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A Comparative Study Of Butorphanol As An Adjunct To Bupivacaine In Comparison To Bupivacaine Alone.

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Abstract: *Neuraxial opioids are widely used in conjunction with local anaesthetics (LA) as they permit the use of lower dose of LA while providing adequate anaesthesia and analgesia. Neuraxial opioids also allow prolonged analgesia in the postoperative period and faster recovery from spinal anaesthesia. Antinociceptive synergism between LA and intrathecal opioids has been demonstrated in various animal studies. The present study was undertaken to compare the safety and efficacy of anaesthesia and hemodynamic stability of different doses of intrathecal bupivacaine-butorphanol mixture with intrathecal bupivacaine alone for lower abdominal & lower limb surgery. This study was conducted as only a limited number of studies have explored the use of intrathecal butorphanol in human subjects previously. Butorphanol is a lipophilic opioid agonist-antagonist analgesic with a published affinity for opioid receptors in vitro of 1:4:25 (mu: delta: kappa). Studies have reported a dose-dependent increase in the duration of analgesia provided by epidural butorphanol for relief of post-caesarean section pain.*

I. Methods

Fourty six patients of ASA grade I and II between 18-58yrs of age of either sex, scheduled for elective lower abdominal & lower limb surgical procedure were included The study protocol was approved by Institutional Ethical Committee and written informed consent was obtained from all patients.

The pre-anaesthetic check-up included a detailed medical and surgical history, and any previous anaesthetic exposure with its outcome. General examination includes general condition, built, weight, pulse rate, blood pressure, respiratory rate, and presence of cyanosis, anaemia, clubbing, jaundice or edema. A careful thorough systemic examination was done to rule out any cardiovascular, respiratory, gastrointestinal and neurological or any other systemic illness.Routine biochemistry investigation included haemoglobin, total leucocyte count, differential leucocyte count, blood sugar, blood urea, and serum creatinine, were done in all patients. ECG and X-Ray Chest were done in patients where indicated and in those over 40 years of age along with other relevant investigation.

After taking detailed history and thorough clinical examination, the patients were excluded from the study on the basis of below mentioned criteria:

Patients with systemic hypertension, hepatic dysfunction, renal dysfunction, endocrine dysfunction, cardiac dysfunction, morbid obesity (body weight more than 20% of the ideal body weight),Other exclusion criteria were patients with known drug hypersensitivity, those on antihypertensive medication or antidepressant drugs and those who refused to give consent.

Patients using2-adrenergic receptors antagonists, calcium channel blockers, angiotensin converting enzyme inhibitors, ornoted to have dysrhythmias on the electrocardiogram(ECG), a body weight of more than 120 kg, or height less than 150 cm were excluded from the study. Standardmonitoring was used, including non-invasive arterial blood pressure, ECG, heart rate (HR) and pulseoximetry (Spo2).

The total 60 patients were randomly divided into two groups of 30 patients each according to a computer generated random table. Group A (n=30) patients received 15mg of bupivacaine & 1 ml of NS and Group D (n=30) patients received bupivacane 15mg & .05mg.Group allocation was done by an assistant who was unaware of the study protocol and was not involved in the study.

Anaesthetic technique

Patients were premedicated with tab. alprazolam 0.25 mg and tab. Ranitidine 150 mg the night before the surgery. All patients were kept fasting for 8 hours prior to surgery.

On arrival to operation theatre routine monitoring was started and base line vital parameters of heart rate, systemic arterial pressure including systolic, diastolic and mean arterial pressure, arterial oxygen saturation (SpO2), and ECG were recorded. An intravenous line was secured and Ringer lactate was given at rate of 6-8 ml/kg. All patients received premedication of intravenous Inj. Midazolam (0.02mg/kg) and inj. glycopyrrolate (0.01mg/kg)..

After preparation with the patient in sitting position spinal anaesthesia was performed at L3-L4 level through a midline approach with quincke needle.Study group A patients were given bupivacaine 15mg & 1ml of NS (total volume 4 ml) and group B bupivacaine 15mg & 0.5mg butorphenol(total volume 4 ml). Study

medication was prepared by an anaesthesiologist who was blinded to the randomization schedule.the anaesthesiologist performing block recorded baseline vitals preoperatively,every 3 min for first 15 min,then every 5 min until patientdischarged from PACU.sensory dermatome was assessed by pinprick & motor by modified bromage score

Results

Out of 60 patients three patient from group A & two from group B were considered as failure.55 patients completed study protocol and included in data.the onset of block & duration is given in Table 1.The various vitals monitoring before during and after procedure are arranged in table2.

Table 1.

