COMPARATIVE STUDY BETWEEN INTRATHECAL BUPIVACAINE 0.5% HEAVY + FENTANYL (0.5 MICROGRAMS/KG) VERSUS INTRATHECAL BUPIVACAINE 0.5% HEAVY + BUPRENORPHINE (2 MICROGRAMS/KG) IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES

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ABSTRACT

BACKGROUND

Various adjuvants have been added to bupivacaine to shorten the onset of block and prolong the duration of block. Present study was undertaken to compare the efficacy of intrathecal fentanyl or buprenorphine with bupivacaine for all infraumbilical surgeries.

MATERIALS AND METHODS

100 ASA I and II patients of both sexes posted for various infraumbilical surgeries were chosen for the study and the patients were divided into two groups of 50 each. Group F received 3mL of 0.5% bupivacaine heavy with 0.5mcg/kg of fentanyl and groupB received 3mL of 0.5% bupivacaine heavy with 2mcg/kg of buprenorphine. The time of onset of sensory block was tested with pinprick method and motor block was assessed by onset of Bromage scale 3 and it was found that the onset of sensory block with buprenorphine was earlier compared to fentanyl.

RESULTS

Bradycardia observed in Group B in 7 patients (14%), which was successfully treated with vagolytic agents. In Group B, it was observed that there was hypotension in 14 patients (28%), and in Group F, 7 patients developed hypotension, which was successfully treated with vasopressors. Also, few patients developed pruritus, nausea and vomiting, which were negligible. Intraoperatively, sedation score was assessed using modified Ramsay. Sedation scale and there was higher incidence of sedation with buprenorphine group. Regression of motor block to Bromage0 was observed and the time to regression was significantly prolonged to 205±37.71 in the buprenorphine group, while it was 152.90±8.31 in the fentanyl group. Postoperatively, VAS scores were significantly low for the buprenorphine group when compared with fentanyl.

CONCLUSION

To summarise, buprenorphine has higher efficacy with intrathecal bupivacaine with prolonged duration of sensory and motor blockade with decreased incidence of side effects, better haemodynamic stability and intraoperative sedation and also analgesic sparing effect in the postoperative period when compared to fentanyl.

KEYWORDS

Bupivacaine, Fentanyl, Buprenorphine, Adjuvants.

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BACKGROUND

Spinal anaesthesia is the most preferred regional anaesthesia technique as it is easy to perform, economical and produces rapid onset of anaesthesia and complete muscle relaxation. The aim of intrathecal local anaesthetic is to provide adequate sensory and motor block necessary for all infraumbilical surgeries. Hyperbaric bupivacaine is the most commonly used intrathecallocal anaesthetic. However, insufficient duration of anaesthesia and postoperative analgesia prevails when it is used as the sole agent. A number of adjuvants have been introduced into clinical practice to prolong the duration of bupivacaine-induced subarachnoid block, postoperative analgesia and to lower the dose of local anaesthetics used thereby reducing the side effects.[1]

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Clinical studies have evaluated the efficacy of both opioids and alpha 2 adrenergic agonists as an adjuvant to intrathecal bupivacaine and found them to be effective. Neuraxial administration of opioids along with local anaesthetics improve the quality of intraoperative analgesia and also provides postoperative pain relief for longer duration.[2]

Fentanyl citrate, a lipophilic opioids agonist is used as an adjuvant to prolong the duration of spinal block.[3]

Buprenorphine is a long-acting, highly lipophilic opioid, which has proved to be a promising analgesic by epidural and intrathecal route. It is about 25 times more potent than morphine and has a low level of physical dependence.[4]

Therefore, the present study was performed to compare fentanyl and buprenorphine in their efficacy as adjuvants to subarachnoid block.

AIMS AND OBJECTIVES OF THE STUDY

The aim of the study is to compare the following factors in two groups, i.e.-

a. Hyperbaric bupivacaine 0.5% and fentanyl (0.5 mcg/kg).
b. Hyperbaric bupivacaine0.5% and buprenorphine (2mcg/kg) when given intrathecally.

Onset and Duration of Analgesia- Speed of onset and duration of analgesia as determined by lack of appreciation to pinprick.

Motor Blockade- Speed of onset and duration of motor blockade as assessed by Bromage scale.

Intraoperative Sedation- Assessed using modified Ramsay sedation scale.

Postoperative Period- Postoperative pain assessed using visual analogue scale. Postoperative complications such as nausea, vomiting, hypotension, shivering, pruritus, seizures and respiratory depression are assessed.

MATERIALS AND METHODS

Source of Data- Inpatients, posted for major surgeries, below umbilical level in Osmania General Hospital and Government Maternity Hospital, Hyderabad, were chosen for the study.

Inclusion Criteria

ASA physical status class I and II patients and age between 18-65 years of either sex were included.

