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Comparative Study of Intrathecal Ropivacaine with Fentanyl Versus Bupivacaine with Fentanyl in Lower Abdominal Surgeries and Lower Limb Surgeries

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ABSTRACT

The subarachnoid block is a common technique of anaesthesia for patients undergoing lower abdominal and lower limb surgeries. Adjuvant drugs improve quality and prolong spinal blockade. Present study was aimed to compare intrathecal ropivacaine with fentanyl versus bupivacaine with fentanyl in lower abdominal surgeries and lower limb surgeries. Present study was single-center, comparative study, conducted in patients from age group of 18-60 yrs of either sex, with ASA physical status scores I and II, posted for elective lower abdominal, lower extremity, gynecological or urological surgeries under spinal anaesthesia., willing to participate in present study. Patients were allotted randomly into 2 groups as Group "RF" and Group "BF". The current study was conducted on 60 patients, randomized into 2 groups. Mean age, gender, mean body weight, mean height, ASA grade and duration of surgery were comparable in both groups and no statistically significant difference was noted. The two groups were comparable with respect to peak sensory level (T4) attained, time to reach peak sensory level was slightly higher in group BF but difference was statistically not significant ($p>0.05$). The mean time to reach peak motor block was higher in group RF, mean for two segment sensory regression in group RF was less, patients in group RF have lesser mean time for motor regression to Bromage Grade 1, duration of analgesia in Group BF was slightly more and difference was statistically significant. ($p<0.05$). Intrathecal administration of Ropivacaine +Fentanyl provides adequate anaesthesia with hemodynamic stability. Also, it has a faster onset time and faster regression time of the sensory block, delayed onset time but comparable regression of motor block to Bromage grade 1 and shorter time is taken for analgesia as compared to intrathecal bupivacaine-fentanyl which will be beneficial for early ambulation.

INTRODUCTION

The subarachnoid block is a common technique of anaesthesia for patients undergoing lower abdominal and lower limb surgeries^[1]. It is obtained by nerve blockade in subarachnoid space^[2]. It is a safe, inexpensive, easy-to-perform technique which gives an advantage of post-operative pain relief and avoids a variety of physiological and psychological phenomena which are vital for early recovery and hospital discharge^[3]. Spinal anaesthesia causes inhibition of stress due to surgery, numbs the autonomic and somatic responses to painful stimuli and allows early ambulation^[4]. This will provide efferent sympathetic blockade which results in vasodilation to the blocked part, which further helps with wound healing^[5]. Several adjuvants are used to improve postoperative analgesia, along with spinal anaesthetic agents. These are epinephrine, clonidine, ketamine, neostigmine, fentanyl and midazolam^[6,7]. Adjuvant drugs improve quality and prolong spinal blockade. They delay the need for postoperative analgesic usage. It will help in reducing the dose of local anaesthetics, as well as the total amount of systemic postoperative analgesics^[5]. Fentanyl is an extensively used opioid adjuvant to local anaesthetics. It helps in enhancing analgesia without much increase in the depth of motor blockade as well as a sympathetic blockade^[8]. Present study was aimed to compare intrathecal ropivacaine with fentanyl versus bupivacaine with fentanyl in lower abdominal surgeries and lower limb surgeries

MATERIALS AND METHODS

Present study was single-center, comparative study, conducted in department of Anaesthesiology, NRI Medical College and General Hospital, Chinakakani, India. Study duration was of 2 years (2021-2022). Study was approved by institutional ethical committee.

Inclusion Criteria:

- Patients from age group of 18-60 yrs of either sex, with ASA physical status scores I and II, posted for elective lower abdominal, lower extremity, gynecological or urological surgeries under spinal anaesthesia, willing to participate in present study.

Exclusion Criteria:

- Patients with ASA physical status score >II.
- Patients <18 years and >60 years.
- The patient refused to give informed consent.
- Patients with gross spinal abnormality, localized active skin infections in the midline of the back, septicaemia, bleeding tendencies or CNS disorders.
- Patients with a head injury.
- Patients with cardiovascular, lung, liver or kidney disorders.

- Obstetric cases
- Patients with mental illnesses.

