ORIGINAL RESEARCH PAPER
Volume - 10 | Issue - 07 | July - 2021 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARISION OF INTRATHECAL FENTANYL VERSUS TRAMADOL WITH HYPERBARIC BUPIVACAINE (0.5%) IN ABDOMINAL AND LOWER LIMB SURGERY AT S.M.S HOSPITAL DURING 2019 TO 2021, A RANDOMISED, INTERVENTIONAL CLINICAL STUDY.

Anaesthesiology

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ABSTRACT

BACKGROUND: The aim of this study is to compare analgesic efficacy of intrathecal fentanyl & tramadol in combination with hyperbaric bupivacaine (0.5%) in abdominal and lower limb surgery under spinal anaesthesia.

METHODS: 60 patients of ASA status I and II scheduled for elective abdominal and lower limb surgery were randomly divided into two groups. Group BF was administered hyperbaric bupivacaine 12.5mg+fentanyl25mcg group BT was administered hyperbaric bupivacaine 12.5 mg + tramadol25mg. Parameters observed were onset of sensory and motor block,highest level of block achieved,degree of motor block, time to two segment regression , time to achieved highest level of block, post operative analgesia period and haemodynamic variables.

RESULTS: Intrathecal fentanyl and intrathecal tramadol acted synergistically to potentiate bupivacaine induced sensory spinal block. Duration of analgesia was significantly higher in group BT (266.30±18.07 minute) as Compared to group BF (253.36±16.51 min).Mean time to two segment regression was significantly longer In group BT(158.33.0±8.90 min) than group BF (125.30±6.18 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

KEYWORDS

Tramadol, Abdominal and Lower Limb Surgery, Spinal anaesthesia, Fentanyl,Bupivacaine

I. INTRODUCTION

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

Abdominal surgeries involves traction of peritoneum &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 equired. Increasing the dose of local anaesthetic increases the risk of higher block. Various adjuvant opioids 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. Primary outcome of this study was to asses and compare the difference in mean time duration and need of first resque analgesia between the groups The secondary outcome was to find out the difference in mean onset time duration of sensory and motor block between the group, and the difference in no. of resque analgesia in first 24 hours in post operatively period between the groups. The aim of this study was to compare anaesthetic & analgesic effectiveness of intrathecal fentanyl and tramadol in combination with hyperbaric bupivacaine (0.5%) in abdominal and lower limb surgery.

II. MATERIAL & METHODS

This hospital based, randomized, double blind, study was conducted after the approval of institutional ethics committee(167-{27}/MC/EC/2020) and obtaining written informed consent from all patients before participation. 60 patients of ASA grade I and grade II, 30-60 years of age, weighing between 40-70kg, scheduled to undergo abdominal & lower limb surgery were enrolled and randomized into two groups.

By using opaque sealed envelope method. A total of 60 envelopes (30 per group) were made, each nvelope mentioning a particular study group. 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 colleague who did not participate further in study and was administered by me to the patient.

Group BF (n=30): Patients received 12.5 mg of 0.5% hyperbaric bupivacaine(2.5ml) + fentanyl 25 Mcg (0.5ml). (total volume 3.0 ml)

Group BT (n=30): Patient received 12.5 mg of 0.5% hyperbaric bupivacaine(2.5ml)+tramadol25mg (0.5ml) (total volume 3.0 ml)

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

Sample size was calculated to be 60 subjects in each of the two group at alpha-error 0.05 & study power 80% ,at 95% confidence interval, assuming expected difference in mean duration of analgesia to be 110(+42)(as per seed article (ISSN:2454-9142, impact factor:RJIF5.54).Hence for study purpose 30 subjects were taken in each of the two groups in order to compensate for drop out.

Inclusion criteria were age group between 30 to 60 years, weight between 40to70 kgs, height >145 cms, Patient belonging to ASA class1st and 2nd , Patient undergoing abdominal and lower limb surgery.

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, contra- indication 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 overnight fasting, patient was taken on the operation .table. A good IV line was secured with 20G cannula and Monitoring of heart rate (HR), noninvasive blood pressure (NIBP), electrocardiogram (ECG) and oxygen saturation (SpO2) was established. Baseline vital parameter 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_3L_4 interspace, with the patient in the sitting 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 was done by the pin prick test at every 2 minutes for 10 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 &Spo2 were monitor 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/minute,was treated with incremental dose of atropine 0.01mg/kg intravenously. Intraoperative nausea or vomiting was treated with 5mg ondansetron.

In postoperative period Visual Analoge 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 theT6-T8level of sensory block. This was assessed by pin prick test bilaterally in midclavicular 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 21.0.0 (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 (3.37±1.0 min) as compared to group BT (4.28±0.65min) while onset of motor blockade was comparable in both groups.

Duration of analgesia was significantly higher in group BT (266.30±18.07min) as compared to group BF(253.36±16.51min). Mean time to two segment regression was significantly longer in group BT (158.0±.33 min) than group BF (125.30±6.18 min). Total duration of motor blockade was higher in fentanyl group(193.0±17.31). Hemodynamicaly, there was no significant difference in the incidence of hypotension(p value=0.182) or bradycardia(p value=0.197) among both groups. Incidences of side effects like nausea(p value=0.030), vomiting and pruritis(p value=0.121) were comparable in both groups.

Table 1: Demographic variables

Variables	GROUP BT	GROUP BF	P value
ASA ½	26/4	26/4	0.704(NS)
Age(Yrs.)	45.07± 7.85	44.77± 9.87	0.792(NS)
Weight(Kgs)	52.04±6.69	52.83± 5.81	0.550(NS)
Height(Cms)	167.30± 7.29	167.23±6.44	0.970(NS)
Duration of surgery (Min)	100.77± 10.87	103.33± 10.21	0.349(NS)

Table 2: Characteristics of block

Variables	Group BT	Group BF	P Value
Onset of sensory block (min)	4.28±0.65	3.37±1.0	0.001(S)
Onset of motor block (min)	6.97±1.9	6.07±0.94	0.001(S)
Maximum sensory level achieved(T6/T8)	11/12	12/8	0.503(NS)
Total duration of motor block(min)	155.40± 11.51	193.0±17.31	0.001(NS)
Mean time to two segment regression(min)	158.33± 8.90	125.30±6.18	0.001(S)
Mean duration of analgesia(min)	266.30± 18.07	253.36±16.51	0.005(S)

Table 3: Comparision of VAS Score Among Study Groups.

Time	Group BT	Group BF	P value
1hour	0.0	0.33± 0.76	0.019(S)
1hour	020±0.0	2.23±0.63	0.045(S)
2hour	2.20 ±0.61	4.0±0.0	0.001(S)
4hour	4.0± 0.0	4.0± 0.0	-

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 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 analgesics 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 upto 4 hrs post operatively. Results of our study were in accordance to previous studies[7,8]. They also found that tramadol significantly prolongs the duration of pain free period in abdominal and lower limb surgery. Same findings also observed by Mostafa G. M. et[9], Brijesh Jain et a[10], and professor D.P et al[11]. Mean onset of sensory block was earlier in fentanyl group as compared to tramadol. Result of this study coincides with study of J M Afolayan et al[12]. Mean time to two segment regression was higher in group BT as compared to group BF our result 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 0.0% of patients in group BT & 13.33% of patients in group BF, but noneof 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.

CONCLUSION

It was concluded that addition of tramadol 25 mg to hyperbaric bupivacaine in subarachnoid block for abdominal & lower limb surgery 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.The only limitation was shorter duration of sensory and motor block compared to fentanyl

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