RESEARCH ARTICLE

COMPARISON BETWEEN HYPERBARIC BUPIVACAINE AND HYPERBARIC BUPIVACAINE PLUS FENTANYL INTRATHECALLY IN MAJOR GYNECOLOGICAL SURGERIES

Jayendra Makwana, Shivraj TN, Amit Khade, Sahil Bansal, Nitish Mandal, Shakuntala Goswami, Bharat Shah
Department of Anaesthesiology, BJ Medical College, Ahmedabad, Gujarat, India

Correspondence to: Jayendra Makwana (j_c_makwana@hotmail.com)

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ABSTRACT

Background: Subarachnoid block is commonest anaesthetic technique used for most gynaecological surgeries. Local anaesthetic agents have traditionally been used for this, but with the discovery of opioid receptors in spinal cord in substantia gelatinosa. Possibility of synergism between opioids & local anaesthetics co-administered intrathecally has been explored for various lower abdominal surgeries.

Aims & Objective: To study was to compare effect of intrathecal bupivacaine with bupivacaine, fentanyl mixture to assess safety and efficacy, peri –operative hemodynamic stability postoperative pain relief in major gynecological surgeries.

Materials and Methods: 60 female patients with American society of anaesthesiologists (ASA) grade I OR II were divided in two groups after matching. Group BF received inj. Bupivacaine 15 mg (0.5%) 3 ml + inj. Fentanyl 25 mcg, (50 mcg/ml), 0.5 ml and Group B: (inj. Bupivacaine 15 mg (0.5%) 3 ml + Normal Saline (0.5 ml), total volume was 3.5 ml in each group. Spinal anaesthesia was given with conventional technique.

Results: Duration of sensory block and effective analgesia was prolonged while there was no change in duration of motor block with intrathecally bupivacaine with fentanyl as compared to inj. Bupivacaine alone.

Conclusion: Intrathecal Fentanyl as an adjuvant to bupivacaine improves quality of block with longer duration of sensory block & prolongs duration of effective analgesia.

Key Words: Bupivacaine; Fentanyl; American Society of Anaesthesiologists (ASA); Anaesthesia

Introduction

Subarachnoid block is commonest anaesthetic technique used for most gynaecological surgeries.[1] Local anaesthetic agents have traditionally been used for this, but with the discovery of opioid receptors in spinal cord in substantia gelatinosa.[2] Possibility of synergism between opioids & local anaesthetics co-administered intrathecally has been explored for various lower abdominal surgeries.[3] Various adjuvants have been used for subarachnoid block.

Bupivacaine is a highly potent local anaesthetic of amide group.[4,5] Its hyperbaric form prepared by addition of dextrose in it.[6] It controls pain at the nerve level by interfering with nerve membrane.[7] It physically blocks the sodium channel by reversibly binding to receptors on the intracellular side of the membrane, while the sodium channel is inactive.[7] An action potential cannot form and nerve impulse conduction cannot occur across the nerve membrane and to the brain.[7] The result of this is the loss of feeling or numbness in the area the drug is given.

Fentanyl has high lipid solubility & high affinity for opiate receptor with rapid onset of action following intrathecal administration.[8] The low dose may however sufficiently augment local anaesthetic mediated block to decrease nociceptive stimulation. It provides effective analgesia & improves intraoperative patient comfort with no motor block, no sympatholytic, and decrease in post-operative nausea vomiting & improves anti-nociceptive action effect of Bupivacaine. It also prolongs postoperative analgesia with lesser incidence of adverse drug reaction.[9]

Considering above facts the study was designed using low dose of bupivacaine with low dose of fentanyl in order to assess the quality of subarachnoid block, hemodynamic stability, perioperative analgesia, quality of motor & sensory block, perioperative sedation and any ADRs in patients undergoing major gynaecological surgeries.

Materials and Methods

After obtaining approval from institutional ethical committee, a written informed consent was obtained from all the patients who participated in this study. The study was carried out in department of anaesthesia, BJ Medical College, Ahmedabad during January 2010 to October 2010.The study was conducted in 60 patients with various indications scheduled for elective abdominal hysterectomy. All patients with significant systemic diseases were excluded from the study and only ASA I and II patients were included. None of the patients had any contraindication to spinal anaesthesia.