Study was explained to participants in local language and written informed consent was taken. After the Pre anaesthetic check, laboratory investigations such as complete blood picture, urine analysis, blood sugar, blood urea, renal function tests, bleeding time, clotting time and PT INR, blood grouping and Rhesus (Rh) typing and ECG were done in all patients. Patients were allotted randomly into 2 groups of 30 each after randomization using a computer-generated random number table. Group "RF"-Receiving Intrathecal 0.75% Ropivacaine with 0.5 ml of 25 mcg of Fentanyl. Group "BF"-Receiving Intrathecal 0.5% Bupivacaine with 0.5ml of 25mcg of Fentanyl. The procedure of intrathecal neuraxial blockade was explained to the patient. Explained to communicate to the anaesthesiologists, any perception of pain or discomfort while performing the procedure which can be recorded using a visual analogue scale. Test dose for Ropivacaine, bupivacaine, and fentanyl was given and observed for the development of any hypersensitivity reaction. After shifting the patient to the operation theatre (OT) IV access was obtained with an 18 gauge (G) IV cannula and IV fluids were started. In the operating room, monitoring procedures, which were composed of electrocardiography, pulse oximetry, heart rate and noninvasive arterial blood pressure (NIBP), were started to record baseline ECG, PR, BP, RR and SpO2 till the end of the surgery. Lumbar puncture was done in the left lateral decubitus position or sitting position under aseptic conditions, by midline approach by using a disposable Quincke spinal needle (23 G) at L3-L4 intervertebral space and then the anaesthetic mixture was deposited into the intrathecal space of the respective group. Oxygen (4L/min) and IV fluids were given and monitored for 24 hours. Vital parameters (Pulse Rate, Blood Pressure, Respiratory rate and Oxygen saturation) monitored at intervals of 3, 5, 15, 30 and thereafter every 30 minutes till the completion of the surgery and one hour after completion of the surgery or up to 360 minutes whichever is later, afterwards. The level of sensory anaesthesia, time for onset of block at T8, maximum block height, total duration of analgesia, time to request for analgesia, time of onset of motor block, degree of motor block, total duration of block and analgesics supplements were given if any were noted. Time of first complaint of pain and request for rescue analgesia was recorded. The data collected was coded and entered in Microsoft excel 2007 and analysed using Statistical Package for Social Sciences (SPSS 22). The data were represented in frequencies, percentages, graphs and tabular forms. Collected data will be presented as Mean+SD, as appropriate. Quantitative data were analyzed by using the student's t-test and categorical data were analyzed by Chi-square test with a P value < 0.05 was considered statistically significant.

RESULTS AND DISCUSSIONS

The current study was conducted on 60 patients. They were randomized into 2 groups. Mean age, gender, mean body weight, mean height, ASA grade and duration of surgery were comparable in both groups and no statistically significant difference was noted.

The minimum and maximum for all the 60 patients was 138 mins and 225 mins. The mean and SD of duration of surgery in Group BF (192.33 ± 22.309) was slightly more compared to Group RF (188.87 ± 19.934), but it was not significant statistically ($p > 0.05$).

The median for peak sensory level is at the level of T4 for all the 60 patients was in the range of T3-T6. The peak sensory level was attained by same proportion of patients that is 14 in each group. Hence the two groups were comparable with respect to peak sensory level (T4) attained. But it was statistically not significant ($p > 0.05$).

The mean time to reach peak sensory level was slightly higher in group BF (6.27 ± 0.740) when compared to group RF (6.07 ± 0.828), but was not significant statistically ($p > 0.05$).

The mean time to reach peak motor block in group BF and Group RF was 7.87 ± 1.224 and 8.53 ± 0.937 . Patients in group RF has higher mean time compared to group BF to achieve peak motor block, which was statistically significant. ($p < 0.05$).

The mean for two segment sensory regression in group BF and Group RF was 66.87 ± 3.54 and 63.13 ± 2.096 respectively. Patients in group RF has less mean time compared to group BF for two segment sensory regression, which was highly significant statistically. ($p < 0.01$).

