A Comparative Study Of Intrathecal Hyperbaric 0.5% Bupivacaine Alone Versus Hyperbaric 0.5% Bupivacaine With Butorphanol As An Adjuvant, In Lower Abdominal Surgeries

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Abstract: Background: The use of spinal opiates along with intrathecal hyperbaric injection Bupivacaine has become increasingly popular as they potentiate the effect of local anaesthetic agent and improve the quality of analgesia and minimize the requirement of postoperative analgesia. Aim: The aim of this study was to evaluate and compare- Block characteristics, hemodynamics, post operative analgesic efficacy & occurrence of adverse effects. Methods: After approval from institutional ethic committee and informed written consent from patients, this prospective randomised double blind study was conducted on 120 healthy adult patients of ASA status 1 and 2, undergoing intrathecal anaesthesia for lower abdominal surgeries. The patients were randomly assigned into two groups including 60 patients in each group, using "closed envelope method". Group A (n=60) received- Hyperbaric 0.5% Bupivacaine 3.5ml + 0.5 ml of Normal saline (total volume 4 ml). Group B (n=60) received -Hyperbaric 0.5% Bupivacaine 3.5ml + 0.5ml(0.5 mg) of Butorphanol (total volume 4 ml) was given. Results: Time of onset of sensory block at T_8 & onset of motor block was rapid in group B as compared to group A. Mean duration of request for analgesia was 214.66 ±23.52 min in group A and 350.00 ± 29.05 in group B, which was highly significant statistically ($p<0.001$).Mean duration for sensory regression to L_5 was 232.75 ± 20.59 min in group A and 366.66 ± 32.85 min in group B ($p<0.001$). Fall in systolic & diastolic blood pressure and heart rate was more in group B as compared to group A, but it was clinically and statistically not significant. Conclusion: it may be concluded that 0.5mg of intrathecal butorphanol is a good adjunct in spinal anaesthesia, providing good and prolonged post-operative analgesia with minimal side effects. [Jyoti M SEAJCRR 2017; 6(1):10-15]

Key Words: Butorphanol, Hyperbaric 0.5% Bupivacaine, Spinal opiates.

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Introduction: Spinal anaesthesia was introduced into clinical practice by Augustus Karl Gustav Bier in 18981, by administration of cocaine into the subarachnoid space. Spinal anaesthesia is a commonly used technique for lower abdominal surgeries because of the relative ease of administration and also because it provides the additional benefits of decreased surgical stress response, increased myocardial stability, and rapid recovery of bowel function and reduced risk of thromboembolism. Among all available local anaesthetic agents administered intrathecally 0.5% hyperbaric injection bupivacaine has become increasingly popular as it provides sensory and motor blockade for longer duration[2].

The first report on the use of intrathecal opioids for acute pain treatment with 0.5mg spinal morphine was in 1979 by Wang and colleagues[3]. Spinal opiates have been of much interest in recent times[4] as they potentiate the effect of local anaesthetic agent and improve the quality of analgesia and minimize the requirement of postoperative analgesia. Although spinal opioids are used frequently, there are many unresolved disputes on the neurotoxicity of opioids injected into the subarachnoid space.[5,6,7,8].

Recently much interest has arisen on butorphanol as an adjuvant with intrathecal hyperbaric bupivacaine, as it produces antinociceptive effects without any major side effects. Butorphanol is a lipophilic opioid agonist antagonist analgesic with affinity for opioid receptors in vitro of 1:4:25(mu:delta:kappa)9 Its analgesic action is mediated by its interaction with kappa and mu opioid receptors. It has been shown that butorphanol in combination with bupivacaine improves the duration and quality of analgesia as compared to plain bupivacaine, and no fatal adverse effects are seen.

Opioids in conjunction with local anaesthetics improve the quality of intraoperative analgesia and prolong the duration of post operative analgesia10. The mu agonist butorphanol and sufentanyl exert their action by opening the K+ channels and reducing the Ca2+ influx resulting in inhibition of transmitter release[11,12]. A combination of these effects may explain the

observed synergism between bupivacaine and butorphanol/sufentanil. The synergism is characterized by enhanced somatic analgesia without an effect on the degree or level of local anaesthetic induced sympathetic or motor blockade[12].

