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Comparative Study of Intrathecal Tramadol Versus Fentanyl With Hyperbaric Bupivacaine (0.5%) In Lower Segment Caesarean Section

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Abstract: *Background: The aim of this study is to compare analgesic efficacy of intrathecal tramadol & fentanyl in combination with hyperbaric bupivacaine (0.5%) in lower segment caesarean section under spinal anaesthesia.*

Methods: 60 patients of ASA status I and II scheduled for elective lower segment caesarean section were randomly divided into two groups. Group BT was administered hyperbaric bupivacaine 10 mg + tramadol 10 mg, group BF was administered hyperbaric bupivacaine 10 mg + fentanyl 10 µg. Our primary objective variable is to assess and compare duration of post operative analgesia and secondary variables include comparison of time of onset and duration of sensory and motor block, hemodynamic variables and to compare proportion of cases with complications between the two groups.

Results: Intrathecal tramadol and intrathecal fentanyl acted synergistically to potentiate bupivacaine induced sensory spinal block. Duration of analgesia was significantly higher in group BT (302.1±55.2 min) as compared to group BF (262.6±40.7 min). Mean time to two segment regression was significantly longer in group BT (76.0±13.4 min) than group BF (66.5±8.2 min).

Conclusion: Intrathecal tramadol is superior to fentanyl as an adjuvant to hyperbaric bupivacaine as it produced longer duration of postoperative analgesia without causing hemodynamic instability and any other adverse effects.

Keywords: *Fentanyl, LSCS, Spinal anaesthesia, Tramadol, postoperative analgesia*

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I. Introduction

Spinal anesthesia is preferred means anaesthesia for obstetrics and gynecological surgery as it has several advantages over general anaesthesia. Various local anaesthetics like lidocaine, bupivacaine, 2-levobupivacaine, ropivacaine are in use but bupivacaine is most commonly used. [1, 2].

Caesarean section involves traction of peritoneum and gut handling resulting in visceral pain which is poorly localized. This type of pain requires more intense block so higher doses of hyperbaric bupivacaine is required. Increasing the dose of local anaesthetic increases the risk of higher block. Various adjuvant opiods have been used in order to provide good operation condition with better patient acceptance, reduction in local anaesthetic dose, prolonged post operative analgesia. [3]

Fentanyl is a potent lipid soluble synthetic µ-opioid agonist, with a rapid onset and short duration of action. Tramadol is a weak opioid analgesic with atypical profile. The purpose of present study was to compare anaesthetic & analgesic effectiveness of intrathecal tramadol & fentanyl in combination with hyperbaric bupivacaine (0.5%) in lower segment caesarean section.

II. Material & Methods

This hospital based, prospective, randomized, double blind, comparative, interventional study was conducted after the approval of institutional ethics committee and obtaining written informed consent from all patients before participation. 60 patients of ASA grade I and grade II, 20-40 years of age, weighing between 40-70 kg, scheduled to undergo lower segment caesarean section were enrolled and randomized into two groups,

using opaque sealed envelope method. A total of 60 envelopes (30 per group) were made, each envelope mentioning a particular study group. One of my colleagues asked the patient to pick up an envelope from the box. Patients were allocated to group mentioned on the envelope. Study drug was loaded by my colleague who did not participate further in study and was administered by me to the patient.

Group BT (n=30) : Patients received 10 mg of 0.5% hyperbaric bupivacaine(2ml) + tramadol 10 mg(0.2ml).(total volume 2.2 ml)

Group BF (n=30) : Patient received 10 mg of 0.5% hyperbaric bupivacaine(2ml) + fentanyl 10μg(0.2ml)(total volume 2.2 ml)

This trial was so planned that neither the doctor nor the participant were aware of the group allocation and the drugs received.

Sample size was calculated to be 24 subjects in each of the two group at alpha-error 0.05 & study power 80% assuming expected difference in mean duration of analgesia to be 50($\pm$60) (as per seed article).Hence for study purpose 30 subjects were taken in each of the two groups in order to compensate for drop outs.

Exclusion criteria were uncooperative patients, Patient with history of hypertension, respiratory, cardiac, hepatic or renal disease (necessitating classification in ASA Class III or above). Patients having obesity, contraindication for spinal anaesthesia and allergic to study disease were also excluded from study.