Inclusion Criteria: (1) Age of patient-18-60 years; (2) ASA I or II; (3) Written and informed consent given. **Exclusion Criteria:** (1) Consent not given; (2) Significant neurological disease; (3) Allergy; (4) Underlying significant systemic disorder; (5) Patient on anticoagulants or bleeding disorder; (6) Incomplete block (GA was given); (7) Psychiatric history

Pre-anaesthetic check-up was done on the previous day and on the morning of operation. Routine and specific investigations were noted. All patients were informed in general terms regarding the procedure of study and their queries were answered. Patients were randomly allocated into 2 groups, each having 30 patients. The study group labelled BF and received Bupivacaine 15 mg (0.5%), 3 ml and Fentanyl 25 µg (50 µg/ml), 0.5 ml, whereas the control group received only Bupivacaine 15 mg (0.5%), 3 ml with saline 0.5 ml to make equal volume with study dose. Total volume of injection was 3.5 ml in each group. All patients received inj. Ondensetron 4 mg i.v. half an hour prior to scheduled surgery

After entering the operation theatre baseline blood pressure, pulse rate, respiratory rate were recorded. All standard monitors (ECG, NIBP, and SpO2) were applied and urine output was measured. All patients were pre-loaded through an 18 G cannula with 1000 ml of Ringer lactate solution. Standard subarachnoid block was then performed under aseptic conditions with patients in right lateral or sitting position. Interspace between lumbar vertebrae 3 and 4 (L2L3/L3L4) was chosen. After aspiration of clear, free flowing cerebrospinal fluid, selected drug was injected according to group slowly (15-20sec) through 23 G BD spinal needle with bevel facing in cephalad direction. Then the patient was turned supine and position of table was kept horizontal. Recording of heart rate, blood pressure, Spo2 , and respiratory rate was done every 2 mins for 10 min, then every 5 mins for 30 mins, then every 15 mins for 1 hr and then hourly till 6 hours. Episode of perioperative hypotension (Systolic BP < 80mm of Hg or 20% or more reduction from baseline) was treated with Inj. Mephenteramine 6 mg IV in Incremental dose and fast infusion of intravenous fluids.

Intraoperative Discomfort was recorded by using *Discomfort Score* (0 to 3): **0:** No distress; **1:** Slight, need of single dose of anxiolytic; **2:** Moderate, needs to repeat anxiolytic; **3:** Intense, needs of more than two doses of anxiolytic. Peri-operative pain was assessed by using 10 point visual analogue scoring method.[10] Sedation score was assessed by *Modified Wilson Sedation Scale*[11], which has scoring from 1 to 4 which is as follows: **1:** Fully awake and oriented and follows verbal command; **2:** Drowsy, eyes closed but arousal only to commands; **3:** Eyes closed but arousal to mild physical stimulation (ear lobe tug); **4:** Eyes closed and unarousable to mild physical stimulation.

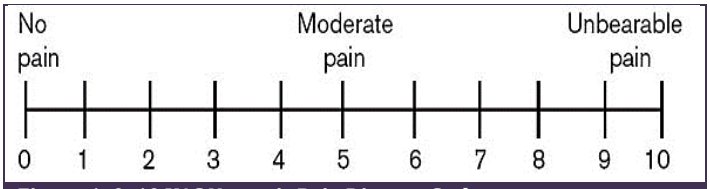

Figure-1: 0–10 VAS Numeric Pain Distress Scale

Level of sensory blockade was assessed by *Pin Prick Method*. A sensory level of T6 was considered adequate to allow surgery to proceed. Time to onset of sensory level of analgesia to T6 as well as regression to T12 level was recorded. Onset and duration of motor block was noted. Grading of motor block was done as per *Modified Bromage Scale*[12], which is as follows: **Grade 0:** No motor block; **Grade 1:** Inability to raise extended leg, able to move knees and feet; **Grade 2:** Inability to raise extended leg and move knee, able to move feet; **Grade 3:** Complete motor block of the lower limbs.

Peri-operative emetic response was recorded. Inj. Ondensetron 4 mg IV was given as rescue antiemetic. Pruritus was treated with Inj. Diphenhydramine 25 mg IV. Urinary retention could not be evaluated as all patients were electively catheterized. Residual sensory blockade was monitored and its wearing off time (level T12 by pinprick) noted. Residual motor blockade was monitored and it's wearing off time (Bromage score) noted.