As very few studies have been reported on the clinical characteristics, with the use of butorphanol intrathecally13.This study has been undertaken to compare the clinical characteristics and analgesic efficacy of intrathecally administered butorphanol combined with 0.5% bupivacaine (heavy) ver sus 0.5% bupivacaine (heavy) alone in patients undergoing lower abdominal surgeries.

Aims & Objective: The aims of this study was to evaluate and compare- Onset & duration of Sensory and Motor block, hemodynamics, post operative analgesic efficacy & occurrence of adverse effects.

Methods: After approval from institutional ethic committee and informed written consent from patients, this prospective randomised double blind study was conducted on 120 healthy adult patients of ASA status 1 and 2, undergoing intrathecal anaesthesia for elective lower abdominal surgical procedures in RIMS, Ranchi.

The patients were randomly assigned into two groups including 60 patients in each group, using "closed envelope method". Group A (n=60) – Hyperbaric 0.5% Bupivacaine 3.5ml + 0.5 ml of Normal saline (total volume 4 ml) was given. Group B (n=60) -Hyperbaric 0.5% Bupivacaine 3.5ml + 0.5ml (0.5 mg) of Butorphanol (total volume 4 ml) was given.

Inclusion Criteria: Patients of either sex posted for elective surgery under spinal anaesthesia, patients who had given written consent, age group between 20-50 years, weight between 40-70kg, ASA grade I and II.

Exclusion Criteria: Patient's refusal, emergency surgeries, ASA grade III and IV, severe anaemia, coagulation abnormalities and bleeding disorders, patients with previous history of surgeries on spine, patients with spinal deformity, patients with history of chronic backache, patients with active skin lesions over the lumbosacral area.

A thorough pre-anaesthetic evaluation was done. The patients were pre-medicated with oral alprazolam 0.25 mg on the night before surgery. On the day of surgery, after identifying the patient, & checking the written informed consent, in the pre-operative room- IV access was obtained with 18G/ 20G IV cannula, patient was preloaded with 1 litre of Ringer Lactate solution & was premedicated with- inj. Ranitidine(50 mg) i.v., inj. Glycopyrrolate 0.2 mg i.v. and inj. Metoclopromide (10 mg) i.v., 30 minutes before induction.

After shifting the patient on a tilting operation table, multipara monitor was attached, and the patient was monitored for basal heart rate (HR), non invasive blood pressure (NIBP), and peripheral oxygen saturation (SpO2). With all aseptic and antiseptic precautionary measures, spinal anaesthesia was given, after explaining the patient about the Spinal Puncture procedure, with the patient in sitting position using a 25-gauge Quincke's needle at the L3-L4 intervertebral space using the midline approach. After confirming the free flow of CSF the study solution (4ml) was injected by a person who was unaware about study. Following the injection, the needle was removed and the patient was turned gently and placed in supine position.

Sensory block was assessed by loss of pain sensation to pin prick with bevelled needle. The onset and degree of motor blockade were recorded according to "Modified Bromage scale". Time since spinal anaesthesia to first complaint of pain and request for rescue analgesia was recorded. Patient's pain was assessed immediate postoperatively, 1, 2, 4, 6, 12, and 24 hours by Visual Analogue Scale (VAS). Any patient with VAS score > 3 was administered Diclofenac sodium (75 mg) intramuscularly. Ramsay sedation scoring was done and noted for each patient in both the groups.

