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Research Article

Comparison between high dose hyperbaric Bupivacaine (12.5 mg) alone versus low dose hyperbaric Bupivacaine (7.5 mg) with Fentanyl (25 µg) in spinal anaesthesia for inguinal hernia surgery

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ABSTRACT

Background: For performing inguinal hernia surgeries, giving spinal anesthesia is a well known technique as it easy and provides fast onset, effective sensory and motor blockade in an awake patient. Now-a-days Bupivacaine is gaining importance as an effective spinal anaesthetic agent in combination with opioid analgesic Fentanyl to reduce the postoperative pain and side effects associated with surgery. This study aims to compare the effectiveness of intrathecal Bupivacaine alone versus combination of Bupivacaine with Fentanyl.
Methods: The study designed was a prospective, randomized, double blinded comparative study. Patients were randomly divided into two groups of 25 each. Group B received hyperbaric intrathecal Bupivacaine 12.5 mg and Group BF received diluted hyperbaric intrathecal Bupivacaine 7.5 mg and Fentanyl 25 µg for spinal anesthesia . Parameters like sensory and motor block were assessed. Side effects produced during perioperative and postoperative period were observed and noted. Satisfactory criteria by the surgeons and patients were considered.
Results: The time taken to attain surgical anesthesia and peak sensory levels in minutes was statistically significant in Group B compared to Group BF. Due to higher dose of Bupivacaine, it was observed that degree of motor blockade is also higher in group B when compared to group BF. The incidence of hypotension, nausea, vomiting and hypothermia are significantly higher in group B due to high dose of Bupivacaine. The surgeons and patients satisfaction was good in both the groups.
Conclusions: Low dose Bupivacaine in combination with Fentanyl is safe and effective alternative for spinal anesthesia for inguinal herniorrphaphy as compared to conventional high dose Bupivacaine alone.

Keywords: Spinal anesthesia, Inguinal herniorrphahy, Bupivacaine, Fentanyl, Postoperative complications

INTRODUCTION

Spinal anesthesia has been found to be a well known technique for inguinal hernia surgeries as it is easy to perform, and provides fast onset of action, effective sensory and motor blockade in an awake patient. It also avoids hemodynamic and airway manipulation problems associated with general anesthesia. Generally lignocaine is commonly employed for inguinal hernia surgeries but due its transient neurological symptoms, 0.5% hyperbaric Bupivacaine has gained importance as a frequently used anesthetic agent for spinal anesthesia[1-3] But the conventional high dose of intrathecal Bupivacaine can cause high level of sensory and motor blockade with haemodynamic derrangements leading to prolonged intensive care monitoring postoperatively, delayed recovery and thus delayed discharge.[4-6]

To avoid these consequences, a low dose of Bupivacaine with an adjunct intrathecal Fentanyl is used as a reliable combination in spinal anaesthesia for inguinal herniorrhaphy.[7,8] This combination produces synergestic

effect, prolonging duration of sensory block without increasing sympathetic block or delaying recovery.[9]

The aim of this prospective study is to compare low dose (7.5 mg) hyperbaric Bupivacaine in combination with 25 µg Fentanyl with conventional high dose (12.5 mg) hyperbaric Bupivacaine alone in spinal anaesthesia for inguinal herniorrhaphy.

METHODS

The study was a prospective, randomized, double blinded and comparative study was carried out in Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai, India. This study included 50 adult male patients undergoing unilateral elective inguinal hernia surgery of 18–75 years age group belonging to ASA physical status I to II. After approval of Institutional Ethics Committee and Institutional Review Board, written consent was taken in every case. Patients who refused to give consent, belonging to ASA physical status III and above, hypersensitivity to local anaesthetics, deformities of spinal column, mental disturbances,neurological disorders, bleeding disorders, obstructed hernia /strangulated hernia /Recurrent hernia/hernias with big sacs were excluded.

After admission to the hospital detailed medical history was taken including history of allergy, use of medication, history of previous surgery and anaesthesia. A detailed physical examination including height, weight, vital parameters were done and systemic examination was performed along with general and spine examination.

Patients were randomly divided into two groups of 25 each named Group B and Group BF. Group B received hyperbaric Bupivacaine 12.5 mg with a volume of 2.5 cc. Patients in Group BF received a combination of hyperbaric Bupivacaine 7.5 mg (1.5 cc) + sterile preservative free Fentanyl 25 µg (0.5 cc) + sterile preservative free normal saline 0.5 cc with a total volume of 2.5 cc.