Exclusion Criteria

Patients with emergency surgery, deformities of the spine, hypersensitivity to any of the drugs, contraindications to spinal anaesthesia, patient refusal, bleeding and diathesis were excluded.

METHODOLOGY

After approval from the ethical committee of our hospital, 100 ASA I and II patients scheduled for major surgeries under spinal anaesthesia were chosen for the study. Preanaesthetic checkup was done one day prior to the surgery.

Patients were evaluated for any systemic diseases and laboratory investigations recorded. The procedure of SAB was explained to the patients and written consent was obtained. The patients were educated about the use of visual analogue scale.

Preparation of patients included period of overnight fasting and were premedicated with Tab.Rantac 150mg and Tab. Alprazolam 0.5 mg h.s.

Preparation of Operating Theatre- Boyle's anaesthesia machine was checked. Appropriate size endotracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus were kept ready before the procedure.

Emergency drug tray consisting of atropine, adrenaline, mephentermine, ephedrine and dopamine were kept ready.

Procedure- Patients shifted to operating table, baseline vitals were recorded. IV access was obtained on the forearm with No. 18G IV cannula and all patients were preloaded with 15mL/kg, Ringer's lactate, 15 mins. before the surgery.

Patients were randomly allocated into groups.

Under strict asepsis, using 23G Quincke-Babcock spinal needle, lumbar puncture was performed at L3-L4 space.

Group F received 3mL, 0.5% hyperbaric bupivacaine + fentanyl (0.5mcg/kg), group B received 3mL, 0.5% hyperbaric bupivacaine + buprenorphine (2mcg/kg).

Intraoperatively, pulse rate, noninvasive blood pressure, electrocardiogram, SpO2 was recorded every 2 minutes for the first 10 minutes, every 10 minutes for the next 50 minutes and every 15 minutes till the end of surgery.

Time of onset of sensory block was noted using pinprick method, time of onset of motor block was noted.

Motor Block was Assessed with Modified Bromage Scale

- Bromage 0 - The patient is able to move the hip, knee and ankle.
- Bromage 1 - The patient is unable to move the hip, but is able to move the knee and ankle.
- Bromage 2 - The patient is unable to move the hip and knee, but able to move the ankle.
- Bromage 3 - The patient is unable to move the hip, knee and ankle.

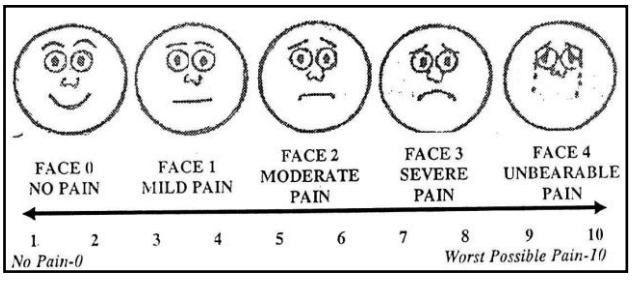
Modified Ramsay sedation scale was used for intraoperative sedation-

- 1 = Agitated, restless.
- 2 = Cooperative, tranquil.
- 3 = Responds to verbal commands while sleeping.
- 4 = Brisk response to glabellar tap or loud noise while sleeping.
- 5 = Sluggish response to glabellar tap or loud noise while sleeping.

- 6 = No response to glabellar tap or loud noise while sleeping.

Following parameters were recorded-

- Hypotension (>20% fall of baseline blood pressure) was treated with bolus dose of 6mg ephedrine intravenous.
- Bradycardia (pulse rate <50bpm) was treated with 0.6mg atropine intravenous.
- Incidence of respiratory depression defined as respiratory rate less than 9/min. and SpO2 less than 90% on room air was noted.
- Side effects if any were noted.
- Postoperatively, regression of the sensory block and the motor blockade to reach modified Bromage was noted.
- Pain was assessed using "visual analogue scale" advocated by Revilland Robinson in 1976. It is linear scale consists of 10cm line anchored at one end.



By a label such as- No pain and other end byworst pain imaginable. Patient simply marks the line to indicate the pain intensity. Supplemental analgesia was given for visual analogue score of more than 6. Time of supplemental analgesia was noted.

Visual analogue scale was used to assess postoperative pain.0 = no pain, 10 = severe pain.

Statistical Methods

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min.-Max.) and results on categorical measurements are presented in number (%). Significance is assessed at 5% level of significance.

The following assumptions on data are made; Assumption- 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random and cases of the samples should be independent.

Student's test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups.

(Intergroup analysis) on metric parameters. Chi-square/Fisher exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

Study Design- A comparative two group randomised clinical study with 100 patients with 50 patients in Group F (fentanyl) and 50 patients in Group B (buprenorphine) is undertaken to study the changes in haemodynamics and side effects.

Statistical analysis was done by applying Chi-square test, ANOVA test and Student's t-test to analyse the data, 'p' value was determined. P>0.05 is not significant; P<0.05 is significant; P<0.001 is highly significant.