	Group A(n=27)	Group D(n=28)
Gender		
Male	14	14
Female	13	14
Surgery		
Abdominal & vaginal hystrectomy	8	7
Appendicitis	5	8
Hernia	7	6
Turp	3	4
Skin grafting	4	3

	Group A (n= 27)	**Group B (n= 28)**	**p value**
Age (yrs)	32.54±10.73	34.07±12.03	0.39
Sex (M/F)	14/13	14 / 14	0.273
Ht (cm)	149.73 ± 4.76	149.03 ± 5.77	0.61
Wt (Kg)	55.8 ±8.41	53.6 ±9.44	0.28
ASA grade I/II	20 / 7	21 / 6	0.198

Various surgical interventions done in patients in both groups

Surgery	**Group A**	**Group B**
Appendectomy	5	8
Hernia	7	6
Hysterectomy	8	7
Skin grafting	4	3
Turp	3	4

Comparative evaluation of Mean Systolic Blood Pressure (mm Hg)

Time interval in min	Group A	Group B	Pvalue
Base line	137.19± 13.18	134.79 ± 14.62	0.14
3 min after spinal anesthesia	131.06 ± 13.09	130.56 ± 13.07	0.40
6 min	127.80 ± 13.74	126.34 ± 12.25	0.24
9 min	125.98 ± 15.79	124.66 ± 19.44	0.33
12 min	123.22 ± 14.78	121.52 ± 13.49	0.22
15 min	119.32 ±15.72	118.92 ± 12.60	0.09
30 min	116.21 ± 12.40	116.43 ± 12.20	0.40
45 min	115.68 ± 10.94	116.10 ± 10.45	0.08
60 min	112.80 ± 10.40	115.16 ± 10.70	0.16
75 min	112.78 ± 10.01	114.39 ± 10.35	0.40
90 min	113.65 ± 7.71	113.34 ± 8.14	0.30
Postoperative	115 ± 7.64	114.39 ± 7.34	0.45

Comparative evaluation of Mean Diastolic Blood Pressure (mm Hg)

Time interval in min	Group A	Group B	P-value
Base line	85.85 ± 9.07	86.08 ± 9.99	0.43
3 min after spinal anesthesia	82.59 ± 7.86	79.61 ± 9.40	0.01*
6 min	80.93 ± 7.78	77.26± 10.33	0.006**
9 min	80.21 ± 8.18	75.38± 9.68	0.0005**
12 min	78.52 ± 8.21	73.61 ± 9.15	0.0003**
15 min	75.69 ± 10.89	73.28 ± 8.38	0.04 *

30 min	74.57 ± 8.29	72.43 ± 8.47	0.05*
45 min	74.52 ± 8.59	71.33 ± 8.32	0.01*
60 min	73.44 ±7.59	70.53 ± 6.98	0.007**
75 min	72.88 ± 6.95	72.67 ± 6.96	0.42
90 min	71.86 ± 6.77	73.05 ± 6.37	0.13
Postoperative	72.48 ± 6.52	73.64 ± 6.47	0.13

Comparative evaluation of Mean Heart rate (beats/min)

Time interval in min	**Group A**	**Group B**	**P -value**
Base line	100.55 ± 11.47	88.03 ± 11.57	1.0
1 min after spinal anesthesia	97.98 ± 10.05	88.08 ± 11.06	1.0
3 min	96.60 ± 9.17	82.87 ± 11.74	0.17
5 min	95.06 ± 10.02	74.67 ± 10.51	0.0**
10 min	92.68 ± 9.53	72.29 ± 10.69	0.0**
15 min	90.23 ± 12.08	69.21 ± 9.41	0.0**
30 min	87.68 ± 8.91	68.61 ± 10.02	0.0**
45 min	86.98 ± 8.79	66.70 ± 9.09	0.0**
60 min	85.48 ± 8.30	65.92 ± 8.06	0.0**
75 min	86 ± 8.59	64.91 ± 7.41	0.0**
90 min	84.05 ± 6.07	65.34 ±7.06	0.0**
Postoperative	83.67±5.44	66.38 ± 5.94	0.0**

Intra-operative and postoperative adverse events

	Group A	**Group B**
Adverse Events	No. of patient	No. of patient
Hypotension	2	4
Bradycardia	1	4
Shivering	1	5
Headache	0	0
Nausea	0	2

II. Conclusion

- Butorphenol when used as an adjunct to bupivacaine in spinal anaesthesia helped in keeping the patient hemodynamically stable throughout the surgery in comparison to bupivacaine alone.
- Although no major neurological complications have been reported so far, larger studies are required to rule out any short term or long term adverse effects.

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