Before surgery patients were confirmed with adequate starvation and their vital signs like BP, pulse rate, respiratory rate were monitored. A peripheral venous access was secured with 20G angiocath. Intravenous infusion of lactated Ringer's solution was started for volume substitution during operation and thereafter intravenous fluids were maintained at 6 ml/kg/hr with 0.9% normal saline. Spinal anaesthesia was administered in L3-L4 space with patient in sitting position with 25G Quincke's spinal needle, with direction of needle aperture towards cranial during injection, after confirming free and clear flow of CSF and the whole drug was injected in 10 seconds without barbotage. All patients were placed in supine position immediately after injecting the spinal drug for the operation. If the level did not reach L_1 within 5 minutes of spinal drug injection, 15^{o} Trendelenberg position was given till level reached T_{10} level and then the table was straightened. No local anaesthesia was injected or infiltrated into any of the patient before or during operation in order to obtain a field block or ilioinguinal nerve block. All patients were monitored with ECG, BP, pulse oximetry, sensory level (pinprick in midclavicular line), motor level (Bromage score), and for complaints like nausea, vomiting, shivering, pruritus, and sedation from the time of spinal injection. Postoperatively, all the patients were shifted to recovery room for monitoring. The interval between injection of spinal anaesthesia to request of first dose of analgesia (i.v. tramadol 1 mg/kg) was noted.

Assessment of sensory block

The level of analgesia was assessed by pinprick method and peak sensory level was assessed for every 5 minutes till end of operation, and then every 10 minutes in recovery room till point of two segment regression of block. Further testing was done every 20 minutes till sensory level receded to L1 and the following parameters were noted. All times were recorded from the time of injection of spinal anaesthesia.

a) Time for onset of surgical anaesthesia
b) Peak sensory level (dermatomal level)
c) Time required to achieve peak sensory level
d) Time for two segment regression
e) Time taken for sensory level to regress to L1 or below.

Assessment of motor block

Motor block was assessed using Bromage scale as follows:

Grade 0 – Full flexion of hips, knees and feet possible.
Grade 1 – Just able to flex knees, but full flexion of feet possible.
Grade 2 – Unable to flex knees, but some flexion of feet possible.
Grade 3 – Unable to move legs or feet

The following parameters were noted:

I. Peak motor block achieved at the time of peak sensory block
II. Time for complete recovery of motor block to Bromage grade 0.

All the patients were monitored for side effects like hypotension, bradycardia, respiratory depression, sedation, pruritus, nausea, vomiting, shivering. Parameters like assessment of recovery room time, duration of analgesia and time to void were also assessed. Later Surgeons were asked to estimate the operating condition as good, satisfactory or poor as per the adequacy of motor and sensory block during surgery and patient satisfaction was also judged as per comfort during surgery, postoperative analgesia and for any other side effects, observed as good, satisfactory and poor. Follow

up was carried out for 1 week postoperatively by surgeons and asked about headache, PDPH (headache mainly occipital or frontal, increased on coughing/sneezing/sitting or erect position and relieved on flat position), backache, transient neurological symptoms (pain or dysesthesia in backs, buttocks, legs or pain radiating to lower extremities after initial recovery from spinal anaesthesia and recovered in 72 hours).

Statistical analysis

Data was analyzed by using statistical software 'SPSS version 15'. The continuous variable like demographic data, duration of surgery, pulse rate, systolic blood pressure, and respiratory rate were presented as mean and standard deviation. The continuous variables were compared using unpaired student 't' test. Intra group variation was compared with paired student't' test. A 'P' value less than 0.05 was considered significant. Adverse effects like nausea, vomiting and pruritis were analyzed with chi square exact test.

RESULTS

Demographic data

The two groups were compared for demographic data and duration of surgery as given in Table 1.

Table 1: Demographic data and duration of surgery.