The patients were closely monitored. Pulse rate, blood pressure and oxygen saturation were recorded every 5 minutes for first 30 minutes; every 15 minutes till the end of surgical procedures then every 30 minutes postoperatively upto 6 hour, then hourly upto 12 hour and 2 hourly upto 24 hour.The following complications were looked for: Hypotension was treated with additional intravenous fluids with/without bolus ephedrine hydrochloride 5-10 mg. Bradycardia was treated with inj. atropine sulphate

(0.5 mg) I.V. Respiratory depression was defined as decrease in respiratory rate <10/minute and decrease in O2 saturation (SpO2) less than 90%. Side effects like nausea, vomiting, pruritus, shivering, urinary retention, neurological deficit etc. were recorded. In the recovery room, time from injection until block regression to L5, duration of grade I motor blockade, voiding and ambulation was checked to rule out any adverse motor or neurological deficits and bowel or bladder dysfunction. Throughout the period pulse, blood pressure and oxygen saturation was monitored.

Observations & Results: Different statistical aggregates like mean, standard deviation were used to analyze numerical parameters. Randomization was done by closed enveloped method and Student t test was used to determine the significance of differences between two groups. Differences were considered as - Significant if the p value is < 0.05, Very significant if the p value is < 0.001, not significant if the p value is > 0.05. In our study, the demographic data regarding age, sex, weight & height and duration of surgery were comparable among two groups.

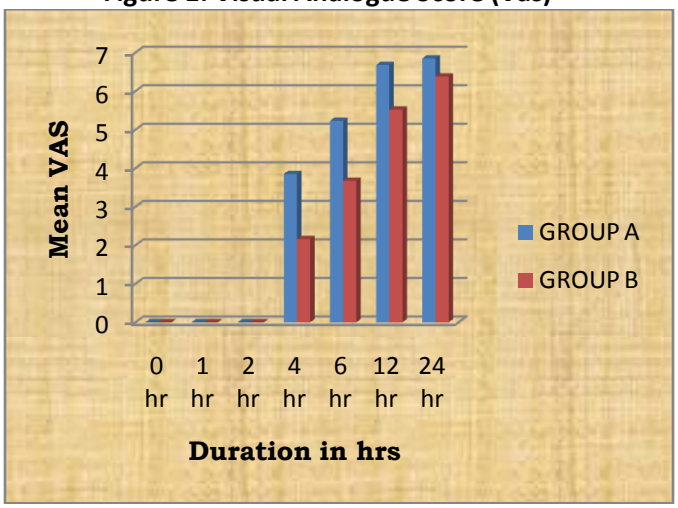
Table No 1: Demographic data & Duration of surgery in group A & B (Mean ± SD)

Variables	Group A (n = 60)	Group B (n = 60)
Age(Yrs)	40.01±6.17	40.83 ± 6.95
Sex(M/F)	19:41	20:40
Weight(kg)	55.10 ± 5.05	55.33 ± 5.76
Height(cm)	156.73 ± 3.98	156.71 ± 3.98
Duration of surgery (Min)	108.66± 23.68	103.91± 24.39

Table No 2: Sensory block, Motor block & Analgesia in group A & B(Mean ± SD)

Parameters	Group A(n=60)	Group B(n=60)	p value
Onset of sensory block at T8(Sec)	303.33± 36.15	287.75±2 6.71	0.0083
Onset of motor block (Grade 3)	368.50 ± 33.38	349.33 ± 42.58	0.007
Duration of motor block (min)	218.50± 15.84	220.75 ± 14.25	0.415
Time of sensory regression to L5	232.75 ± 20.59	366.66 ± 32.85	<0.0001
Time of request for analgesia(min)	214.66± 23.52	350.00±2 9.05	<0.0001

Figure 1: Visual Analogue Score (Vas)



The pain intensity at the time of administration of rescue analgesic and thereafter was less in group B as compared to group A. Any patient with VAS score > 3 was administered Diclofenac sodium (75 mg) intramuscularly as rescue analgesics.