RESULTS

	Group	Number	Mean	Std. Deviation	T	Df	'p' value
Age	Group F	50	45.56	12.078	4.061	98	<0.001
	Group B	50	35.66	12.297			
Height	Group F	50	155.66	5.161	-0.4	98	0.69
	Group B	50	156.1	5.832			
Weight	Group F	50	58.12	12.355	0.539	98	0.591
	Group B	50	56.9	10.185			
Gender	Group F	50			0.000	1	1.000
	Group B	50					

Table 1. Age, Height and Weight Distribution of Patients Studied

Comparison of the age and height between the two groups shows that age is higher in Group F with a t-value of 4.061 and is statistically significant with a 'p' value of <0.001, whereas height is higher in Group B with a 't' value of -0.4 and is statistically nonsignificant with a 'p' value of 0.69 and weight is higher in Group F group with a 't' value of 0.539 and is statistically nonsignificant with a 'p' value of 0.591. Both groups are gender matched with p=1.00.

			Group F	Group B	Total	Value	df	'p' value
ASA	Grade 1	Count	26	31	57	1.020	1	0.313
	Grade 2	Count	24	19	43			
Total			**50**	**50**	**100**			

Table 2. ASA Grade in Two Groups of Patients Studied

ASA grade is statistically similar in two groups with P = 0.313.

Time of onset of sensory block (min.) is higher in Group F group with a 't' value of 0.967 and is statistically nonsignificant with a 'p' value of 0.336 and Time of Sensory regression to S1 (min.) is higher in Group B group with a 't' value of -6.47 and is statistically significant with a 'p' value of <0.001.While onset of motor block (min.) is higher in Group F group with a 't' value of 4.268 and is statistically significant with a 'p' value of <0.001and regression to Bromage0 (min.) is higher in Group B group with a 't' value of -9.539 and is statistically significant with a 'p' value of <0.001.

Duration of Analgesia (min.) is higher in Group B group with a 't' value of -23.235 and is statistically significant with a 'p' value of <0.001.

	Group	N	Mean	Std. Deviation	T	Df	'p' value
Time of onset of sensory block (mins.)	Group F	50	3.38	0.83642	0.967	88.173	0.336
	Group B	50	3.24	0.59109			
Time of sensory regression to S1 (mins.)	Group F	50	187	8.142	-6.47	52.706	<0.001
	Group B	50	226	41.838			
Onset of motor block (mins.)	Group F	50	3.88	0.8179	4.268	84.477	<0.001
	Group B	50	3.29	0.5354			
Regression to Bromage0 (min.)	Group F	50	159.2	8.311	-9.539	53.747	<0.001
	Group B	50	205	37.718			
Duration of analgesia (mins.)	Group F	50	169	10.698	-23.24	57.648	<0.001
	Group B	50	292	35.871			

Table 3. Comparison of (A) Time of Onset of Sensory Block, (B) Time of Sensory Regression to S1, (C) Onset of Motor Block, (D) Regression to Bromage0 and (E) Duration of Analgesia

	Group	N	Mean	Std. Deviation	T	Df	'p' value
SBP 0	Group F	50	129.22	11.689	2.798	98	0.006
	Group B	50	123.08	10.202			
DBP 0	Group F	50	81.92	9.18	1.807	98	0.074
	Group B	50	78.52	9.626			
SBP 2	Group F	50	125.12	12.114	5.412	90.555	<0.001
	Group B	50	113.56	9.02			
DBP 2	Group F	50	77.38	9.68	3.382	95.993	0.001
	Group B	50	71.26	8.369			
SBP4	Group F	50	119.1	11.348	3.172	98	0.002
	Group B	50	112.56	9.15			
DBP 4	Group F	50	72.46	8.57	1.348	98	0.181
	Group B	50	70.02	9.505			
SBP 6	Group F	50	115.24	9.774	3.205	98	0.002
	Group B	50	108.84	10.193			
DBP 6	Group F	50	69.04	8.652	0.525	98	0.601
	Group B	50	68	11.031			
SBP 8	Group F	50	112.42	9.047	0.568	98	0.571
	Group B	50	111.42	8.55			
DBP 8	Group F	50	65.76	7.875	-2.618	98	0.01
	Group B	50	70.16	8.897			
SBP 10	Group F	50	110.22	9.873	-0.137	98	0.891
	Group B	50	110.5	10.504			
DBP 10	Group F	50	62.3	8.399	-2.328	94.136	0.022
	Group B	50	66.68	10.314			
SBP 20	Group F	50	109.46	9.702	0.039	98	0.969
	Group B	50	109.38	10.78			
DBP 20	Group F	50	60.92	9.236	-2.186	98	0.031
	Group B	50	65.12	9.967			
SBP 30	Group F	50	107.66	9.492	-0.338	96.88	0.736
	Group B	50	108.34	10.575			
DBP 30	Group F	50	61.36	7.403	-1.998	91.779	0.049
	Group B	50	64.8	9.664			
SBP 40	Group F	50	106.64	9.985	-0.337	98	0.737
	Group B	50	107.32	10.209			
DBP 40	Group F	50	60.9	8.252	-2.253	98	0.026
	Group B	50	64.94	9.627			
SBP 50	Group F	50	106.82	10.189	-0.15	98	0.881
	Group B	50	107.12	9.753			
DBP 50	Group F	50	61.28	8.502	-1.954	98	0.053
	Group B	50	64.76	9.286			