	Group B	Group BF	P value
Age in years (Mean±SD)	36.40±11.72	35.24±8.33	0.689
Weight in kgs (Mean±SD)	59.20±5.50	61.40±3.63	0.103
Height in cms (Mean±SD)	161.56±3.73	162.24±3.87	0.530
ASA I : ASA II (n;%)	19 (76%): 6 (24%)	20 (80%): 5 (20%)	0.733
Duration of surgery (minutes) (Mean±SD)	54.40±12.69	54.80±12.20	0.910

Sensory block

The time taken to attain surgical anaesthesia and peak sensory levels in minutes was statistically significant in Group B compared to Group BF as shown in Table 2. This is due to induction of high dose of Bupivacaine in Group B patients. The time taken for two segment regression and sensory regression to L1 was higher in group B patients may be due to prolongation of sensory block by Fentanyl in group BF. This difference was statistically insignificant.

Table 2: Sensory characteristics of block.

	Group B (Mean±SD)	Group BF (Mean±SD)	P value
Onset of Surgical anaesthesia in minutes	7.04±3.634	9.88±5.341	0.033
Peak sensory level (range)	T7 (T6–T10)	T9 (T6-T10)	0.000
Time for peak sensory level in minutes	15.00±6.124	15.60±6.819	0.745
Time for 2-segment regression in minutes	91.20±40.447	73.2±41.279	0.126
Time for sensory regression to L1 in minutes	153.60±39.987	132.60±44.933	0.087

Degree of motor block

Due to high dose of Bupivacaine a significant (P value 0.000) peak motor blockade was achieved in group B patients with grade Bromage 3, compared to group BF.

Table 3. Maximum degree of motor block.

	Group B	Group BF	P value
Bromage 0	0 (0%)	0 (0%)	0.000
Bromage 1	0 (0%)	6 (24%)	
Bromage 2	0 (0%)	7 (28%)	
Bromage 3	25 (100%)	12 (48%)	
Total	25 (100%)	25 (100%)	

Recovery characteristics of the block

The time taken for complete recovery of motor block was significantly higher in Group B compared to Group BF. This might be due to lower dose of Bupivacaine in BF group and also Fentanyl did not prolong the motor block. The time for shift from recovery in minutes was also significantly (P value 0.000) longer in Group B than in Group BF as given in Table 4. This is because Fentanyl prolongs sensory block without prolonging motor block and thus hastening the recovery.

Additional analgesia intraoperatively & failed block

4% of Group B and 12% of Group BF required additional analgesia intraoperatively. The difference was not statistically significant. There was no failed block in either group.

Table 4: Recovery characteristics of the block.

	Group B (Mean±SD)	Group BF (Mean±SD)	P value
Time for recovery of complete motor block in minutes	171.00±40.389	111.60±41.551	0.000
Recovery room time	175.80±37.380	138.60±30.397	0.00

Table 5: Additional intraoperatively analgesia and failed block.

	Group B	Group BF	P value
Additional analgesia intraoperatvely	1 (4%)	3 (12%)	0.297
Failed Block	0 (0%)	0 (0%)	

Table 6: Duration of analgesia and voiding time.

	Group B (Mean±SD)	Group BF (Mean±SD)	P value
Duration of analgesia in minutes	175.20±40.091	446.40±173.922	0.000
Time for voiding in minutes	344.40±40.731	319.20±36.620	0.026

Comparison of side effects

The incidence of hypotension was observed in group B (28%) patients due to high sensory and sympathetic blockade and not observed in group BF. The difference between the two groups was statistically significant. An insignificant difference was observed in group B (4%) and group BF (8%) of patients for bradycardia. The episodes of nausea and vomiting are higher in group b (20%) compared to group BF (8%).

This may be related to higher episodes of hypotension in group b and some incidence in both groups may be due to traction on nerve plexus via vagus during surgical handling.

The incidence of shivering was significantly higher in group B (36%) than in group BF (8%). This may be due to high sympathetic block leading to vasodilatation with hypothermia leading to increased episodes of shivering in group B and administration of intrathecal fentanyl in group BF decreased shivering**.** None of the patients in either group experienced respiratory depression, urinary retention, postdural puncture headache or transient neurological symptoms.

Table 7: Comparison of side effects.