Figure 2: Ramsay Sedation Score

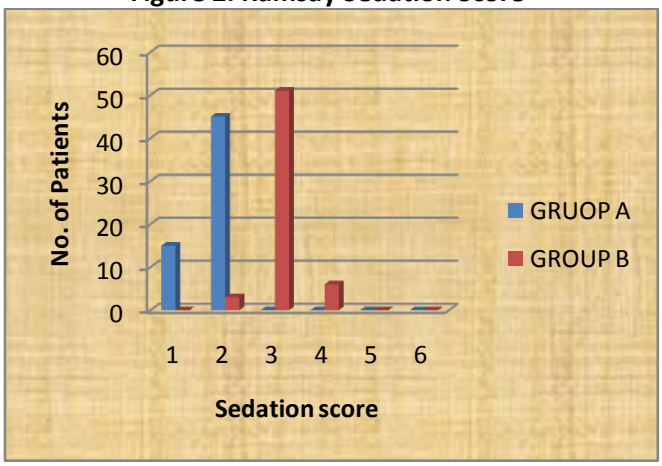


Figure 3: Heart Rate

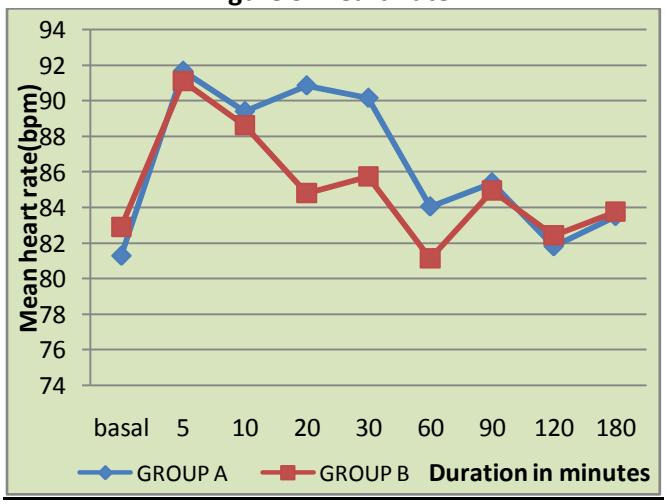


Figure 4: Systolic Blood Pressure

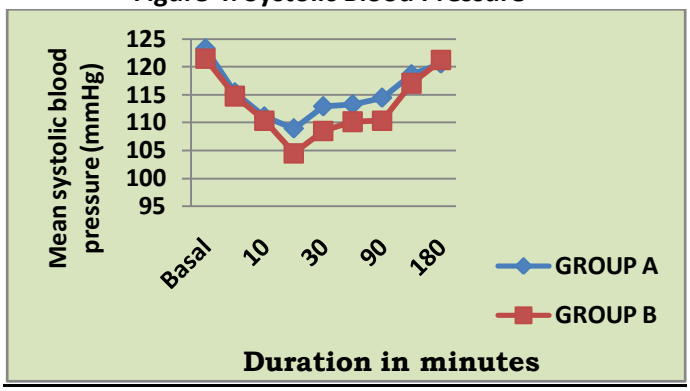


Figure 5: Diastolic Blood Pressure

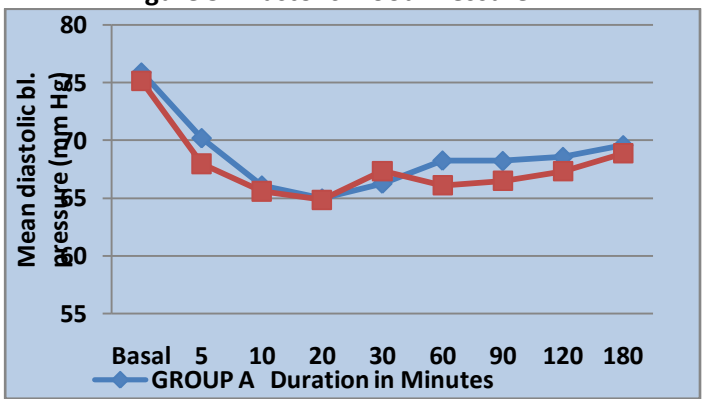


Figure 6: Oxygen Saturation

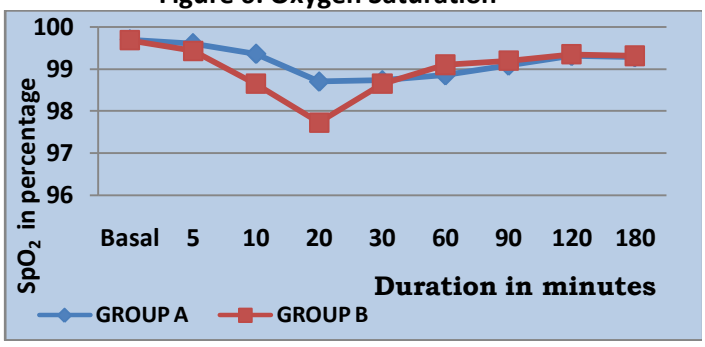
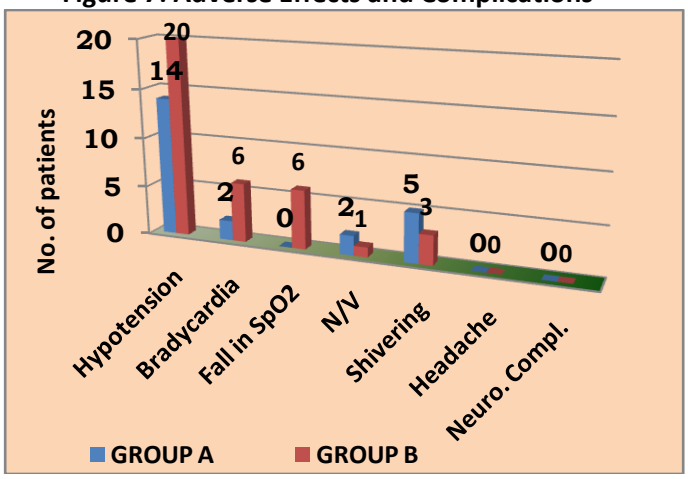


Figure 7: Adverse Effects and Complications



Discussion: Spinal anaesthesia is a commonly employed technique for lower abdominal surgeries. It is safe, inexpensive, easy to administer, and avoids many complications associated with general anaesthesia. In our study we used butorphanol 0.5mg as an adjuvant to intrathecal bupivacaine(0.5%) heavy for lower abdominal surgeries and compared its block characteristics, hemodynamics, post operative analgesia, and adverse effects with intrathecal bupivacaine (0.5%) alone.

The most characteristic finding in our study are, excellent pain relief in the post operative period and increased duration of request for analgesia in the butorphanol group as compared to control group. It may be due to the fact that "antinociceptive synergism exists between LA and intrathecal opioids as demonstrated in various animal studies[14]. In our study the mean duration of time of request for analgesia was 214.66 ±23.52 min in group A and 350.00 ± 29.05 min in group B. Mean Visual Analogue Score (VAS) during postoperative period was statistically significant between two groups (p value < 0.05). VAS was more in group A patients as compared to group B which shows that the pain intensity at the time of administration of rescue analgesics and thereafter was less in group B as compared to group A.

There are various studies which are comparable with our study with respect to post-op analgesic effect of inj butorphanol as an adjuvant intrathecally.

B. Kumar et al in 2011[15] compared intrathecal bupivacaine-fentanyl and bupivacaine-butorphanol mixture for lower limb surgeries and found that Bupivacaine-butorphanol mixture provides longer duration of sensory blockade and superior analgesia than bupivacaine-fentanyl mixture. The patients in the fentanyl group requested rescue analgesia earlier than patients in the butorphanol group.

M. Kaur et al in 2011[16] also found that there was a significant prolonged duration of analgesia in all the patients enrolled in the sufentanil group and the butorphanol group over the bupivacaine-alone group.They also showed that, VAS was of a significantly higher value in group A than in groups B and C. No significant difference in VAS scores was observed between groups B and C (*P*-value < 0.05) this is in corraboration with the present study. Similarly V.

R. Ranga Chari et al in 2013[17] used Inj. Butorphanol intrathecally with hyperbaric bupivacaine in patients undergoing L.S.C.S. and concluded that intrathecal butorphanol potentiates bupivacaine induced sensory spinal block and reduces the analgesic requirement in early post operative period without prolonging motor block recovery time and without any major side effects to the mother as well as neonates.

