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Dexmeditomidine as Intrathecal Adjuvant to Isobaric Ropivacaine in Spinal Anaesthesia for Lower Limb Orthopaedic Surgeries – A Randomized Double Blind Controlled Study

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Abstract

Background: Despite the introduction of new and excellent inhalational and intravenous anaesthetic agents, as well as advent of potent neuromuscular relaxants, it is generally agreed that there is still a place for spinal anaesthesia, today because of definite advantages of spinal anaesthesia.

Aims and Objective: present study was planned to find out the effect of addition of 5µg of dexmedetomidine with 3ml of 0.5% ropivacaine for lower limb orthopaedic surgery on sensory-motor block characteristics and postoperative analgesia.

Material and Methods: Spinal anaesthesia with 15mg of plain Ropivacaine alone (R) or with dexmedetomidine 5µg (RD) for orthopaedic surgery was compared.

Result - The present study demonstrated that addition of dexmedetomidine (5µg) to ropivacaine (15 mg .5% isobaric) was associated with early onset and prolonged duration of sensory and motor blockade with hemodynamically stability and long duration of postoperative analgesia without incidence of postoperative complication as compare to ropivacaine alone intrathecally.

Keywords: Dexmedetomidine, Ropivacaine, Spinal Anaesthesia.

Introduction

Spinal anaesthesia has the definitive advantage that profound nerve block can be produced in a large part of the body by the relatively simple injection of a small amount of local anaesthetic. The common side effects of general anaesthesia (nausea, vomiting, and drowsiness) are reduced, the risks of general anaesthesia (difficult intubation, pulmonary aspiration or malignant hyperthermia) are minimized, and improved analgesia is provided in the post-operative period.

Bupivacaine is commonly used drug in spinal anaesthesia. However, concerns have been raised in the past few years regarding, the safety of this drug as bupivacaine is more cardiotoxic, its prolonged effects may lead to a delay in motor block resolution, urinary retention, and a prolonged hospital stay. These problems limit the use of bupivacaine in day-case settings[1]. Alternatively, agents with a short effect such as lidocaine are associated with transient neurological symptoms[2,3].

Ropivacaine was approved for a new route of administration, the intrathecal route, in the European Union in February 2004[4]

It has certain advantages over bupivacaine & lignocaine

1. Ropivacaine has less potential for both cardiac and CNS toxicity[5].
2. Ropivacaine causes preferential blockade of sensory nerve fibers[6].

Time to recovery from sensory and motor blocks with ropivacaine was considerably shorter than bupivacaine which allows early mobility of patient[6]. Early ambulation reduces postoperative complications and augments prognosis in some clinical settings.

Dexmedetomidine was approved by the US Food and Drug Administration at the end of 1999 for use in humans as a short-term medication (<24 hours) for analgesia and sedation in the Intensive care unit[7]. It is suitable for sedation and analgesia during the whole perioperative period[8]. Its applications as a premedication, as an anaesthetic adjunct for general and regional anaesthesia, and as a postoperative sedative and analgesic are similar to those of the benzodiazepines[9]

Therefore the present study was planned to find out the effect of addition of 5µg of dexmedetomidine with 3ml of 0.5% ropivacaine for lower limb orthopaedic surgery on sensory-motor block characteristics and postoperative analgesia.

Material and Methods

Spinal anaesthesia with 15mg of plain Ropivacaine alone (R) or with dexmedetomidine 5µg (RD) for orthopaedic surgery was compared regarding:

1. Onset, extent and duration of sensory and motor block.
2. Success rate to conduct surgery in spinal anaesthesia.
3. Postoperative analgesia in terms of 'time to first rescue analgesia' VAS score and total rescue analgesic (tramadol) consumption in first 24h postoperative period .
4. Hemodynamic stability, sedation, adverse effect if any

Inclusion Criteria: The present study was conducted on 60 patients with 30 in each group of ASA physical status I-II of both sex posted for elective lower limb orthopaedic surgery(except hip, knee replacement) under subarachnoid block, was included in this prospective, randomized, and double blind study. All the patients in this study were between 18-60 yr age, 30-80 kg weight and more than 140cm height.