SBP 60	Group F	50	108.98	9.747	0.612	98	0.542
	Group B	50	107.82	9.209			
DBP 60	Group F	50	62.98	8.791	-1.232	98	0.221
	Group B	50	65.16	8.906			
SBP 75	Group F	50	129.71	129.6162	1.149	98	0.253
	Group B	50	108.6	8.8847			
DBP 75	Group F	50	66.06	7.747	0.274	98	0.785
	Group B	50	65.62	8.308			
SBP 90	Group F	50	114.58	8.328	2.381	98	0.019
	Group B	50	110.56	8.558			
DBP 90	Group F	50	69	7.546	1.138	98	0.258
	Group B	50	67.18	8.427			

Table 4. Comparison of Systolic and Diastolic Blood Pressure(mmHg) in Two Groups of Patients Studied

Haemodynamic Stability- Recorded at 0 min. (preoperative), 2 mins., 4 mins., 6 mins., 8 mins., 10 mins., 20 mins., 0 min., 40 mins., 50 mins., 60 mins., 75 mins. and 90 mins.

Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

- Comparison of the SBP 0, DBP 0 between the two groups shows that SBP 0 is higher in Group B group with a 't' value of -0.997 and is statistically nonsignificant with a 'p' value of 0.323, whereas DBP 0 is higher in Group F group with a 't' value of 1.807 and is statistically nonsignificant with a 'p' value of 0.074.
- SBP 2 is higher in Group F group with a 't' value of 5.412 and is statistically significant with a 'p' value of <0.001 and DBP 2 is higher in Group F group with a 't' value of 3.382 and is statistically significant with a 'p' value of 0.001.
- SBP 4 is higher in Group F group with a 't' value of 3.172 and is statistically significant with a 'p' value of 0.002 and DBP 4 is higher in Group F group with a 't' value of 1.348 and is statistically nonsignificant with a 'p' value of 0.181.
- SBP 6 is higher in Group F group with a 't' value of 3.205 and is statistically significant with a 'p' value of 0.02 and DBP 6 is higher in Group F group with a 't' value of 0.525 and is statistically nonsignificant with a 'p' value of 0.601.
- SBP 8 is higher in Group F group with a 't' value of 0.568 and is statistically nonsignificant with a 'p' value of 0.571 and DBP 8 is higher in Group B group with a 't' value of -2.618 and is statistically significant with a 'p' value of 0.01.
- SBP 10 is higher in Group B group with a 't' value of -0.137 and is statistically nonsignificant with a 'p' value of 0.891 and DBP 10 is higher in Group B group with a 't' value of -2.328 and is statistically significant with a 'p' value of 0.022.
- SBP 20 is higher in Group F group with a 't' value of 0.039 and is statistically nonsignificant with a 'p' value of 0.969 and DBP 20 is higher in Group B group with a 't' value of -2.186 and is statistically significant with a 'p' value of 0.031.
- SBP 30 is higher in Group B group with a 't' value of -0.338 and is statistically nonsignificant with a 'p' value of 0.736 and DBP 30 is higher in Group B group with a 't' value of -1.998 and is statistically significant with a 'p' value of 0.049.
- SBP 40 is higher in Group B group with a 't' value of -0.337 and is statistically no significant with a 'p' value of 0.737 and DBP 40 is higher in Group B group with a 't' value of -2.253 and is statistically significant with a 'p' value of 0.026.
- SBP 50 is higher in Group B group with a 't' value of -0.15 and is statistically nonsignificant with a 'p' value of 0.881 and DBP 50 is higher in Group B group with a 't' value of -1.954 and is statistically nonsignificant with a 'p' value of 0.053.
- SBP 60 is higher in Group F group with a 't' value of 0.612 and is statistically nonsignificant with a 'p' value of 0.542 and DBP 60 is higher in Group B group with a 't' value of -1.232 and is statistically nonsignificant with a 'p' value of 0.221.
- SBP 75 is higher in Group F group with a 't' value of 1.149 and is statistically nonsignificant with a 'p' value of 0.253 and DBP 75 is higher in Group F group with a 't' value of 0.274 and is statistically nonsignificant with a 'p' value of 0.785.
- SBP 90 is higher in Group F group with a 't' value of 2.381 and is statistically significant with a 'p' value of 0.019 and DBP 90 is higher in Group F group with a 't' value of 1.138 and is statistically nonsignificant with a 'p' value of 0.258.

