1). The duration of analgesia or pain free period in Group A was 210 ± 10.12 min, whereas, in Group B, it was 380 ± 11.82 min, as shown in (Table 2) which was found to be extremely statistically significant. P-value less than 0.0001.

Side-effects observed (Table 3) in this study included hypotension, bradycardia, nausea, vomiting, pruritus, respiratory depression and sedation score. No clinically significant changes were observed in the heart rate, blood pressure, respiratory rate and sedation score in each of the two groups, intra operatively and/or postoperatively. No patient had residual neurological deficit, postdural puncture headache or transient neurologic symptoms.

DISCUSSION

Tramadol, is a centrally acting weak μ-receptor agonist, inhibits noradrenaline re-uptake as well as promotes seratonin release and can be used to treat moderate and severe pain.[19] In addition to its systemic effect, the local anesthetic effect of tramadol on peripheral nerves has been shown in both clinically and laboratory studies.[20] More complete data have been produced the effect of tramadol on the release of monoaminergic neurotransmitters in the central nervous system and its agonist action at peripheral and central opioid receptors. Desmolues and co-workers[21] have confirmed in humans that the analgesic effect of tramadol is apportioned between the opioid and monoaminergic components. Pang et al[22] observed a local anesthetic effect with intradermal injection of tramadol and lignocaine. Jou et al[23] suggested that tramadol affects sensory and motor nerve conduction by a similar mechanism to that of lignocaine which acts on the voltage dependent sodium channel leading to axonal blockage.

Our results showed that tramadol 20 mg when added to 0.75% hyperbaric bupivacaine intrathecally, significantly prolongs postoperative analgesia after major urological surgeries without any clinically significant side effects.

Chakraborty et al[24] has studied the effect of intrathecal tramadol (20mg) added to bupivacaine in patients undergoing major gynecological surgery and they found that the duration of analgesia provided by intrathecal administration of 20 mg tramadol with 15 mg of 0.5% hyperbaric bupivacaine was significantly longer than that provided by intrathecal bupivacaine alone. They found using dose of 20mg of tramadol intrathecally with 15 mg of 0.5% hyperbaric bupivacaine can prolongs postoperative analgesia without serious adverse effects after major gynecological surgeries.

Mostafa and colleagues[25] concluded that intrathecal administration of tramadol and intrathecal nalbuphine when used with 0.5% bupivacaine had a similar postoperative analgesia in the patients without producing significant related side effects like nausea, vomiting, pruritus and respiratory depression.

CONCLUSION

In conclusion, this study has demonstrated that tramadol 20 mg when added to 0.75% hyperbaric bupivacaine intrathecally, significantly prolongs postoperative analgesia after major urological surgeries.

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