Duration of complete analgesia (time from subarachnoid injection to first reports of pain) and effective analgesia (time from subarachnoid injection to first dose of rescue analgesia at vas score 4 or more) were recorded. Postoperative pain was treated with intramuscular Diclofenac. Total amount of Diclofenac used in postoperative period was also recorded. Surgical analgesia was graded in 4 categories as described by Atkinson et al: **Grade I:** No pain, patient comfortable; **Grade II:** Mild pain, only elicited on close questioning; **Grade III:** Moderate pain, bothering patient but controllable; **Grade IV:** Severe pain, calling for urgent relief

Observations were recorded and all the results were analyzed. Statistically data are presented as mean ± S.D. For comparing data between 2 groups, unpaired student's "t" test was used and p values <0.05 were interpreted as statistically significant.

Results

Present study is a randomized, double blind comparative

study of Comparison between Hyperbaric Bupivacaine and Hyperbaric Bupivacaine plus Fentanyl Intrathecally in Major Gynaecological Surgeries. Distribution of patients according to mean age, height, weight and surgical time with standard deviation were tabulated. Matching was done in both groups on the basis of age, height, weight. There was no significant difference between the groups with respect to lowest mean Intraoperatively systolic blood pressure and lowest mean intraoperative pulse rate. There was no significant change in pulse or BP in the two groups till 4 minutes after subarachnoid block. Thereafter there was a fall in blood pressure in 2 patients each in both group which was successfully treated with rapid I.V. infusion of ringer lactate and O_2 supplementation. However this fall was comparable between 2 groups. There was a fall in pulse rate in both groups for which 0.6 mg atropine was administered. This fall was comparable between the two groups. There was no incidence of respiratory depression in either group.

Effect on onset and duration of sensory & motor blockade: Effects of drugs on onset and duration of sensory & motor block were given in table 1. An adequate surgical sensory block, that is T6, was documented in all patients before start of surgery and time taken to achieve it was comparable between the two groups. An adequate motor block, that is modified Bromage[12] scale 3, was documented in all patients before start of surgery and time taken to achieve it was comparable between two groups. Table 2 shows (mean ± SD) time of regression of sensory and motor block. Regression of sensory level to T12 is delayed in Group BF and this difference is highly significant while regression of motor block was not significant in both groups which indicate Fentanyl prolongs duration of sensory level while no effect on motor regression.

Effect on duration of analgesia: Table 3 shows duration of pain relief in both groups. Duration of pain relief was calculated from induction of drug to first demand of analgesic by patient. This duration was significantly prolonged by addition of fentanyl to bupivacaine. Quality of surgical analgesia was excellent (Grade I) in most of patients. Mild discomfort was experienced during uterine manipulation by 3 patients of Group BF and 2 patients of Group B.

Perioperative complications: 3 (10%) patients in group BF and 3 (10%) patients in group B had hypotension which was successfully treated with rapid infusion of ringer lactate and O2 supplementation and inj. Mephenteramine 6 mg IV. 7 (23%) patients in Group BF and 6 (20%) patients in Group B had episodes of bradycardia and treated with inj. Atropine 0.6mg I.V. successfully in both groups. 4 (13%) patients in each group had nausea which was mild and was managed with verbal assurance and inj. Ondensetron 4 mg IV. 4 (13%) patients in Group BF had pruritus, not severe enough to require any treatment. There was no incidence of respiratory depression or dizziness. 5 (16%)patients in group BF were sedated (mild sedation Grade 1) but easily arousable. 2 (7%) patients in BF group and 3 (10%) patients in group B experienced mild discomfort (discomfort grade 1) requiring a single dose of anxiolytic.

Table-1: Onset and duration of sensory and motor blockade

Time (Minutes)	Group -BF	Group - B	P value
To achieve T6 (sensory)	6.74 ± 0.84	6.69 ± 0.92	NS
To Bromage scale 3(motor)	5.74 ± 0.46	4.70 ± 0.86	NS

Table-2: Regression of sensory level & Motor block

Time (Minutes)	Group -BF	Group - B	P value
For Regression to T12	192.00 ± 29.05	165.98 ± 25.07	0.0004
To Bromage scale 0	165.32 ± 29.69	162.00 ± 26.83	>0.05

Table-3: Duration of analgesia

Time (Minutes)	Group -BF	Group - B	P value
First demand of analgesic	310.44 ± 41.53	213.20 ± 21.46	<0.01 (significant)