Heart Rate (HR)

	Group	N	Mean	Std. Deviation	T	Df	'p' value
HR 0	Group F	50	82.68	12.426	-0.642	98	0.522
	Group B	50	84.36	13.715			
HR 2	Group F	50	82.04	12.16	-0.504	98	0.615
	Group B	50	83.36	13.947			

HR 4	Group F	50	81.02	11.166	-1.09	92.47	0.279
	Group B	50	83.82	14.329			
HR 6	Group F	50	79.78	10.727	-1.297	98	0.198
	Group B	50	83.02	14.039			
HR 8	Group F	50	78.58	9.679	-0.787	98	0.433
	Group B	50	80.34	12.514			
HR 10	Group F	50	77.6	8.799	-0.122	98	0.903
	Group B	50	77.84	10.716			
HR 20	Group F	50	76.42	8.142	0.081	98.727	0.936
	Group B	50	76.26	11.385			
HR 30	Group F	50	75.46	7.704	-0.01	86.881	0.992
	Group B	50	75.48	11.202			
HR 40	Group F	50	74.68	7.673	-0.127	88.078	0.899
	Group B	50	74.92	10.879			
HR 50	Group F	50	74.48	7.71	-0.251	98	0.802
	Group B	50	74.92	9.703			
HR 60	Group F	50	74.18	7.572	-0.494	98	0.624
	Group B	50	74.98	8.644			
HR 75	Group F	50	73.4	7.57	-0.929	98	0.355
	Group B	50	74.9	8.543			
HR 90	Group F	50	72.78	7.115	-0.689	98	0.492
	Group B	50	73.84	8.222			

Table 5. Distribution of Heart Rate in Two Groups

- Comparison of the HR 0 between the two groups show that HR 0 is higher in Group B group with a 't' value of -0.642 and is statistically nonsignificant with a 'p' value of 0.522.
- HR 2 is higher in Group B group with a 't' value of -0.504 and is statistically nonsignificant with a 'p' value of 0.615; HR 4 is higher in Group B group with a 't' value of -1.09 and is statistically nonsignificant with a 'p' value of 0.279; HR 6 is higher in Group B group with a 't' value of -1.297 and is statistically nonsignificant with a 'p' value of 0.198; HR 8 is higher in Group B group with a 't' value of -0.787 and is statistically nonsignificant with a 'p' value of 0.433; HR 10 is higher in Group B group with a 't' value of -0.122 and is statistically nonsignificant with a 'p' value of 0.903; HR 20 is higher in Group F group with a 't' value of 0.081 and is statistically nonsignificant with a 'p' value of 0.936; HR 30 is higher in Group B group with a 't' value of -0.01 and is statistically nonsignificant with a 'p' value of 0.992; HR 40 is higher in Group B group with a 't' value of -0.127 and is statistically nonsignificant with a 'p' value of 0.899; HR 50 is higher in Group B group with a 't' value of -0.251 and is statistically nonsignificant with a 'p' value of 0.802; HR 60 is higher in Group B group with a 't' value of -0.492 and is statistically nonsignificant with a 'p' value of 0.624; HR 75 is higher in Group B group with a 't' value of -0.929 and is statistically nonsignificant with a 'p' value of 0.355; and HR 90 is higher in Group B group with a 't' value of -0.689 and is statistically nonsignificant with a 'p' value of 0.492.

	Group	**N**	**Mean**	**Std. Deviation**	**t**	**df**	**'p' value**
RR	Group F	50	16.1	1.619	0	98	1
	Group B	50	16.1	1.619			
SPO_2	Group F	50	97.92	0.752	0	98	1
	Group B	50	97.92	0.752			

Table 6. Distribution of Respiratory Rate and SpO2 in Two Groups Studied

Comparison of the RR, SpO2 between the two groups shows that RR is higher in Group F group with a 't' value of 0 and is statistically nonsignificant with a 'p' value of 1, whereas SpO2 is higher in Group F group with a 't' value of 0 and is statistically nonsignificant with a 'p' value of 1.

	Group	**N**	**Mean**	**Std. Deviation**	**t**	**df**	**'p' value**
Modified Ramsay sedation score (30 mins.)	Group F	50	2	0	-2.064	49	0.0444
	Group B	50	2.16	0.548			
Modified Ramsay sedation score (60 mins.)	Group F	50	2	0	-27.87	49	<0.001
	Group B	50	3.08	0.274			
Modified Ramsay sedation score (90 mins.)	Group F	50	2.16	0.37	-14.52	90.197	<0.001
	Group B	50	3.44	0.501			
Modified Ramsay sedation score (120 mins.)	Group F	50	2.2	0.404	0.415	98	0.679
	Group B	50	2.16	0.548			
Modified Ramsay sedation score (150 mins.)	Group F	50	2.08	0.274	0	98	1
	Group B	50	2.08	0.274			

