Original Article

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Comparative Evaluation of Intrathecal Dexmedetomidine with Fentanyl as an Adjuvant to Hyperbaric Bupivacaine in Lower-Limb Orthopaedic Surgeries

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Abstract

Background: Spinal anesthesia is an age old, tested, effective and economical technique of regional anaesthesia especially for lower-limb orthopaedic surgeries because of its excellent muscle relaxation and intraoperative and postoperative analgesia profile. *Aims:* To compare the efficacy of adjuvants dexmedetomidine and fentanyl when added to intrathecal bupivacaine. *Setting & Design:* 120 patients were enrolled in the study. They were randomly allocated into dexmedetomidine group (BD) and fentanyl group(BF) and received 5µg dexmedetomidine and 25 µg fentanyl respectively as adjuvants to 2.5ml intrathecal bupivacaine. *Materials & Methods:* Both group BD and BF were compared with respect to age, sex, weight, height, time to onset of maximum motor blockade (Bromage 4), maximum level of sensory level achieved, intraoperative VAS score, hemodynamics, postoperative VAS score, time to two – segment regression, time to regression to S2 level and regression to Bromage 0 were noted. *Statistical Analysis:* Unpaired t-test and chi-square test were used. *Conclusion & Results:* Significant difference was found between both groups with BD group having prolonged time to regression in two-segment and S1 level and Bromage -0 postoperative VAS scores were lesser with BD group.

Keywords: Intrathecal Dexmedetomidine; Intrathecal Fentanyl; Hyperbaric Bupivacaine; Orthopaedic Surgeries.

Introduction

From time immemorial, man has been suffering from pain due to disease, trauma or surgery.

Pain management poses a difficult challenge to the anaesthesiologist in its effective approach and handling.

Among techniques available, spinal anaesthesia offers unique advantages. Studies have been going on, on adjuvants added to prolong postoperative analgesia.

Fentanyl has been studied to be a promising drug for intrathecal use [7].

Dexmedetomidine a highly selective a2 adrenergic receptor agonist produces prolonged analgesia without respiratory depression [1,8].

We undertook this study to evaluate and compare the effects of adding dexmedetomidine or fentanyl to heavy bupivacaine for spinal anaesthesia for lower limb orthopaedic procedures.

Material and Methods

The study was undertaken at our institution following ethical committee approval. Informed written consent was taken from all patients. 120 adult patients were subjected to the study

ASA I and II patients aged 16-60 years presenting for lower limb orthopaedic interventions were randomly allocated onto 2 groups of 60 each.

Exclusion Criteria

- Patient refusal
- Allergy to drugs
- Concomitant cardiac disease
- On therapy with ACE inhibitors, CCB or adrenergic receptor blockers
- Other routine contraindications for spinal anaesthesia
- Body weight >120kg
- Height <150 cm.

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All patients received Tab. Diazepam 0.2 mg/kg orally on the previous night. Intravenous line was secured 30 min before surgery. All patients were given Inj. Ranitidine 1mg/kg IV and IM, Ondansetron 4mg IV followed by RL infusion at a rate of 10ml/kg.

Base line ECG, pulse oximetry and NIBP were monitored. In sitting position spinal anaesthesia was performed under all aseptic antiseptic precautions at L3 – L4 level with 23G Quincke – Babcock spinal needle.

The first group BD was given 12.5 mg (2.5ml) of 0.5% heavy bupivacaine with 5 µg (0.5 ml) of dexmedetomidine (50µg/ml, 1 cc diluted to 5 cc with 0.9% normal saline) to make a total volume of 3 ml.

The second group BF was given 12.5 mg (2.5ml) 0.5% hyperbaric bupivacaine with (0.5ml) 25 µg fentanyl to make a total volume of 3ml.

The spinal injection was given over a period of 15-20 seconds, following this patients were placed in supine position.

Sensory block level was assessed by an anaesthetist unaware of the drug used for sensation of pinprick to a hypodermic 23G needle bilaterally. Dermatomal levels were tested every 2 minutes uptil maximum level of sensory block was achieved. The time interval was noted - motor blockade was assessed using modified Bromage score [3] every 2 min.

Bromage:
1- Ablility to raise legs above table
2- Ablility to flex knees
3- Ablility to move feet only
4- No movement in legs or feet

Time taken to achieve motorblock of Bromage 4 was taken note of. Once the highest sensory block and Bromage score of 4 was achieved the patient was handed over to the surgeon. Oxygen was given at 4 l/min. Heart rate, blood pressure, ECG and $Sa0_2$ were monitored every 5 min for first 20 min and then every 10 min till complete procedure. Inj. Ephedrine 5mg IV was given when SBP fell <20% below baseline. A heart rate of 50 beats/min was treated with Inj. Atropine 0.5mg/kg i.v.