This study was conducted in a randomized double blind fashion. All patients under study was subjected to a detailed pre-anaesthetic examination and investigations was carried out during this evaluation. A patient was randomly divided into two groups of 30 patients in each group using sealed envelope technique.

Group R: Patients were received 3 ml 0.5% isobaric ropivacaine hydrochloride [ROPIN 10 ml ampoule (50 mg/10 ml) neon laboratories limited]

Group RD: Patients were received 3ml 0.5% isobaric ropivacaine with 5µg dexmedetomidine hydrochloride [DEXTOMID 1ml ampoule (100µg/ml) neon laboratories limited]

Result

Table 1: Comparison of age (Year) in both group

Age	Group R (n=30)	Group RD (n=30)	P- Value
18-30	13(43.33%)	12(40%)	0.92
31-40	10(33.33%)	5(16.67%)	
41-60	7(23.33%)	13(43.33%)	
Range	20-55	22-55	
Mean±SD	36.56±12.95	36.33±11.70	

Test used: T-test

Data are expressed as n (%) or mean±SD

Table 1shows that both group were statistically comparable regarding mean age. (P =0.92)

Table 2: Comparison of weight (kg) in both group

Weight (kg)	Group R (n=30)	Group RD (n=30)	P –Value
30-60	8(26.66%)	5(16.66%)	0.282
61-70	15(50%)	14(46.66%)	
71-80	7(23.33)	11(36.66%)	
Range	53-80	54-79	
Mean±SD	66.03±7.15	68.07±7.32	

Test used :T-test

Data are expressed as n (%) or mean±SD

Table 2 shows that both group were statistically comparable regarding mean age. (P =0.282)

Table 3 : Denotes duration of surgery (min) in both groups

Duration (min)	Group R (n=30)	Group RD (n=30)	P -Value
60-80	6(20%)	8(26.66%)	0.278
81-100	15(50%)	18(60%)	
>101	9(30%)	4(13.33%)	
Range	60-110	85-110	
Mean±SD	91.67±13.604	88.17±11.024	

Test used: T-test

Data are expressed as n (%) or mean±SD

Table 6 shows that both group were statistically comparable regarding mean duration of surgery (P =0.278).

Table 4. Comparison of sensory block

Sensory onset (min)	Group R	Group RD	P value
Time to T10 (Mean±SD)	7.07±1.23	6.17±1.05	0.00
Range	5-9	5-8	
Time to peak sensory (Mean±SD)	10.40±2.04	9.76±2.07	0.239
Range	7-13	7-13	

Test used: T-test

Data are expressed as mean ± SD

Table 7 shows that time to reach T10 sensory level was significantly shorter in group RD (6.17±1.05) min as compared to group R (7.07±1.23) min (P=0.00).

Time to reach peak sensory was 10.40±2.04 min in group R and 9.76±2.07 min in group RD, which was statistically comparable in both groups (P=0.239).

Table 5: Comparison of peak sensory level

		Group R (n=30)	**Group RD (n=30)**	**P-value**
Patients distribution according to peak sensory level n (%)	T6	4(13.33%)	5(16.66%)	0.488
	T7	13(43.33%)	15(50%)	
	T8	8(26.66%)	6(20%)	
	T9	5(16.66)	4(13.33%)	
Mean±SD		7.46±0.93	7.30±0.91	
Range		T6-T9	T6-T9	
Median		T7	T7	

Test used: T-test

Data are expressed as mean±SD

Table 8 shows that mean peak sensory level was 7.13±1.02 in group R and 7.17±1.34 in group RD, but both group were statistically comparable regarding mean peak sensory level (P = 0.598).

