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A Comparative Evaluation of Intrathecal Hyperbaric Bupivacaine versus Hyperbaric Bupivacaine with Minidose Fentanyl in Lower and Orthopaedic Surgeries

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Abstract: *By exploiting the synergism between intrathecal opioids and local anaesthetics it may be possible to augment the quality of spinal anaesthesia both intra and post operatively. We had evaluated in this prospective randomized double blind study to evaluate the effect of 25µg of fentanyl added to 12.5mg hyperbaric bupivacaine regarding time of onset and level of sensory block,intensity of motor block, duration of analgesia, haemodynamic stability and complications (if any). Eighty ASA I-II patients of 20-60 yrs age scheduled for elective surgery under spinal anaesthesia were divided into two groups. Patients were randomly allocated to receive either fentanyl 25µg (GroupF, n=40) or normal saline 0.5ml (GroupS,n=40) combined with 12.5 mg hyperbaric bupivacaine. Subarachnoid block was given with 23G spinal needle at L_{3-4} intervertebral space with patient in sitting position. Time of onset and highest level of sensory block was assessed using Pin Prick test, intensity of motor block by modified Bromage scale and quality of analgesia by VAS (Visual analogue scale). In group F there was faster onset of sensory block, more intensified motor block and statistically better haemodynamic stability than group S. In addition fentanyl-bupivacaine combination required less top up analgesics postoperatively with minimal side effects compared to bupivacaine-normal saline combination.*

Keywords*: Intrathecal, Spinal Anaesthesia, Fentanyl, Bupivacaine*

I. Introduction

Pain is a multidimensional human perception. Among the remedies which have pleased almighty God to give man relief of his suffering none is so universal and so efficacious as opium . Spinal anaesthesia is a very commonly used technique for lower abdominal and orthopaedic surgeries . Being simple to perform, economical it offers complete muscle relaxation. The use of neuraxial opioids has gained popularity over last few years as they augment anesthesia produced by local anaesthetics. Intrathecal opioids deliver the drug molecules to or near the site of action within the spinal cord and bypass the blood brain barrier thus reducing the amount of opiod needed to obtain clinical effects similar to that of oral opioid at much lower dose.

Neuraxial administration of opioids in conjunction with local anaesthetics improves quality of analgesia, prolongs duration of postoperative analgesia[1,2]. Lipophilic opioid (fentanyl) is increasingly being administered intrathecally as adjunct to local anaesthetics. It is the µ-receptor agonist and 75-100 times more potent than morphine[3,4]. It does not migrate to fourth ventricle in sufficient concentration to cause delayed respiratory depression.

II. Methods

After approval of ethics committee a written informed consent was taken. This prospective double blind, randomized study was conducted at Ram Manohar Lohia Combined Hospital, Lucknow . Eighty patients of ASA I & II, 20 to 60 yrs of age, either sex undergoing elective lower abdominal and orthopaedic surgeries under spinal anasthesia were included in the study. The patients were randomly allocated into 2 groups ; Group F (n=40) received intrathecal hyperbaric bupivacaine 12.5 mg with 25 µg fentanyl (0.5ml) and groupS (n=40) received intrathecal hyperbaric bupivacaine 12.5mg with normal saline 0.5ml. **Exclusion criteria :** Patients with known history of allergy to drug, any contraindication to spinal anesthesia, emergency surgery, patients not willing to participate in the study, hepatic and renal insufficiency.

2.1 Study Procedure

After the standard monitors were placed and intravenous access was established patients were preloaded with 10ml/kg 0.9% normal saline. Spinal block was performed with 23G spinal needle at L_{3-4} intervertebral space with patient in sitting position. Depending on the study group the injection of anesthetic solution with needle aperture cranially was administered in 10 seconds thereafter patients were placed supine.

Vitals (heart rate, blood pressure, SPO_2, respiratory rate) were monitored continuously. Time of onset and highest level of sensory block (Pin Prick Test), intensity of motor blockade (Modified Bromage Scale) were recorded at 5 min, 15 min, 30 min, 60 min, 120min and then every half an hour till complete recovery of motor block. Duration of analgesia was assessed by time of administration of first injection of analgesic in the postoperative period. Need for analgesic injection was assessed by VAS.