Our results showed that the onset of sensory and motor block was rapid in the butorphanol group as compared to control group. The mean time for onset of sensory block in group A patients was 303.33 ± 36.15 sec, where as in group B patients it was 287.75 ± 26.71 sec. In contrast to our study, V.R. Ranga chari et al(2013)[17] have shown that there were no significant differences in the onset of sensory and motor blockade between two groups of 30 patients each, who underwent LSCS, group A receiving inj. Bupivacaine 0.5% heavy alone whereas group B receiving inj butorphanol 25µg to intrathecal bupivacaine 0.5% heavy. This disparity in the onset of blockade could be related to lower dose of butorphanol used in this study.

In our study the mean duration for sensory regression to L_5 was 232.75 ± 20.59 min in group A and 366.66 ± 32.85 min in group B, which was very significant ($p<0.001$) between two groups i.e. the duration of sensory blockade was more in butorphanol group than in control group. Several other studies are also consistent with this finding[15,16,17] In our study duration of motor block was significantly not affected by adding butorphanol intrathecally. Hence while providing prolonged duration of post-op analgesia it also helps in early recovery from anaesthesia and early ambulation. Mean duration of motor block was 218.50± 15.84 minutes in group A and 220.75 ±14.25 minutes in group B. (p value > 0.05).It is consistence with the other studies[2,16].

In our study fall in systolic and diastolic blood pressure was observed in both the groups after giving spinal anaesthesia, fall was more in group B as compared to group A, but it was clinically and statistically not significant. Neuraxial administration of opioids has been reported to be associated with hypotension (Singh H, et al, 1995)[18].14 patients had hypotension in group A, while in group B, hypotension was developed in 20 patients, which was easily managed by intravenous fluid or inj. ephedrine bolus as per need Similarly fall in heart rate was observed more in groups B as compared to group A, which was also clinically and statistically not significant.

Our results are comparable with the V.R. Ranga Chari (2013)[17] results which also showed that fall in systolic and diastolic blood pressures was more in butorphanol group as compared with the control group, particularly in the early stages of observation

In our study fall in SpO_2 was observed in six patients in groups B after giving butorphaol intrathecally, which was clinically not significant as it was due to sedation of the patient(all six patients had sedation score 4) and not because of resp. depression and got corrected after awakening the patient, or sometime by supplementing oxygen by mask. Sedation is a reported side effect of neuraxially administered butorphanol[19].

During spinal anaesthesia, as the patient is conscious about the surroundings, most of the time it becomes imperative to sedate the patient which not only allays his/her anxiety but also minimizes awareness about routine operating room proceedings. Intrathecal butorphanol has an added advantage of providing intraoperative sedation thus reducing or even abolishing the need for any other sedative drug.

In our study Ramsay sedation scoring shows that group A patients had sedation score 1 & 2 while group B patients had sedation score 3 & 4 which was a desirable effect for group B patients.

Intraoperative sedation of the patient by giving butorphanol intrathecally along with 0.5% bupivacaine(heavy) was beneficial as it helped in preventing jerky movement of the diaphragm thus providing a better surgical field intraoperatively, which is comparable with the study done by B. Kumar et al (2011)[15]

Post-operative shivering, nausea and vomiting were observed more in group A as compared to group B, but was clinically not significant. Headache and neurological complications were not seen in any patient of either group.

Conclusion: From the present study, it may be concluded that 0.5mg of intrathecal butorphanol is a good adjunct in spinal anaesthesia, providing good

and prolonged post-operative analgesia and increases the duration of request for analgesia without affecting the early recovery from anaesthesia. It is also helpful in providing prompt onset, adequate anaesthesia and better surgical field intraoperatively with minimal side effects.

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Conflict of interest: None
Funding: None
Cite this Article as: Jyoti M, Rajesh K, Usha S, Ekramul H, Vivek R, Ranjit A. A Comparative Study Of Intrathecal Hyperbaric 0.5% Bupivacaine Alone Versus Hyperbaric 0.5% Bupivacaine . SEAJCRR 2017; 6(1):10-15