Table-4: Quality of surgical analgesia

Grade	Group –BF N (%)	Group – B N (%)
Grade I	28 (93%)	27 (90%)
Grade II	3 (10%)	2 (06%)
Grade III	0 (0%)	0 (0%)
Grade IV	0 (0%)	0 (0%)

Table-5: Perioperative complications

ADRs	Group -BF	Group - B	P value
Hypotension (SBP<80)	3	3	NS
Bradycardia (HR < 60/min)	7	6	NS
Nausea	4	4	NS
Vomiting	0	0	NS
Pruritus	4	0	P <0.01
Respiratory depression	0	0	NS
Sedation	05	0	NS
Dizziness	0	0	NS
Discomfort	2	3	NS

Discussion

Spinal anaesthesia is the preferred anaesthetic technique in vaginal and abdominal hysterectomy. The choice of local anaesthetic depends upon duration of action and potential for neurological injury. Bupivacaine has duration of action that is intermediate between that of lignocaine and tetracaine, lower incidence of transient radicular irritation than lignocaine, and more rapid and shorter duration of motor blockade than tetracaine. Bupivacaine has longer duration than levobupivacaine and ropivacaine[13], and higher success rate than an identical dose of levobupivacaine. Most important determinant of both successful surgical anaesthesia and time until recovery is dose of local anaesthetic drug. Intrathecal Bupivacaine has no selectivity for afferent and efferent pathways, and Intrathecal Fentanyl acts synergistically to enhance the

effect of Bupivacaine on the afferent pathway without a measurable effect on sympathetic outflow.[14] Using an intrathecal opioid, reduces period of recumbence after spinal anaesthesia by allowing early ambulation, and results in decreased incidence of post dural puncture headache and duration of hospital stay.

We have chosen dose of Fentanyl as 25 µg as most studies[15] have shown this dose provides maximum duration of post-operative analgesia with minimal side effects like respiratory depression and pruritus. Seewal et al[16] suggest that in non-obstetric population receiving spinal anaesthetic for superficial lower abdominal surgery (hernia repair), addition of 10 µg Fentanyl to Bupivacaine 0.5% (hyperbaric) significantly improves quality and duration of analgesia. No further advantage occurs if the dose is increased up to 40 µg. In addition to minimal side effects, the ideal intrathecal opiate should have rapid onset and long duration of action, thus providing improved intra and post-operative analgesia. Our study was conducted to compare the efficacy, safety, hemodynamic stability along with postoperative pain relief with Bupivacaine and Bupivacaine–Fentanyl mixture through intradural route.

We have observed and compared age, height & weight of patients, time to achieve highest sensory level and motor block ,hemodynamic changes, duration of sensory and motor block, duration of effective analgesia, peri-operative incidence of side effects. We evaluated the use of 15 mg hyperbaric Bupivacaine with 25 µg Fentanyl in subarachnoid space and its hemodynamic stability, duration of spinal anaesthesia, time taken for onset of sensory and motor block, time taken for recovery of sensory and motor block, duration of analgesia, patient comfort, and adverse reactions. From our data we observed that both groups were comparable by age, height, body weight distribution & total surgical time. In our study, indication for hysterectomy did not influence any group.

It was observed that addition of 25 µg of Fentanyl does not have any significant effect on patient's hemodynamic status. Berman JC et al[17] & Rajesh Mahajan et al[21] also had similar results. Level of sensory analgesia was same in both groups in our study. In our study addition of Fentanyl has not affected the onset of sensory block significantly, mean onset time, (measured from administration of drug to achieving T6 level by pinprick method) was 6.74 ± 0.84 min. with Group BF v/s 6.69 ± 0.92 min. with Group B. Maximal block height in our study was T6 in both groups. It indicates that level of sensory analgesia was not influenced by intrathecal Fentanyl. Harbhej Singh et al[9], BJ Chandra et al[17], Dr. MS Khanna[19], Rajesh Mahajan et al[21], S Liu et al[22], all observed similar results.