The mean for motor regression to Bromage Grade 1 in group BF and Group RF was 256.73 ± 15.026 and 224.1 ± 13.397 respectively. Patients in group RF have lesser mean time compared to group BF for motor regression to Bromage Grade 1, which was highly significant statistically. ($p < 0.01$).

The mean and SD of duration of analgesia in Group BF (289.20 ± 16.382) was slightly more compared to Group RF (242.27 ± 12.809) and it was highly significant statistically ($p < 0.05$).

There was an initial moderate fall in BP in all the patients, which was produced by the sympathetic blockade. After that, the dip in systolic BP got stabilized after 90 min in RF group, indicated by the recovery of BP which was early when compared to BF group where the stabilization of BP was delayed. There is a statistically significant difference among the two groups with respect to systolic blood pressure at all the time intervals. This also coincides with the early recovery of motor power in RF group, when compared to the BF group.

The mean diastolic blood pressure was slightly higher for patients belonging to group RF compared to Group BF which was significant statistically at only 3 intervals i.e. 3min, 15 mins and 30 minutes ($p < 0.05$). The

diastolic blood pressure between the two groups is comparable at other intervals of time and it was not significant statistically ($p > 0.05$).

The mean spO_2 was slightly higher in group RF compared to group BF which was significant statistically at 5 mins, 60 mins, 90 mins, 150 mins, 210 mins, 270 mins and 300 mins ($P < 0.05$). At other intervals the difference seen is not significant statistically. ($p > 0.05$).

The mean of motor block was significantly higher in group BF compared to group RF at 150, 270, 300 and 360 minutes. The difference in the Motor block grade at other points of time was not statistically significant. Mean of MAP of Group RF was significantly high when compared with group BF at 0 mins, 3mins, 5 mins, 15 mins, 90 mins, 120 mins, 180 mins, 210 mins, 240 mins, 270 and 300 mins. The difference at other intervals of time was not significant statistically.

The mean of PR of group RF was slightly higher than group BF which was significant statistically at 5 mins. The difference at any other point of time though present was not significant statistically.

Out of 60 patients 15 patients had side effects. Most common side effect was nausea which was seen in more patients belonging to group BF compared with Group RF. Shivering was experienced by 3 patients, vomiting by 3 patients and urinary retention in 2 patients. Patients belonging to group RF (23.3%) have a better side effect profile, when compared to group BF (30%) but was not significant statistically.

Ropivacaine is a long-acting, enantiomerically pure (S enantiomer) amide local anaesthetic, with a high pKa which has low lipid solubility. The low lipid solubility of ropivacaine may result in a lesser duration of analgesia when compared with Bupivacaine. Also, the early motor recovery of ropivacaine is due to the blockade of nerve fibres involved in the transmission of pain (Ad and C fibres) to a greater degree, compared to controlling motor functions (A β fibres). This feature favours early ambulation and allows for the detection of any neurological side effects if occurred. In the present study, median peak sensory level is at the level of T4 for all 60 patients in the range of T4-T6. The peak sensory level was attained by the same proportion of patients which is 14 (46.7%) in each group. Hence the two groups were comparable concerning the peak sensory level (T4) attained. But it was statistically not significant ($p > 0.05$). In a study by Kumar^[9] maximum sensory block was at the T8 level for 22% in Group R and 37% in Group B which was significant statistically. In a study by Jagtap^[10] Maximum sensory block was at the T6 level in 2 groups. In a study by Prajwal^[11] maximum sensory level was at T6 which was achieved in 56% of patients in group A compared to 66% in group B, the maximum level of T4 was achieved in 18% of patients of group A (ropivacaine + fentanyl) patients compared to 26% in patients of group B (bupivacaine + fentanyl). A maximum sensory level of only up to T8

Table 1: General Characteristics

Characteristics	Group RF (n=30)	Group BF (n=30)	P value
Mean Age (in years)	42.97±13.91	44.93±10.83	0.544
Gender			
Female	25 (83.3 %)	25 (83.3 %)	1
Male	5 (17.7 %)	5 (17.7 %)	
Height (cms)	167.83±8.11	166.7±7.75	0.582
Weight (kgs)	69.5±7.22	68.37±5.01	0.482
ASA grade			
1	12 (40 %)	14 (46.67 %)	0.184
2	18 (60 %)	16 (53.33 %)	
duration of surgery (min)	192.33±22.309	188.87±19.934	0.403