Modified Ramsay sedation score (180 mins.)	Group F	50	2.08	0.274	0	98	1
	Group B	50	2.08	0.274			

Table 7. Comparison of Modified Ramsay Sedation Score between Two Groups Studied

- Comparison of the modified Ramsay sedation score 30 mins., 60 mins., 90 mins. between the two groups shows that modified Ramsay sedation score 30 mins., 60 mins., 90 mins. are higher in Group B group with a 't' value of -2.064, -27.867, -14.52 and is statistically significant with a 'p' value of 0.044, <0.001, <0.001, respectively.
- Comparison of the modified Ramsay sedation score 120 mins., 150 mins. and 180 mins. between the two groups shows that modified Ramsay sedation score 120 mins., 150 mins. and 180 mins.is higher in Group F group with a 't' value of 0.415, 0, 0 and is statistically nonsignificant with a 'p' value of 0.679, 1, 1, respectively.

	Group	**N**	**Mean**	**Std. Deviation**	**t**	**df**	**'p' value**
Visual analogue scale 6 hrs.	Group F	50	3.5	0.505	12.43	72.719	<0.001
	Group B	50	1.54	0.994			
Visual analogue scale 12 hrs.	Group F	50	5.9	0.974	9.152	73.535	<0.001
	Group B	50	4.48	0.505			
Visual analogue scale 18 hrs.	Group F	50	7.28	0.948	11.584	74.687	<0.001
	Group B	50	5.52	0.505			
Visual analogue scale 24 hrs.	Group F	50	7.24	0.96	12.351	98	<0.001
	Group B	50	4.7	1.093			

Table 8. Comparison of VAS among the Two Groups Studied

- Comparison of the visual analogue scale at 6 hrs., 12 hrs., 18 hrs. and 24 hrs. between the two groups show that visual analogue scale is higher in Group F group with a 't' value of 12.43, 9.152, 11.584, 12.351 and is statistically significant with a 'p' value of <0.001, respectively.

Variable	**Group F**	**Group B**	**Total**
Count	30	33	63
Bradycardia	0	6	6
Hypo, brady	0	1	1
Hypotension	13	6	19
Hypotension, nausea	1	0	1
Nausea	2	4	6
Pruritus	3	0	3
Vomiting	1	0	1

Table 9. Comparison of Side Effects among the Two Groups Studied

In group F, hypotension observed in 13 patients; hypotension, nausea in 1 patient; nausea in 2 patients; pruritus in 3 patients and vomiting in 1 patient, whereas in group B bradycardia observed in 6 patients; hypo, bradycardia in 1 patient; hypotension in 6 patients and nausea observed in 4 patients.

DISCUSSION

Spinal anaesthesia is the most preferred regional anaesthesia technique as it is easy to perform, produces rapid onset of anaesthesia and complete muscle relaxation and is also economical. These advantages are sometimes offset by a relatively short duration of action.

The aim of intrathecal local anaesthetic is to provide adequate sensory and motor block necessary for all infraumbilical surgeries. Hyperbaric bupivacaine is the most commonly used intrathecal local anaesthetic. Various adjuvants have been added to bupivacaine to shorten the onset of block and prolong the duration of block.

Fentanyl, a lipophilic opioid agonist when used as an adjuvant prolongs the duration of spinal anaesthesia. Fentanyl is a lipophilic μ-receptor agonist opioid. Intrathecally, fentanyl exerts its effect by combining with opioid receptors in the dorsal horn of spinal cord and may have a supraspinal spread and action. Buprenorphine is a mixed agonist-antagonist type of opioid with a long duration of action. The high lipid solubility, high affinity for opioid receptors and prolonged duration of action makes buprenorphine a suitable choice for intrathecal and peripheral nerve site administration. Therefore, the present study was performed to compare fentanyl and buprenorphine in their efficacy as adjuvants to spinal anaesthesia.

In our study design, Group F received 0.5% of hyperbaric bupivacaine 3mL with fentanyl (0.5mcg/kg) and Group B received 0.5% hyperbaric bupivacaine 3mL with buprenorphine(2mcg/kg) injected intrathecally to the patients undergoing infraumbilical surgeries.

The following parameters were observed-

- Time of onset of sensory block.
- Time of sensory regression to S1.
- Onset of motor block.
- Regression to Bromage0.
- Intraoperative blood pressure, heart rate, SpO2.
- Intraoperative sedation.
- Postoperative analgesia.

Supporting Studies for the Present Study are-

Fauzia A. Khan, Gauhar A. Hamdani et al[5] compared the characteristics of spinal block, its postoperative analgesic effects and side effects using intrathecal bupivacaine and its combination with fentanyl or buprenorphine in elderly patients undergoing urological surgery.