Table 6. Motor block characteristics

Motor block characteristics	**Maximum Bromage score (5 min after SAB)**		
Patient distribution	**Group R (n=30)**	**Group RD (n=30)**	**P value**
0	0	0	0.561
1	0	0	
2	2(6.66%)	1(3.33%)	
3	28(93.33%)	29(96.66%)	
Mean±SD	2.93±0.25	2.96±0.18	
Onset of motor block (min) mean	10.17±1.8	8.63±1.37	0.00
Range	8-14	6-10	
Return to max. Bromge score 0 (min)	143.67±10.33	244.83±9.92	0.00
Range	130-160	240-250	

Test used: T-test

Data are expressed as mean±SD

Table 10 shows that mean bromage score was (2.87±0.50) in group R and (2.85±0.55) in group RD which was statistically comparable (P =0.765).

Time to reach Maximum bromage score is significantly shorter in group RD (8.63±1.37) min as compare to group R (10.17±1.8) min (P=0.00).

Time to regression to bromage score 0 (duration of motor block) is significantly shorter in group R (143.67±10.33) min as compare to group RD (244.83±9.92) min (P=0.00).

Discussion

The present study encompasses the study of spinal anaesthesia in patients underwent lower limb surgery in respect to onset and duration of sensory and motor blockade, highest level of sensory block, duration of analgesia, haemodynamic effects and adverse effects.

The study was confined to 60 patients of 20 to 60 years of age of ASA grade I-II group underwent lower limb surgery at R.N.T. hospital Udaipur.

The patients were divided into two groups of 30 patients each.

Group R (n=30 control group) patients received 15 mg of 0.5% isobaric Ropivacaine.

Group RD (n=30 study group) patients received 15 mg of 0.5% isobaric ropivacaine + 5µg dexmedetomidine.

1. There were no statistically significant differences regarding demographic data (age, weight) between two groups. There was no significant difference in the type and the duration of surgery.

2. Time of onset of sensory blockade was significant less in Group RD than Group R ($p<0.05$). The onset of sensory block was (6.17 ± 1.05 minutes, 7.07 ± 1.23 minutes) in Group RD, and group R respectively.

3. There were no statistically significant difference time to reach peak sensory level in group R (10.40±2.04) min and group RD (9.76±2.07) min ($p>0.05$)

4. There were no statistically significant difference peak sensory level in group R (7.46±0.93) and group RD (7.30±0.91) ($p>0.05$).

5. Time of onset of motor blockade was significantly less in Group RD then Group R ($p<0.05$). The onset of motor block was (8.63 ± 1.37 minutes, 10.17 ± 1.80 minutes), in Groups RD, and group R respectively.

6. Duration of motor blockade was significantly more in Group RD then Group R ($p<0.0$ 1).The duration of motor block was (244.83 ± 9.92 minutes and 143.67 ± 10.33 minutes) in Groups RD and group R respectively.

7. Time of sensory regression up to S1 segment was as follows

In group R (227.50 ± 11.65 minutes)

In group RD (424.33 ± 16.75 minutes)

Time of sensory regression up to S1 segment was significantly more in Group RD then Group R ($p<0.05$).

8. Duration of analgesia in (time to first rescues analgesia) was as follows:

In group R (260.00 ± 14 minutes)

In group RD (400 ± 20.10 minutes)

Duration of analgesia was significantly more in Group RD then Group R ($p<0.05$)

9. Total number of analgesia in 24h

In group RD (1.01±.19)

In group R (2.60±.50)

In group RD number of analgesia is requirement was less compare to group R ($p<0.05$).

10. Patients with different drug combinations did not show statistically significant difference in the incidence of adverse effect.

Conclusion

The present study demonstrated that addition of dexmedetomidine (5µg) to ropivacaine (15 mg .5% isobaric) was associated with early onset and prolonged duration of sensory and motor blockade with haemodynamically stability and long duration of postoperative analgesia without incidence of postoperative complication as compare to ropivacaine alone intrathecally.

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