Thorough pre anesthetic check up done one day prior to surgery, written informed consent was obtained after detailed explanation about the study protocol and study drugs.

After checking informed written consent and overnight fasting status, patient was taken on the operation table. A good IV line was secured with 18G cannula and Monitoring of heart rate (HR), noninvasive blood pressure (NIBP), electrocardiogram (ECG) and oxygen saturation (SpO2) was established. Baseline vital parameters like HR, BP and SpO2 were recorded. Infusion of ringer lactate was started at the rate of 10ml/kg. Under all aseptic precautions spinal anaesthesia was performed at $L_3 - L_4$ interspace, with the patient in the left lateral position and study drug was given as per group assigned using 25-gauge spinal needle. Patient was placed in supine position with a slight head low tilt immediately after spinal injection to achieve level of block up to T6.

Intra-operative sensory loss assessment includes the pin prick test at every 2 minutes for 20 minutes after spinal injection, at the end of surgery and in recovery room until S2 segment regression.

Motor blockage was assessed by Modified Bromage Scale. Blood pressure, heart rate and Spo2 were monitored every 2 minutes for first 10 minutes, then after every 5 minutes throughout surgery.

Hypotension was defined as decrease in mean arterial pressure greater than 15% below the baseline value, was treated by incremental doses of inj. mephentermine 6 mg intravenously.

Bradycardia was defined as decrease in heart rate below 50 beats/min, was treated with incremental doses of atropine 0.01mg/kg intravenously. Intraoperative nausea or vomiting was treated with 5mg Ondansetron.

In postoperative period Visual Analogue Scale, Duration of motor and sensory block and adverse effects were noted. Patients were allowed to receive rescue analgesics on demand. Mean duration of analgesia was measured as time from the Intrathecal drug administration to the patient's first request for analgesics or VAS>3. Patient's first request for rescue analgesia constituted the end point of the study.

The **onset of sensory block** was defined as the time from the intrathecal injection of the bupivacaine to the time taken to achieve the T5-T6 level of sensory block. This was assessed by pin prick test bilaterally in mid clavicular line by using 25G hypodermic needle, every 2 minutes till the highest level of the block was reached (0- Sharp pain,1- Touch sensation only, 2- Not even touch sensation).

Regression of sensory block was defined as the time taken for the sensory block to regress upto 2 segments of dermatome from the highest level achieved.

Onset of motor block was defined as the time from intrathecal injection to the time taken to achieve complete motor block.

Duration of motor block was assessed by recording the time elapsed from the maximum to the lowest Bromage score.

Post operative pain analysis was done by visual analogue scale (VAS) ranging 0-10. (0- No pain,1,2,3 - Mild pain, 4,5,6- Moderate pain,7,8,9- Severe pain and 10 Worst imaginable pain).VAS score was serially assessed at half an hour interval starting from 60 mins till the patient complains of pain (VAS >3). Intramuscular Diclofenac (75mg) was given as rescue analgesic. Patient was kept under observation for 24

hours for routine post-operative monitoring. The total number of analgesic doses required in 24 hours was also noted.

Statistical analysis of data was done by using SPSS (Statistical Package for the Social Science) version 20.0.0 (SPSS Inc., Chicago, Illinois, USA). The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data was presented as mean and standard deviation and were compared by student's t-test. Probability was considered to be significant if less than 0.05.

III. Results

There was no significant difference in demographic characteristics between the groups. (Table 1) Onset of sensory block was significantly faster in group BF (4.9±1.3 min) as compared to group BT (5.9±1.8min) while onset of motor blockade was comparable in both groups. Duration of analgesia was significantly higher in group BT (302.1±55.2 min) as compared to group BF (262.6±40.7 min). Mean time to two segment regression was significantly longer in group BT (76.0±13.4 min) than group BF (66.5±8.2 min). Total duration of motor blockade was comparable in both the groups. (Table 2) Hemodynamicaly, there was no significant difference in the incidence of hypotension or bradycardia among both groups. Incidences of side effects like nausea, vomiting and pruritus were comparable in both groups.