Table 2: Distribution of Peak Sensory Level Attained

Group	Peak sensory level (thoracic)				Total	Chi-square / p value
	T3	T4	T5	T6		
BF	1	14	11	4	30	2.143/0.543
RF	4	14	9	3	30	
Total	5	28	20	7	60	

Table 3: Anaesthesia Characteristics

Characteristics	Group RF	Group BF	P value
Time (in mins) to reach peak sensory level	6.27±.740	6.07±.828	0.974
Time (in mins) to reach peak motor level	7.87±1.224	8.53±.937	0.021
Two segment sensory regression time (in min)	66.87±3.540	63.13±2.097	0.000
Time to motor regression to Bromage grade 1	256.73±15.02	224.10±13.39	0.000
Duration of analgesia	289.20±16.382	242.27±12.809	0.000

Table 4: Comparison of Mean SBP

Time (in mins)	Group RF		Group BF		P* Value	
	Mean SBP	SD SBP	Mean SBP	SD SBP		
0	124.57	3.730	121.50	2.446	0.000	HS
3	122.40	4.789	118.53	4.524	0.002	S
5	121.20	3.517	116.50	4.305	<0.000	HS
15	116.93	2.545	115.27	1.911	<0.006	S
30	109.27	2.016	111.83	2.755	<0.000	HS
60	107.63	2.883	108.50	3.981	0.338	NS
90	108.73	110.50	106.93	3.151	0.021	S
120	113.20	2.235	107.8	1.064	0.000	HS
150	114.23	2.487	109.90	0.960	0.000	HS
180	118.73	1.507	111.03	1.474	0.000	HS
210	119.07	1.760	111.80	1.157	0.000	HS
240	118.83	3.239	111.97	1.884	0.000	HS
270	119.00	2.435	114.30	2.2	0.000	HS
300	118.53	2.788	116	1.875	0.000	HS
330	119.07	0.828	116	1.682	0.000	HS

Table 5: Comparison of Mean Diastolic BP

Time in minutes	Group RF		Group BF		P* Value	
	Mean DBP	SD DBP	Mean DBP	SD DBP		
0	82.93	7.674	79.87	4.183	0.06	NS
3	79.10	0.803	78.33	1.493	0.016	S
5	82	1.619	81.93	1.507	0.869	NS
15	82.10	1.605	80.97	0.850	0.001	HS
30	83.13	2.080	82.03	1.474	0.021	S
60	79.97	1.497	80.10	1.709	0.749	NS
90	81.80	1.518	81.93	1.507	0.734	NS
120	79.87	1.525	80.03	1.608	0.682	NS
150	85	0.830	85	0.830	1	NS
180	84.10	1.517	84.03	1.497	0.865	NS
210	85.17	2.069	85.33	2.264	0.767	NS
240	78.90	4.452	78.83	5.011	0.957	NS
270	79.33	3.575	79.20	3.305	0.881	NS
300	77.43	2.223	77	2.334	0.465	NS
330	119.07	0.828	116	1.682	0.510	NS

Table 6: Comparison of Mean SPO2

Time in mins	Group RF		Group BF		P* Value	
	Mean SPO2	SD SPO2	Mean SPO2	SD SPO2		
0	98.27	1.015	98.30	1.119	0.904	NS
3	98.87	0.776	98.27	1.048	0.015	S
5	98.33	1.093	98.90	0.803	0.026	S
15	98.27	1.048	98.33	1.124	0.813	NS
30	98.27	1.143	98.27	1.081	1.000	NS
60	98	1.017	99.50	0.509	0.000	HS
90	98.40	1.102	98.93	0.785	0.035	S
120	97.97	1.299	98.27	1.081	0.335	NS
150	98.3	1.119	99.50	0.509	0.000	HS
180	97.80	1.448	98.47	1.167	0.054	NS
210	98.37	1.066	98.93	0.785	0.023	S
240	98.40	1.102	98.77	0.728	0.134	NS
270	98.30	1.022	99.50	0.509	0.000	HS
300	97.50	1.333	98.93	0.785	0.000	HS
330	98.40	1.102	98.47	1.167	0.821	NS