Unpleasant events like nausea, emesis, shivering, pruritus, respiratory depression/apnoea and sedation using (modified Ramsay sedation [8] scale), were assessed.

Modified Ramsay sedation scale:

- Anxious, agitated, restless
- Cooperative, oriented, tranquil
- Responds to commands only
- Brisk response to light glabellar tap/loud noise
- Sluggish response to light glabellar tap/loud noise
- No response

Time taken for surgery was noted. Time lapsed for sensory regression to S2 level and motor block regression to Bromage 0 level were made not of. All time periods were taken with reference to the spinal injection time.

Postoperative pain was assessed by visual analog score (VAS) which consists of 1-10 cm line anchored at one end by a label 'No Pain' and at the other end by a label 'Worst Pain Imaginable'. The patients were instructed preoperative to mark the line to indicate pain intensity, which was recorded every hour for 2 hours, then every 2 hours for the next 10 hours and every 4 hours for the next 12 hours.

Data was collected and tabulated. Results were calculated as mean ± SD and unpaired 't' test was used to compare mean values of 2 groups. Comparison was studied using chi-square test with $p<0.05$ considered statistically significant.

Results

Significant difference between the two groups in age, height, weight and gender were not consistent. Duration of surgery was also almost similar between two groups (Table 1, $p>0.05$).

Time taken to reach highest level of block were similar in both groups.(T7 and T8) (Table 2).

The onset time to achieve highest sensory as well as motor block was almost same in both the groups (Table 2).

Time for two segment regression for group D (127±8.3) and for group F (101.9±8.) showed significant results. Time taken for sensory regression to S2 was 485.9±5.9 in group D and 189.5±4.3 in group F(Table 2)

Duration of analgesia was significantly prolonged in group D (264.2±10.0) compared to group F (190.9±4.4) (Table 2).

No unpleasant events were recorded in either group (Table 3).

There were no major changes in HR (Table 4), SBP (Table 5) and DBP (Table 6) in both the groups.

VAS scores postoperative showed significant

difference with dexmedetomidine group having lower VAS scores (Table 7).

Table 1: Demography

Characteristic	Group D	Group F	D v/s F		p-value
			t-value	p-value	
Age	38.6±11.7	38.3±12.8	0.08	0.93, NS	>0.05
Sex (M:F)	20:10	20:10	No diff.	NS	>0.05
Height (cm)	5.49±0.31	5.46±0.32	0.37	0.71, NS	>0.05
Weight (kg)	56.2±6.73	58.13±8.37	0.99	0.33, NS	>0.05
ASA I : II	22:8	22:8	No diff.	NS	>0.05
Duration of surgery (min)	195±12	187±21	1.90	0.06, NS	>0.05

Unpaired t-test : p<0.05, Sig, P>0.05, NS

Table 2: Characteristics of Sensory Block / Motor Block

Characteristic	Group D	Group F	D v/s F		p-value
			t-value	p-value	
Motor onset (Bromage 4)	11.3±0.61	11.23±0.40	0.53	0.59	>0.05
Highest sensory level	T7 (T6-T10)	T8 (T6-T10)	1.83	0.07	>0.05
Time for highest sensory level (min)	11.45±0.67	11.3±0.63	0.64	0.52, NS	>0.05
VAS intra op	0.03±0.2	0.1±0.3	1.02	0.30, NS	>0.05
Quality of intra op analgesia	3.6±0.6	3.6±0.5	0.00	1.00, NS	>0.05
Time for two segment regression	127.4±8.3	101.9±8.0	12.17	0.00	<0.05
Time for sensory regression to S2 from highest sensory level	485.2±5.9	189.5±4.3	222.41	0.00	<0.05
Duration of analgesia	264.2±10.0	190.9±4.4	36.72	0.00	<0.05
Regression to Bromage – 0	414.6±15.6	156.3±5.8	85.15	0.00	<0.05

Unpaired t-test : p<0.05, Sig, P>0.05, NS

Table 3: Side effects

Side effects	Group D n (%)	Group F n (%)	D v/s F		p-value
			z-value	p-value	
Nausea	2 (6.7)	3 (10.0)	0.46	0.65	>0.05
Vomiting	0	2 (6.7)	1.47	0.14	>0.05
Pruritus	0	2 (6.7)	1.47	0.14	>0.05
Hypotension	3 (10.0)	2 (6.7)	0.46	0.65	>0.05
Bradycardia	1 (3.0)	0	0.96	0.34	>0.05
Urinary retention	3 (10.0)	2 (6.7)	0.67	0.51	>0.05

z-test for proportions p>0.05, NS

Table 4: Heart Rate

Time in minutes	Group D(mean±SD)	Group F	P value	p-value
0	82±7.39	80.93±11.58	0.678	>0.05
5	77.13±8.67	78.46±11.17	0.613	>0.05
10	73.86±7.76	74.83±9.28	0.644	>0.05
15	71±7.45	73.3±10.22	0.309	>0.05
20	70.53±7.31	73.46±12.38	0.289	>0.05
30	73.13±5.43	73.9±9.55	0.709	>0.05
120	75.2±4.83	76.26±8.82	0.577	>0.05