Table 1: Demographic variables

Variables	Group BT	Group BF	P value
ASA I/II	27/3	27/3	0.667(NS)
Age(Yrs.)	24.7±3.2	25.6±3.0	0.287 (NS)
Weight(Kgs)	60.4±6.6	62.6±10.7	0.348 (NS)
Height(Cms)	156.1±4.3	149.8±16.8	0.051 (NS)
Duration of surgery (Min)	36.2±7.0	36.5±7.8	0.890 (NS)

Table 2: Characteristics of block

Variables	Group BT	Group BF	P value
Onset of sensory block(min)	5.9±1.8	4.9±1.3	0.041 (S)
Onset of motor block(min)	5.3±3.9	4.6±1.4	0.314 (NS)
Maximum sensory level achieved(T4/T5)	5/25	24/6	0.063 (NS)
Total duration of motor block(min)	126.1±14.0	127.2±14.1	0.749 (NS)
Mean time to two segment regression(min)	76.0±13.4	66.5±8.2	0.002 (S)
Mean duration of analgesia(min)	302.1±55.2	262.6±40.7	0.003 (S)

Table 3: Comparison of VAS score among study groups

Time	Group BT	Group BF	P value
1 hour	0	0	-
2 hour	0.33 ± 0.71	0.5 ± 0.73	0.374
3 hour	2.57 ± 0.97	2.83 ± 1.15	0.335
4 hour	2.37 ± 1.03	2.97 ± 0.89	0.019 (S)
5 hour	2.97 ± 0.81	3.3 ± 0.70	0.094

IV. Discussion

Intrathecal opioid, most commonly used adjutants cause segmental analgesia by binding to opioid receptors in the dorsal horn of the spinal cord. They prolong the duration of analgesia without affecting motor or autonomic nervous function. Their combination with intrathecal local anesthetics limits the regression of the sensory block seen with local anesthetics alone. Respiratory depression is the most serious side effect of intrathecal opioids. Tramadol, in contrast, is a centrally acting analgesic that has minimal respiratory depressant effects, by virtue of its 6000 fold decreased affinity for μ receptors compared to morphine. [4] The analgesic effect of tramadol is not totally due to opiate agonist effects. Tramadol also inhibits the reuptake of nor epinephrine and serotonin in the central nervous system, which inhibits pain transmission in the spinal cord. Intrathecal tramadol has been used for postoperative analgesia and labour analgesia, and importantly, it appears to have a safe pharmacokinetic profile in the neonate.

Fentanyl is a highly selective μ receptor agonist, has a rapid onset and shorter duration of action following intrathecal administrations. It prolongs the duration of the bupivacaine induced sensory blockade. This suggests a potential synergism between fentanyl and bupivacaine as reported in previous studies. [5, 6] Analgesia is produced principally through interaction with μ receptors at supraspinal sites. Fentanyl also binds to κ receptors causing spinal analgesia, sedation and anesthesia.

The mean duration of analgesia was significantly prolonged in tramadol group as compared to fentanyl group. We also observed that VAS score was significantly higher in group BF as compared to group BT from 4 to 5 hrs post operatively. Results of our study were in accordance to previous studies. [7, 8] They also found that intrathecal tramadol significantly prolongs the duration of pain free period after caesarean section. Same findings also observed by Mostafa G. M. et al [9], Brijesh Jain et al[10] and Prosser D.P. et al.[11]

Mean onset of sensory block was earlier in fentanyl group as compared to tramadol. Results of this study coincides with study of J M Afolayan et al. [12]

Mean time to two segment regression was earlier in group BF as compared to group .Our results were similar to study done by also supported by Subedi et.al. [8]

Patients in both groups remained hemodynamicaly stable in peri-operative period. Alhashemi J.A et al [13] also found that intrathecal tramadol did not seem to influence the intra operative hemodynamic profile. Same findings also with the study conducted by Mostafa G.M. et al. [9]

Pruritus has been reported in 3.3% of patients in group BT & 16.7% of patients in group BF, but none of them was severe enough to be treated.

None of the patients in our study experienced respiratory depression. Baraka A et al [14] and Scott et al [15] also observed that not a single patient had respiratory depression.

V. Conclusion

We concluded that addition of tramadol 10 mg to hyperbaric bupivacaine in subarachnoid block for caesarean section produces a longer duration of pain relief, reduces post-operative analgesic demand in the first 24 hours as compared to intrathecal fentanyl without causing significant change in hemodynamics variables and any adverse effect.

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