Table 7: Comparison of Mean Motor Block Grade (MBG)

Time in mins	Group RF		Group BF		P* Value	
	Mean of MBG	SD of MBG	Mean of MBG	SD of MBG		
0	0	0	0	0	NA	
5	2.80	0.407	2.90	0.305	0.286	NS
15	3	0.00	3	0.0	NA	
30	3	0.00	3	0.0	NA	
60	3	0.00	3	0.0	NA	
90	3	0.00	3	0.0	NA	
120	3	0.00	3	0.0	NA	
150	2.73	0.521	3	0.0	0.007	S
180	2.47	0.571	2.70	0.466	0.088	NS
210	1.80	0.761	2	0.643	0.276	NS
240	1.40	0.675	1.60	0.498	0.197	NS
270	1.00	0.643	1.40	0.498	0.009	S
300	0.60	0.498	1.20	0.407	0.000	HS
360	0.30	0.466	0.90	0.305	0.000	HS

Table 8: Comparison of Mean Arterial Pressure

Time in mins	Group RF		Group BF		P* Value	
	Mean MAP	SD MAP	Mean MAP	SD MAP		
0	96.80	4.951	93.80	3.145	0.007	S
3	93.50	1.815	91.70	1.985	0.001	HS
5	95.30	1.903	93.50	2.097	0.004	S
15	93.77	1.357	92.40	1.133	0.000	HS
30	91.93	1.701	92	1.531	0.874	NS
60	89.17	1.683	89.57	1.995	0.405	NS
90	90.77	1.455	90.23	1.382	0.151	NS
120	91	1.390	89.30	1.179	0.000	HS
150	94.73	1.112	93.33	0.802	0.000	HS
180	95.57	1.305	93.03	1.159	0.000	HS
210	96.50	1.614	94.07	1.680	0.000	HS
240	92.23	3.739	89.73	3.562	0.01	S
270	92.57	2.674	91.00	2.586	0.025	S
300	91.13	1.795	89.97	1.921	0.018	S
330	92.67	1.863	92	2.244	0.216	NS

Table 9: Comparison of Mean Pulse Rate

Time in mins	Group RF		Group BF		P* Value	
	Mean PR	SD PR	Mean PR	SD PR		
0	78.83	7.600	74.37	7.6	0.083	NS
3	75.53	8.613	75.37	8.783	0.941	NS
5	81.77	11.863	74.53	8.303	0.008	S
15	77.30	11.830	79.53	10.471	0.442	NS
30	76.73	11.061	75.10	6.925	0.496	NS
60	79.4	11.211	77	6.544	0.315	NS
90	78.3	10.616	74.93	7.051	0.153	NS
120	78.13	10.464	73.83	6.352	0.059	NS
150	77.37	11.266	76.73	6.873	0.794	NS
180	78.80	9.349	76.07	8.350	0.237	NS
210	77.17	10.952	75.70	7.382	0.545	NS
240	77.60	10.230	73.40	6.647	0.064	NS
270	80.03	10.176	76.63	6.926	0.136	NS
300	76.83	9.542	77.17	8.987	0.890	NS
330	77.53	10.543	73.93	7.483	0.133	NS

Table 10: Side Effects

Parameter	Group RF	Group BF	Total
Nausea	3	8	11
Shivering	1	2	3
Vomiting	1	2	3
Urinary retention	1	1	2

was achieved in 24% of patients in group A while it is only 8% in group B. The upper level of sensory blockade was a bit higher in patients of group B as compared to group A. In this study, the mean and SD of time to reach peak sensory level was slightly higher in group BF (6.27±0.740) when compared to group RF (6.07±0.828), but was not significant statistically ($p>0.05$). Similar results were found in a study by Saran^[12] where the mean onset time in group B was found to be 5.26±0.986 min, while it was 6.24±1.001 min in Group R. The difference was significant and they concluded that the onset of sensory blockade was earlier in Group B compared to Group R. In a study by Kumar^[9] the time of onset of maximum sensory block