Incidence of nausea, vomiting, shivering, itching, backache, headache and urinary retention were also recorded .

Hypotension (fall ≥ 20% of baseline MAP) was treated with 5 mg increments of injection ephedrine i.v. and intravenous fluids. Criteria for respiratory depression was respiratory rate ≤8 bpm and oxygen saturation <92% on room air. Intra and postoperative pain was assessed on visual analogue scale (VAS: a horizontal 0 to 10 c.m. straight line with left of the line expressing no pain and the right end of line the worst pain). The patients were interviewed regarding their opinion of anesthetic procedure whether they would like to have the same anesthesia next time for similar operations.

III. Results

There was no significant difference between the study groups regarding mean age, weight, height, sex ratio and duration of surgery (Table.1)

Group F showed better heart rate control throughout surgery compared to group S . There was a significant rise in mean heart rate value in group F at 5 min after subarachnoid block and thereafter there was a gradual fall in mean heart rate which came to baseline in 60 min which was not statistically significant ($p < 0.05$) but in group S there remained a significant difference in mean heart rate even after 2 hrs compared to baseline mean heart rate (Table .2a).

There was fall in MAP in both the groups at all time intervals as compared to preoperative value but there was less fall in MAP in group F compared to group S, thus patients receiving intrathecal fentanyl were haemodynamically more stable . (Fig.1)

Mean time of onset of sensory block was faster in group F (4.9±1.3 mins) than group S (7.5±16 min), The maximum upper level of sensory block attained was T6 in both the groups. Thus the mean value of upper level of sensory block was comparable in both the groups (Table 2 b) .

In group F Grade I motor blockade (Modified Bromage Scale) was seen in 35 patients (n=35/40) (87.5%) and grade II in 5 patients (n=5/40) (12.5%). In group S 29 patient showed group I motor blockade (72.5%), 7 patients (17.5%) grade II and 4 patients (10%) grade III motor blockade. It was found that intensity of motor block was better in group F compared to group S ($p=0.002$) (Table .3)

Mean duration of analgesia in group F was 363.07±166.30 min while in group S it was 226.95±119.97 min. Duration of analgesia was significantly prolonged in group F than group S and also less top up analgesics were required in postoperative period in group F thus making it cost effective (Fig.2).

Pruritis was the most common complication in group F ($p=0.003$). Seven patients (17.5%) in group S complained of shivering ($p<0.05$) while no patient had shivering in group F. One patient in group F had urinary retention and was catheterized. There was no complaint of headache, nausea, vomiting, bradycardia or O_2 desaturation in any of the study groups .

IV. Discussion

Recent trends for lower abdominal and orthopaedic surgery show increased acceptance of regional anesthesia. The μ agonist fentanyl act by opening K^+ channels and reducing Ca^{++} influx resulting in inhibition of transmitter realease. Local anesthetic bupivacaine acts mainly by blockage of voltage gated Na+ channels in the axonal membrane. A combination of these effects may explain synergism between bupivacaine and fentanyl found in this study.

In the present study patients in fentanyl group were haemodynamically more stable compared to control group. Wang, Chakrabarti & Whitman (1993)[5] examined the effect of bupivacaine administered intrathecally on sympathetic efferent , AS & C- fibre mediated afferent pathways in dogs and the interactions with intrathecal fentanyl. They concluded that intrathecal bupivacaine has no selectivity for the afferent and efferent pathways and acts synergistically to enhance the effect of bupivacaine on the afferent pathways without a measurable effect on sympathetic outflow. Similar was the findings of few other studies [6,7,8,9]

Time of onset of sensory block was faster in group F (4.9± 13 min) compared to group S (7.5 ± 1.6 min) in this study similar to that of Shende, Cooper, Bowden et al. (2002)[10] and Bano, Sabbar, Zafar et al (2006)[11.] Contrary observation were found by Singh, Yang, Thorton et al. (1995)[12] and Belzarena et al., (1992)[13] who observed that fentanyl as an adjuvant do not alter the onset of sensory or motor block.