In this study, 60 patients aged 60 and above scheduled for elective Transurethral Resection of Prostate (TURP) randomly received hyperbaric bupivacaine 0.75% 2mL (Group L control, n=20), buprenorphine 30mcg with hyperbaric bupivacaine 0.75% 2mL (Group B, n=20) or fentanyl 10mcg with hyperbaric bupivacaine 0.75% 2mL (Group F, n=20). Characteristics of spinal block, haemodynamic stability, postoperative analgesia and incidence of adverse effects were compared. All patients were followed for 24 hrs.

Patient's blood pressure remained within 20% of baseline values. The mean time for the sensory block to reach T10 dermatomal level was 3.2±2 mins.in Group F vs. 4.3 ± 1 mins. in group B and 4.5 ± 2 in Group L. The duration of sensory block was significantly longer in group B. Median block levels reached T8 in all groups. All patients required postoperative analgesia in group L and F except 6 in Group B.

Buprenorphine 30mcg in combination with bupivacaine 0.75% 2 mL provided analgesia of comparable clinical onset and longer duration, but was associated with a clinically increased incidence of nausea and vomiting in elderly patients.

A study by Capogna G et al[6] worked on 90 patients aged 56-85 years scheduled for suprapubic prostatectomy randomly received intrathecally either bupivacaine 3 mL (Group A), bupivacaine 3mL plus buprenorphine 0.03 mg (Group B) or bupivacaine 3 mL plus buprenorphine 0.045 mg (Group C). They concluded that prolonged postoperative analgesia, minimal disturbance of consciousness and comfortable breathing were common to the groups that received buprenorphine.

A study was done by Celleno D et al[7] to compare two doses of intrathecal buprenorphine for postoperative analgesia in 45 women undergoing elective caesarean section under spinal anaesthesia. Group A received hyperbaric bupivacaine, group B received bupivacaine with 0.03 mg buprenorphine and group C received bupivacaine with 0.045 mg buprenorphine. They concluded that patients receiving buprenorphine had a longer pain-free interval and those patients receiving the higher dose had a longer effect than those receiving the lower dose without any increase in side effect.

A study was done by Nishimi Y et al[8] to investigate the effect of intrathecal buprenorphine (0.05 mg and 0.075 mg) and morphine (0.5 mg) on the MAC of halothane and the relief of postoperative pain. They concluded that the decrease in halothane MAC with 0.05 mg intrathecal buprenorphine was equipotent with the intrathecal 0.5 mg morphine. Adequate postoperative analgesia and severe pruritus were observed in 0.5 mg morphine group. The intrathecal administration of 0.05 mg and 0.075mg buprenorphine has shown analgesia effect without any side effects.

A study was done by Shah FR[9] et al to compare the efficacy of addition of midazolam to a mixture of buprenorphine and bupivacaine used for spinal anaesthesia. Study involved 60 patients (30 per group), ASA I and II, age 20-40 years undergoing minor and intermediate lower abdominal surgery under spinal anaesthesia. The control group received a spinal injection of hyperbaric bupivacaine 15mg plus buprenorphine (0.15mg) and the experimental group received a spinal injection of the same two drugs, but supplemented with intrathecal midazolam (2mg). They concluded that intrathecal midazolam 2mg improves the quality and duration of postoperative pain relief afforded by intrathecal buprenorphine and bupivacaine.

Dixit S[10] compared intrathecal bupivacaine0.5% and buprenorphine 60µg with bupivacaine 0.5% for postoperative analgesia in caesarean section. Sixty participants undergoing elective Lower Segment Caesarean Section (LSCS) were randomly selected after dividing into two groups of 30 each. Control group (C) received 1.70 mL (8.5mg) of bupivacaine (0.5%), while patients of study group (S) received 1.70mL (8.5mg) of bupivacaine (0.5%) +60µg buprenorphine. They concluded that combination of buprenorphine 60µg with (0.5%) bupivacaine (8.5mg) provided analgesia of clinical onset and longer duration of postoperative analgesia after caesarean section with no effects on neonatal Apgar scores with minimal side effects.

A study by Thomas W.[11] et al was done to assess the efficacy of intrathecal buprenorphine for postoperative relief and to study the incidence of side effects. Study involved 60 patients, 30 in each group. First group received 15 mg bupivacaine 0.5% with 1mcg/kg buprenorphine intrathecally upto a maximum of 50mcg and served as the study group. Control group received 15mg of plain 0.5% bupivacaine. The side effects were minimal and the intensity of analgesia in the study group was15.28 hours (mean) compared to 3.8hours (mean) in control group.

In the present study, the onset of analgesia for the study group varied from 2-5 mins., mean 2.3 mins., on the other hand, onset of analgesia in the control group varied from 4-10 mins. with mean of 5.36 mins.

The results of this study show that there is statistically highly significant difference in the onset of analgesia and that the addition of buprenorphine hastens the onset of action of bupivacaine.