for Group R and Group B was 15.41±9.31 and 12.62±3.66 respectively. In study by Jagtap^[10] time of onset of maximum sensory block for Group RF and Group BF was 15.41±9.31 and 12.62±3.66 respectively. In a study by Prajwal^[11] the mean onset time of sensory blockade (maximum sensory level in mins) was 13.64±4.82 mins in group A (ropivacaine+fentanyl) as compared to 15.5±4.87 mins in group B (bupivacaine+fentanyl) with a significant statistical difference ($p<0.05$). This difference in various studies could be due to variation in volume and baricity of drug administered. In the current study mean and SD of time to reach peak motor block in group BF and Group RF was 7.87±1.224 and 8.53±0.937. Patients of group

RF has a higher mean time compared to group BF to achieve peak motor block, which was statistically significant ($p < 0.05$). In a study by Kumar^[9] time for onset of maximum motor block for Group R and Group B was 18.50 ± 11.77 and 12.53 ± 4.32 which was not significant statistically. In a study by Saran^[12] mean onset time of motor blockade was 9.72 min in Group B which was significantly low as compared to 13.18 min in Group R. In a study by Jagtap^[10] complete motor block (Group RF- 6.02 ± 2.1 min, Group BF- 6 ± 3.6 min, $P = 0.31$). In a study by Prajwal^[11] the onset of motor blockade was rapid in 2 groups with a mean onset of 15.6 ± 3.4 min in group A and 17.3 ± 4.6 min in group B., these observations were comparable in all the studies and also coincide with the current study. In the current study, the mean and SD of the duration of analgesia in Group BF (289.20 ± 16.382) was slightly more than Group RF (242.27 ± 12.809) and it was highly significant statistically ($p < 0.05$). In a study by Kumar^[9] duration of sensory block for Group R and Group B was 257.17 ± 39.12 and 284.64 ± 32.33 which was significant statistically. In a study by Saran^[12] the mean time duration of sensory blockade of Group B was 191.38 min and in group, R was 191.24 which was comparable in both groups and the difference was not found to be statistically significant. Study by Jagtap^[10] the duration of sensory block in Group R and Group F was 257.17 ± 39.12 and 284.64 ± 32.33 which was significant statistically. Study by Prajwal^[11] duration of analgesia in minutes for Group RF was 234.44 ± 58.76 min and for Group BF was 263.33 ± 63 min, with $P = 0.021.56$ These studies were comparable with our results. In the present study, most common side effect was nausea which was seen in more patients belonging to group BF compared with Group RF. Patients belonging to group RF (23.3%) have a better side effect profile, when compared to group BF (30%) but was not significant statistically. In a study by Jagtap^[10] 1 patients in Group RF had nausea, vomiting and shivering whereas no symptoms in patients of Group BF. Our study findings show that spinal anaesthesia with RF gives good anaesthesia with better hemodynamic stability. It can give similar sensory but shorter motor block time compared to BF which favours early ambulation. A study by Kumar^[9] stated that Isobaric ropivacaine was associated with a slower onset, less time taken for sensory and motor block and lesser grade of the motor block when compared to bupivacaine. Postoperatively, patients who received ropivacaine had increased pain reliever requirement, more complications, and similar discharge time as compared with bupivacaine. In a study by Jagtap^[10] concluded that almost all the features of the sub-arachnoid block were comparable., there was significant early motor recovery with RF whereas BF provided prolonged post-operative analgesia. Limitations of present study was, dosage of drugs Ropivacaine and Bupivacaine used in this study

were different., also, the differences in baricity were not taken into consideration. Any impact of baricity on the spinal block characteristics was not measured. Another limitation was the small sample size

CONCLUSION

Our study findings show that intrathecal administration of Ropivacaine+Fentanyl provides adequate anaesthesia with hemodynamic stability. Also, it has a faster onset time and faster regression time of the sensory block, delayed onset time but comparable regression of motor block to Bromage grade 1 and shorter time is taken for analgesia as compared to intrathecal bupivacaine-fentanyl which will be beneficial for early ambulation.

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