Highest level of sensory block achieved was (T6) which was same in both group F and Group S. This was similar to study of Anchalee, Pakorn, Predee et al., (2004)[14] who assessed the effectiveness of the administration of fentanyl in spinal anesthesia for appendicectomy and concluded that there was no significant

difference in the highest level between the groups.However Obara, Swamura, Satoh et al. (2003)[15] found that upper level of sensory block was higher in fentanyl group compared to control.

Patients who received intrathecal fentanyl had more intensified motor block compared to control group. Kristina, Kalevi, Mikko et al. (2000)[16] evaluated the effect of 25 μg of fentanyl added to 10 mg bupivacaine in patients undergoing urologic surgery, it increased the intensity of motor blockade. Contrary observations were seen by Ben-David,Soloman,Levin et al;(1997)[17] and Grewal Katyal Kaul et al; (2003)[18].

Duration of analgesia (the time interval from subarachnoid block to first request of analgesic in postoperative period) was significantly prolonged in group F (363.07±166.30 min) compared to group S (226.95±119.97 min) .Improved perioperative analgesia after co-administration of fentanyl and bupivacaine can be explained by synergistic inhibitory action of fentanyl (an opoid) & bupivacaine (a local anesthetic) on AS and C- fibre conduction. Sergio and Belzarena (1992)[13] studied the clinical effects of intrathecally administered preservative free fentanyl with 0.5% hyperbaric bupivacaive and observed that effective postoperative analgesia lasted longer.

Dahlgren, Hultstrand, Jakobsson (1997)[19] compared the effects of intrathecal fentanyl, sufentanyl and placebo when administered with hyperbaric 0.5% bupivacaine and found that analgesia was prolonged in all groups receiving opioids. Bogra, Arora and Pratima (2005)[20] also found that bupivacaine -fentanyl combination increases the duration of analgesia. Singh, Yang, Thorton et al,(1995)[21]evaluated the effect of intrathecal fentanyl on the onset and duration of hyperbaric bupivacaine induced spinal block in adult male patients and observed that addition of intrathecal fentanyl did not prolong the bupivacaine induced sensory or motor block .Similar observations were found in other studies . [22,23,24]

Pruritis was seen in 8 patients in group F. Reuben, Dunn, Duprat et al. (1994)[25] evaluated the dose-response effect of intrathecal fentanyl in an elderly patient population undergoing lower extremity revascularization procedures and found that in the 50μg fentanyl group, five of ten patients complained of pruritis. Khanna & Ikwinder (2002)[26]evaluated the risk & benefits of the administration of fentanyl during spinal anesthesia in the elderly. Their result showed that 25 μg i00ntrathecal fentanyl does not alter the characteristics of motor block, prolongs the sensory block, improves intraoperative analgesia but induces pruritis and decreases oxygen saturation. Our findings agree with those of Vaghadia, Mcleod, Mitchell et al.(1997)[27] . and Chu, Shu, Lim et al.,(1998)[28] .

Less number of patients experienced shivering in group F compared to group S. Other studies [8], [14] ,[29] found similar findings.

None of the patients experienced respiratory depression (SPO_2 <92%, R.R. <8bpm).Varrassi, Celleno, Capogna et al., (2007)[30] studied 25 patients scheduled for urological surgery who were randomly assigned to receive subarachnoid hyperbaric bupivacaine 15mg with 50 μg fentanyl. They concluded that 50μg subarachnoid fentanyl can cause an early respiratory depression .

This study reveals that when fentanyl 25μg was added to hyperbaric bupivacaine 12.5 mg the combination leads to faster onset and more intense sensory and motor blockade which is haemodynamically more stable. The duration of postoperative analgesia was also prolonged without any remarkable side effects .

Thus overall combined effect of intrathecal bupivacaine-fentanyl is far superior over bupivacaine alone.