The duration of analgesia with intrathecal buprenorphine is dose dependent. Capogna et al used two doses of intrathecal buprenorphine. Patients who received 30 mcg had duration of analgesia for 8 hrs., while patients who received 45 mcg had duration of analgesia 7-12 hrs.

In the present study, the duration of analgesia with 60 mcg buprenorphine along with 10 mg bupivacaine was 6-10 hrs. with mean of 7.8 hrs.in contrast to control group, which had a duration of analgesia 2-4 hrs. with mean of 2.38 hrs.

In 1989, Cellemo D Capogna G.in their study on intrathecal buprenorphine had showed that patients with intrathecal buprenorphine had a longer duration pain relief than control group and higher the dose longer the duration of action.

Present study also showed similar results. The duration of analgesia in the study group was significantly prolonged

when compared to control group.

Capogna et al assessed the degree of analgesia of two doses of intrathecal buprenorphine using visual analogue scale. They found that 45 mcg intrathecal buprenorphine has better quality and duration of analgesia than 30 mcg.

A study by Shaloo Ipe[12] et al was done to assess the effects of intrathecal and epidural buprenorphine like respiratory depression, haemodynamics, nausea, vomiting and newborn outcome in caesarean section.

In our study, none of the patients in the study groups had respiratory depression. Arterial oxygen saturation in all the cases remained above 96% and mean respiratory rate of the patients were above 17. None of the patients required any respiratory support.

The mean fall in BP was comparable in all groups and hypotension if present was transient. The blood pressure and heart rate were acceptable in all groups. This was similar in earlier studies.

The incidence of nausea and vomiting was 20% in Group B, which was slightly higher than the other group. Pruritus is one of the commonest side effects of neuraxial opioids. It is more likely to occur in obstetric patients due to the interaction of oestrogen with opioid receptors. Previous studies show the incidence of pruritus after epidural administration of 50 mcg fentanyl was 47% and with 300mcg buprenorphine was 10%.

Incidence of PDPH, backache and drowsiness were not reported. This was comparable to the results obtained by Fuller JG.[13] et al and Escarment J.[14] et al. The high rate of nausea and vomiting in those patients warrants the use of ondansetron as premedication and for at least 24 hours postoperatively till the effect of opioids wearoff.

Neonatal outcome was good in all the groups assessed by 1 min. and 5 mins. Apgar and due to unavailability umbilical arterial blood pH was not done.

In all patients, the anaesthesiologist and surgeon found the anaesthesia to be adequate for the operative procedure in terms of pain relief and relaxation. All patients were comfortable and willing to accept the same anaesthetic technique for a similar procedure in future.

This study results are comparable to the study- A comparative study of intrathecal and epidural buprenorphine using combined spinal-epidural technique for caesarean section.

Present study demonstrated that even low dose (60mcg) could give good postoperative analgesia with minimal, easily manageable side effects. The intrathecal route has advantages of greater technical ease and a single injection producing pain relief of sufficient duration is always beneficial.

Wang et al[15] demonstrated that intrathecal opioids had no postural hypotension and exaggerated sympathetic blockade with use of opioids, which allows parturient to ambulate early and mother can breastfeed child effectively, thereby improving interaction between mother and child. During pregnancy risk of thromboembolic disease is increased as good pain relief postoperatively provided by intrathecal buprenorphine improves mobility, thereby reducing chances of thromboembolic phenomenon. Buprenorphine increases sensory block without affecting motor block and haemodynamics. Intraoperatively, quality of analgesia was excellent in study group, visceral or traction pain, pain during exteriorisation of uterus was obtunded as observed by Shah et al due to favourable property of intrathecal opiates.

Thomas et al[11]assessed the efficacy of buprenorphine as postoperative analgesic using the Magill's classification. High affinity of buprenorphine for narcotic receptors produces longer duration of action. The concern regarding late respiratory depression from neuraxial opioid perhaps has been the main reason for reluctance in the widespread use of these analgesics in this technique, but this was not observed in any of the patients in our study. As buprenorphine is a lipid soluble drug and rapid absorption into the spinal venous plexus occurs, there is minimal increase in spinal fluid concentration, thus minimal risk of respiratory depression is associated with rostral spread.

CONCLUSION

Addition of buprenorphine (2 mcg/kg) with hyperbaric bupivacaine significantly prolongs both sensory and motor block.

Intraoperatively, there were fewer incidences of side effects with intrathecal buprenorphine when compared to intrathecal fentanyl with hyperbaric bupivacaine.

The postoperative 24 hours analgesic requirements were significantly less in the buprenorphine group than fentanyl group.

To conclude, buprenorphine (2mcg/kg) seems to be an attractive alternative to 0.5mcg/kg fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, haemodynamically stable conditions and excellent quality of postoperative analgesia.

Hence, buprenorphine seems to be a better choice as intrathecal adjuvant with bupivacaine when compared with fentanyl.

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