In our study also onset of motor block was (5.74 ± 0.46 min in group BF) compared to (4.70 ± 0.86 min in group B) respectively. That indicate the level of motor block was not influenced by intrathecal Fentanyl. Harbhej Singh et al[9], BJ Chandra et al[17], Rajesh Mahajan et al[21], S Liu et al[22] also had similar results. In our study regression of sensory level to T12 is highly significant ($P < 0.05$) 192.00 ± 29.05 (mean ± SD) min. with Group BF v/s Group B 165.98 ± 25.07(mean ± SD) min. It indicates that Fentanyl produce longer duration of sensory block due to binding to opioid receptor and decrease analgesia requirement in early postoperative period. Harbhej Singh et al[9], BJ Chandra et al[17], Dr. MS Khanna[19], Rajesh Mahajan et al[21], S Liu et al[22], also concluded similar results.

In our study, duration of motor block, that is, the time to Bromage score 3 was (165.32 ± 29.69 min. vs. 162.00 ± 26.83 min.) in group BF and group B respectively. Regression of motor block is comparable in both groups, which indicate there is no difference in regression of motor block with use of Fentanyl. Harbhej Singh et al[9], Barman Jagadish Chandra et al[17], Rajesh Mahajan et al[21], S Liu et al[22], also concluded similar results. Effective analgesia means time from administration of spinal block and the first request for supplemental analgesia or (VAS score > 4). In our study, this time in minutes was 310.44 ± 41.53 min. v/s 213.20 ± 21.46 min. for Group – BF and Group B respectively ($P <0.05$), showing that addition of Fentanyl prolongs duration of analgesia significantly. This is highly significant indicates Fentanyl prolongs duration of analgesia up to 2 hour post-operative and decrease requirement of analgesic in early postoperative period. Dr. Lalita Gouri Mitra et al[24] observed similar findings. Intra-thecal Fentanyl inhibits afferent synaptic transmission via C and A fibres, and also has direct postsynaptic effect with hyperpolarisation and reduced neuronal activity causing prolongation of postoperative pain relief. This could be attributed to potential synergism between Fentanyl and Bupivacaine as reported in various studies. Harbhej Singh et al[9], Barman Jagadish Chandra et al[17], Rajesh Mahajan et al[21], found lower postoperative analgesic requirement with addition of Fentanyl and time to first analgesic requirement was longer in Fentanyl group.

Quality of surgical analgesia was excellent (Grade I) in most of patients. Mild discomfort was experienced during uterine manipulation by 3 patients of Group BF and 2 patients of Group B. Manjushree Ray et al have observed same finding like our study. All patients in a study by Liu S et al[22] developed pruritus, common complication of intrathecal opioid use. Four (13.33%) patients in our study developed pruritus in group BF whereas none in group B ($P< 0.001$). Liu S et al[22] (2009) where 20 µg Fentanyl

associated with increased analgesia but increased pruritus. Mitra LG et al[24] & colleague (2006) have observed pruritus in 9.67% patients.

Harbhej Singh et al[9] found more frequent hypotension in Fentanyl group (43% vs 14%; P < 0.05). In our study frequency of hypotension was same with both groups, which is comparable to Dr. MS Khanna[19] & colleague. They observed that addition of fentanyl do not alter cardiovascular response to spinal block. In our study 7 (23%) patients in Group BF and 6 (20%) patients in Group B had episodes of bradycardia which is statistically not significant. All patients were treated with inj. Atropine 0.6mg I.V. successfully. Berman JC et al[17] observed nausea & vomiting more in frequency with fentanyl+ bupivacaine group. In our study it was same with both group. In our study 5 (16%) patients in group BF were sedated (mild sedation Grade 1) but easily arousable. Berman JC et al[17] observed 10% of patient were drowsy in both groups but easily arousable, which is not comparable with our results. Dr. MS Khanna[19] found significant degree of discomfort with Bupivacaine group compared to Bupivacaine – Fentanyl group (P< 0.05). In our study 2 (7%) patients in BF group and 3 (10%) patients in group B experienced mild discomfort (discomfort grade 1) requiring a single dose of anxiolytic, which is not significant. None of patients developed respiratory depression in our study. Khanna MS et al[19] has observed respiratory depression in Fentanyl group. In their study decrease in SPO_2 cannot be attributed to the effect of Fentanyl, but rather to interaction of Fentanyl and benzodiazepines on respiration, so patients in saline group did not show a decrease in SPO_2 after block.

Conclusion

Intrathecal Fentanyl as an adjuvant to bupivacaine improves quality of block with longer duration of sensory block & prolongs duration of effective analgesia.

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