Table and Graphs:

Table 1:Comparison of Demographic data in two groups

	Group F (n=40)		**Group S (n=40)***			
	Mean	**SD**	**Mean**	**SD**	**"t"/χ^2**	**"p"**
Age (in years)	45.5	17.3	52.7	19.2	-1.748	0.084
Weight (in kg)	63.9	10.5	61.6	9.0	1.037	0.303
Height (in cm)	162.7	7.0	157.6	22.8	1.362	0.177
Duration of surgery (min)	108.4	45.6	104.5	36.96	0.417	0.678
Gender (M:F)	25:15		24:16		0.053	0.818
ASA Grade						
I	19 (47.5%)		27 (67.5%)			
II	21 (52.5%)		13 (32.5%)		3.274	0.070

Table 2(a): Comparison of Heart Rate (bpm) in two groups at different time intervals (mean±SD)

	Group F (n=40)		**Group S (n=40)**			
Time (in hrs)	**Mean**	**SD**	**Mean**	**SD**	**"t"**	**"p"**
PRE OP	88.65	15.74	85.45	20.06	0.794	0.430
5 min	94.63	19.41	96.65	16.88	-0.498	0.620
10 min	92.20	16.68	96.38	16.18	-1.136	0.259
15 min	91.78	16.38	94.68	16.32	-0.793	0.430
30 min	90.78	17.98	93.80	17.97	-0.753	0.454

Time (in hrs)	Group F (n=40)		Group S (n=40)		"t"	"p"
	Mean	SD	Mean	SD		
60 min	89.80	17.24	91.05	18.16	-0.316	0.753
120 min	87.78	18.40	90.63	13.80	-0.784	0.435

Fig .1Comparition of MAP (mmHg) in to groups at different time intervals.

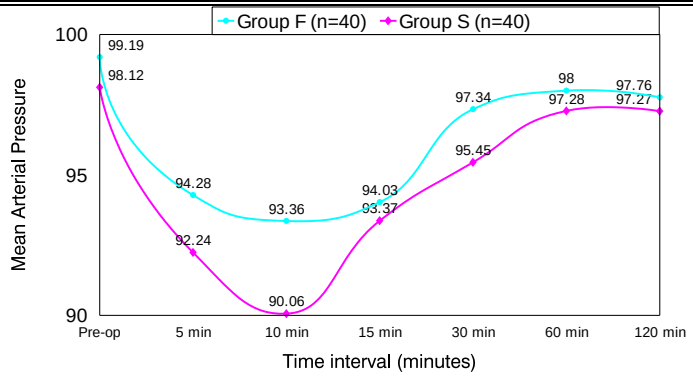


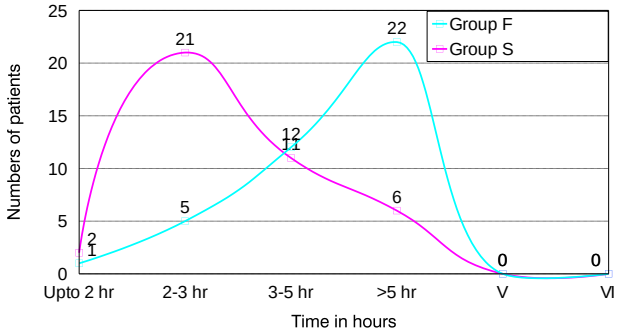
Table 2(b): Time of Onset and highest level of sensory block

Upper Level of Sensory Block		Time of onset of sensory block						
		4 min	6 min	8 min	10 min	12 min	14 min	Total
T_6	Group S	1	2	4	3	–	–	10
	Group F	10	3	1	–	–	–	14
T_8	Group S	1	2	12	6	1	–	22
	Group F	14	4	2	–	–	–	20
T_{10}	Group S	1	1	4	2	–	–	8
	Group F	1	3	–	2	–	–	6
Mean onset time	Group S	7.5±1.6 min			"t"=-6.908; p<0.001			
	Group F	4.9±1.3 min						

Table.3 Intensity of motor blockade (Modified bromage scale)

Motor Blockade (Modified Bromage scale)	Group F (n=40)	Group S (n=40)	χ^2	"p"
I	35	29		
II	5	7		
III	0	4		
IV	0	0		
V	0	0		
VI	0	0	7.805	0.022

Fig.2 Duration of analgesia (in Hours)



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