	Group B	Group BF	P value
Hypotension	7 (28%)	0 (0%)	0.004
Bradycardia	1 (4%)	2 (8%)	0.552
Respiratory depression	0 (0%)	0 (0%)	-
Nausea & Vomiting	5 (20%)	2 (8%)	0.221
Shivering	9 (36%)	2 (8%)	0.017
Pruritus	0 (0%)	0 (0%)	-
Excessive sedation	0 (0%)	0 (0%)	-
PDPH	0 (0%)	0 (0%)	-
TNS	0 (0%)	0 (0%)	-

Surgeon's and patient's satisfaction

The surgeons and patients expressed satisfactory result as good in both the groups. The patients in group BF produced good motor and sensory blockade 24 (96%) compared to group B 22 (88%). The same group of patients declared of having good comfort during surgery, reduced requirement of postoperative analgesia and experience of less side effects 24 (96%) compared to group B 20 (80%). This difference between the groups are statistically insignificant.

Table 8: Comparison of surgeons' satisfaction.

	Group B	Group BF	P value
Good	22 (88%)	24 (96%)	0.297
Satisfactory	3 (12%)	1 (4%)	
Poor	0 (0%)	0 (0%)	
Total	25 (100%)	25 (100%)	

Table 9: Comparison of Patients' satisfaction.

	Group B	Group BF	P value
Good	20(80%)	24 (96%)	0.206
Satisfactory	4 (16%)	1 (4%)	
Poor	1 (4%)	0 (0%)	
Total	25 (100%)	25 (100%)	

DISCUSSION

Spinal anaesthesia for hernia repair has attained a widespread popularity due to advantage of awake patient, minimal drug and equipment cost. However, technique may be burdened by a risk (albeit low) of postspinal headache, undesirable hemodynamic response and urinary retention. The use of small gauge pencil point needles has improved the feasibility of spinal anaesthesia as it reduces the incidence of postspinal headache.[6,9]

Use of high dose 12.5 mg, i.e. 2.5 cc of 0.5% hyperbaric Bupivacaine in spinal anaesthesia is routine for inguinal herniorrhaphy. But this dose produces high level of sensory, motor block and arterial hypotension. Even small dose of 7.5 mg dilute Bupivacaine spinal anaesthesia yields comparably rapid recovery profile, but may provide insufficient anaesthesia.[12] Hence, it is advisable for neuraxial administration of opioids in conjunction with local anaesthetics to improve the anaesthetic effect, quality of intraoperative analgesia and for prolonged duration of postoperative analgesia.[4-6,9] Animal studies have also demonstrated antinociceptive synergism between intrathecal opioids and local anaesthetic during visceral and somatic nociception.[9,13]

In the present study, the aim of adding Fentanyl was to provide good surgical conditions without significant delay in recovery or increase in adverse effects with good postoperative analgesia in patients undergoing inguinal herniorrhaphy. Intrathecal Fentanyl has already shown to prolong the duration of local anaesthetic blockade in dose dependent manner.[5,14-16]

A combination of Bupivacaine 7.5 mg + Fentanyl 25 µg as a spinal anaesthesia proved to be safe and effective in relieving the intense pain associated with inguinal herniorrhaphy by the studies conducted by Gupta et al, H Singh et al, Song et al.[7,9,17] Kuusniemi et al, also evaluated the effect of addition of 25 µg Fentanyl to various doses of Bupivacaine (10, 7.5, 5 mg) in urological surgeries, and found increase in the intensity and duration of sensory block by Fentanyl.[18]

In our study, the earlier onset of surgical anaesthesia and peak sensory level in Group B may be because of cephalad spread of spinal blockade.[12,19] Our results are comparable to the results of Ben David et al on the effect of saline dilution of Bupivacaine in ambulatory knee arthroscopies.[12]

Block intensity is reflected by the degree of motor block and intraoperative sensation. In our study the maximum degree of motor block achieved in group B at Bromage 0-1-2-3 was 0-0-0-25 patients and in group BF 0-6-7-12 patients respectively. It is also observed that none of the patients in either group required general anaesthesia for failed block. This is due to the intensity of motor block depends only on the concentration of Bupivacaine and Fentanyl dose intensifies only sensory block but not motor block. These results are similar to the results observed by Ben David et al.[12]