Statistical test- Student t test Significant at p<0.05

Table 5: Systolic BP

Time in minutes	Group D(mean±SD)	Group F	P value	p-value
0	130.13±9.68	132.96±16.25	0.410	>0.05
5	120.13±12.08	123.06±14.80	0.394	>0.05
10	112.53±11.61	118.43±15.03	0.127	>0.05
15	110.86±11.66	114.6±13.01	0.262	>0.05
20	112.4±9.73	114.7±10.77	0.419	>0.05
30	113.96±8.96	116.7±9.53	0.326	>0.05
120	120.5±8.79	121.5±9.26	0.646	>0.05

Statistical test- Student t test, Significant at p<0.05

Table 6: Diastolic BP

Time in minutes	Group F (mean±SD)	Group D	P value	P value
0 min	78.9±7.93	81.2±7.94	0.245	>0.05
5 min	73.43±6.69	72.53±8.38	0.667	>0.05
10 min	69.03±7.34	67.46±9.37	0.501	>0.05
15 min	69.03±7.64	66.53±8.28	0.196	>0.05
20 min	71.06±6.81	68.46±6.67	0.295	>0.05
30 min	72.96±6.01	71±4.44	0.139	>0.05
120 min	74.23±6.78	76.53±4.42	0.170	>0.05

Statistical test- Student t test, Significant at p<0.05

Table 7: Changes in VAS

Time interval	Group D	Group F	D v/s F		p-value
			t-value	p-value	
Pre-op	0.03 ± 0.18	0.18 ± 0.30	1.03	0.31, NS	>0.05
3 Hrs	0.07 ± 0.25	0.73 ± 1.05	3.39	0.002	<0.05
6 Hrs	2.033 ± 0.889	2.96 ± 1.37	3.118	0.00289	<0.05
12 Hrs	6.30 ± 0.84	5.80 ± 0.89	2.25	0.03	<0.05