Block duration was measured by time for two segment regression, time for sensory regression to L1 and time for complete recovery of motor block. The time taken for two segment regression in Group B and BF was 91 and 73 while The time taken for sensory level to regress to L1 was 153 and 132 respectively. This is similar to the results obtained by Ben David et al, in their study the time to two segment regression was 53 and 67 minutes in Bupivacaine and Bupivacaine + Fentanyl groups respectively. Similarly, the time taken for sensory level to recede to S2 was 120 and 146 minutes respectively. Our results also corresponds with the results by Singh et al, time for two segment regression was 74 and 93 minutes and time for sensory level to regress to L1 was 110 and 141 minutes respectively in Bupivacaine and Bupivacaine + Fentanyl groups. Similar results were also obtained in the study by Goel et al and Belzarano et al.[9,12,16]

In our study, the time taken for complete recovery of motor block was comparable with the observations obtained in the study conducted by Singh et al, Belzareno et al[37], and Kuusniemi et al.[9,16,18]

In our study, hemodynamic stability was found to be unaffected due to addition of Fentanyl to small dose of diluted Bupivacaine. In the present study 7 (28%) of patients in Group B had hypotension whereas none of the patients in Group BF had hypotension. This is due to decrease in sympathetic efferent activity related to Bupivacaine but not by intrathecal Fentanyl.[13] This finding is quite important because it also reduces the need for intense monitoring of the patient in the immediate postoperative period. Similar findings were observed by Ben David and his colleagues, in which they used minidose of Bupivacaine with Fentanyl as a spinal anaesthesia for surgical repair of hip fracture in the elderly paients, and found less hypotension that nearly eliminates need of vasopressor agents to support blood pressure.[20]

In this study bradycardia was observed in the both the groups, requiring treatment. This finding is comparable to the studies done by Singh et al and Ben David et al.[9,12] Thus, it is evidenced that intrathecal Fentanyl was not involved in the incidence of bradycardia. Similarly, there was no respiratory depression, excessive sedation or drowsiness observed in both the groups that was in accordance with the studies of Gupta et al, Singh et al, Ben David et al and Belzarena et al.[7,12,9,16]

In our study, shivering occurred in 36% of group B and only 8% of group BF patients. Similar significant findings were reported by Biswas et al and Techanivate et al.[21,22] This is due to added Fentanyl to the Bupivacaine.

In our study, 20% of Group B and only 8% of Group BF had nausea and vomiting. The higher incidence of nausea and vomiting may be due to higher incidence of hypotension in group B or may be due to visceral pain due to vagal stimulation in either groups. This suggests that the addition of Fentanyl does not increase the incidence of nausea and vomiting. Various studies by Kuusniemi et al, Ben David et al, Biswas et al, Manullang et al also correlates with our findings.[18,20-23]

All our patients were shifted to recovery room in the immediate postoperative period. The less recovery room time in group BF was a result of earlier recovery of motor

block due to low dose of Bupivacaine used, while Fentanyl enhanced sensory block without enhancing motor block. Our results are comparable to the results in the studies by Singh et al and Belzarena et al.[9,16]

The duration of analgesia was 175 and 446 minutes in Group B and Group BF respectively. Similar observations was seen in the study done by Ben David et al.[13] It was observed that 59% patients of Bupivacaine alone group and only 19% in Bupivacaine + Fentanyl group required pain relief in postoperative period. This shows that Fentanyl enhances analgesia without delaying recovery profile.

Thus, 96% of patients in group BF rated the satisfaction as good, as opposed to 80% in group B. Similarly, 96% of surgeons rated the satisfaction as good in group BF, as opposed to 88% in group B. This difference in patients and surgeons satisfaction in both groups may be due to the dense motor block caused by higher dose of Bupivacaine in group B and enhanced sensory block caused by Fentanyl with low dose of Bupivacaine in group BF.

In our study, as the patients were at high risk of urinary retention as observed in the previous studies of Mulroy et al and Petros et al, we monitored the time to void.[24,25] But none of the patients in either group had to be catheterized for urinary retention.

CONCLUSION

In our study, we observed that low dose Bupivacaine with Fentanyl gives adequate intraoperative analgesia & thus making it a reliable anaesthetic alternative. And also profound hemodynamic stability, better postoperative analgesia with faster recovery from motor block, reducing recovery room stay without increasing any other side effects like sedation, respiratory depression, or pruritus as compared to conventional high dose Bupivacaine was observed. So, we conclude that low dose Bupivacaine with Fentanyl is a better choice for spinal anaesthesia for inguinal herniorrphaphy as compared to conventional high dose Bupivacaine.

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