Unpaired t-test : p<0.05, Sig, P>0.05, NS

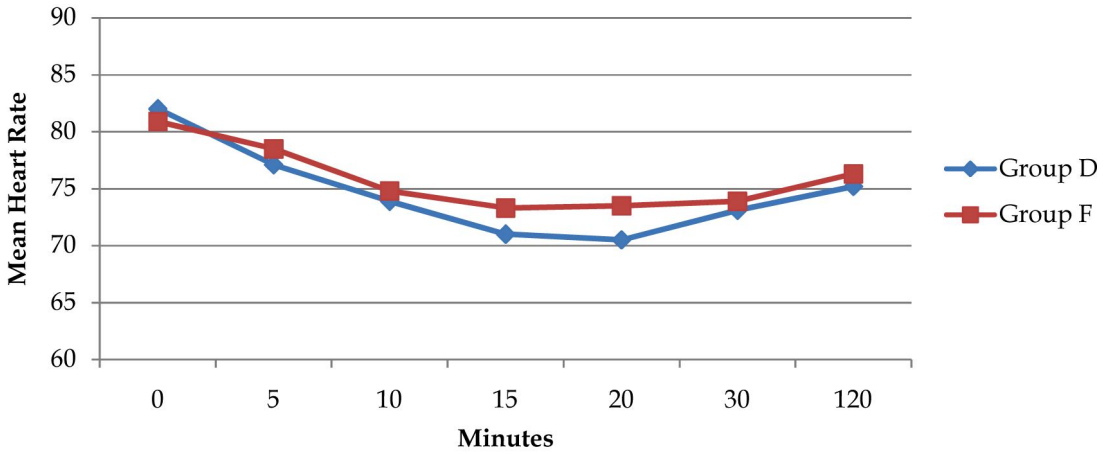

Fig. 1: Intraoperative Heart Rate

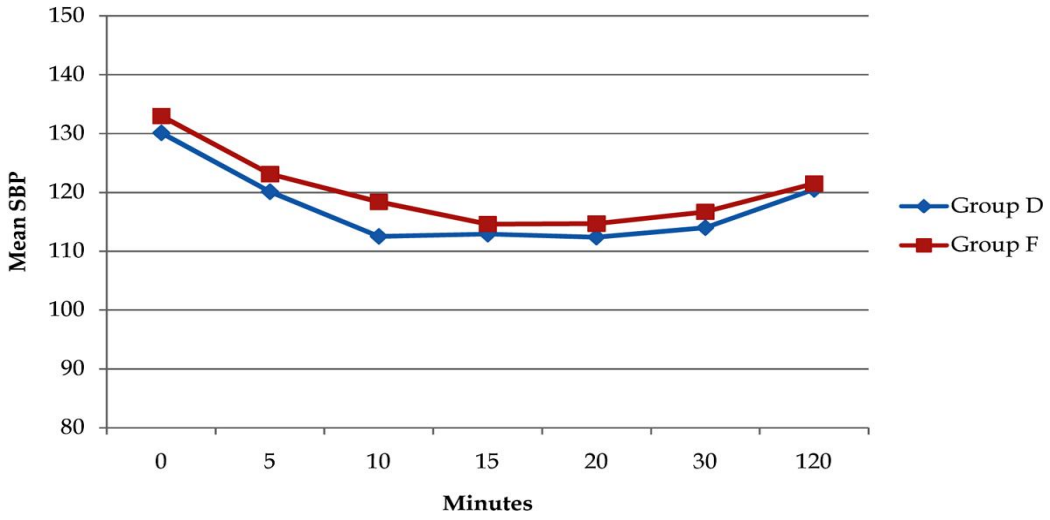

Fig. 2: Intraoperative Systolic BP

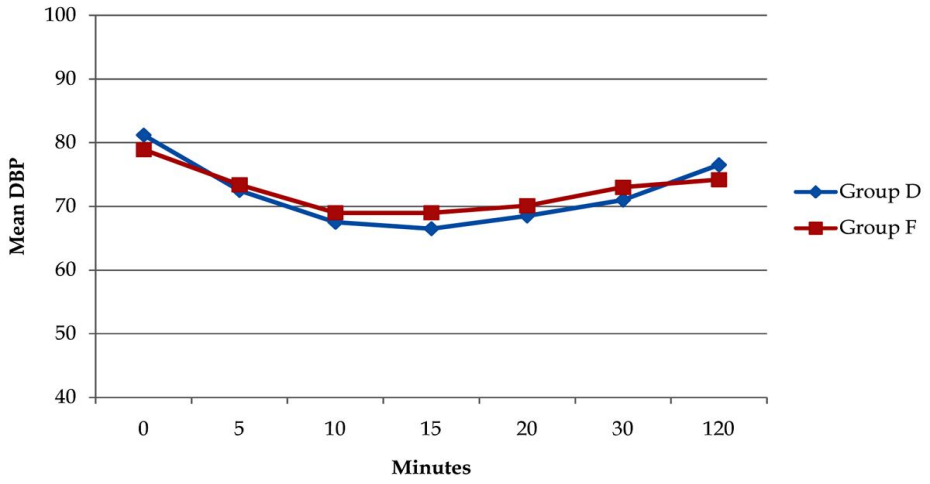

Fig. 3: Intraoperative Diastolic BP

Discussion

Dexmedetomidine has about ten times higher affinity for α_2-adrenoreceptors than clonidine [4].

Dexmedetomidine exerts its analgesic action by inhibiting C fibre transmitter release causing hyperpolarisation of post synaptic dorsal horn neuron [2,4].

The prolongation of motor effect might be caused by direct impairment of excitatory amino acid release from spinal inter neurons [4,6] and also by α_2 adrenoreceptor agonists binding to dorsal horn neuron.

Antinociceptive action on both somatic and visceral pain has also seen to be exerted by spinal α_2 adrenoreceptor agonists [4].

Intrathecal opioids are among the most popular adjuvants commonly combined with local anaesthetics to improve the onset time of block, duration and quality of analgesia both intraoperatively and postoperatively. The addition of morphine and fentanyl have been used regularly.

Fentanyl is a lipophilic opioid and has rapid intrathecal action. Chances of it spreading to the fourth ventricle with resultant respiratory depression on intrathecal administration are weak.Therefore, fentanyl provides better analgesia and a safe alternative than morphine in management of early postoperative pain.

Mainly studies have been conducted using intrathecal dexmedetomidine [7] alone and intrathecal fentanyl alone Eg: knee arthroscopy [5].

Addition of dexmedetomidine or fentanyl to heavy bupivacaine for spinal anaesthesia in gynaecological procedures has already been studied . Lastly in one more study they have compared intrathecal dexmedetomidine Vs fentanyl for lower abdominal procedures.

In our study we have compared both the drugs for orthopaedic surgeries because orthopaedic procedures take more time compared to other surgeries. And at the same time they need prolonged postoperative pain relief.

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