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Addition of dexmedetomidine to ropivacaine for lower limb orthopaedic surgery under spinal anaesthesia to study its effect on block characteristics- An observational study

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ABSTRACT

Introduction: Spinal anaesthesia provides faster onset, effective sensory and motor block, adequate muscle relaxation and profound analgesia simply by injecting a small amount of local anaesthetic drug directly into CSF in subarachnoid space. This present study was conducted to assess the efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in terms of duration of sensory and motor block, post-operative analgesia and side effects in lower limb orthopedic surgeries.

Materials and Methods: This prospective study was done on 50 ASA I/II patients of age 18-60 years undergoing spinal anaesthesia for lower limb orthopaedic surgery. In this study patients received an intrathecal injection of 22.5 mg Ropivacaine (3ml Ropivacaine 0.75%) & 5μg dexmedetomidine i.e. 0.5 ml. Onset of sensory/motor block, duration of sensory/motor block, duration of analgesia and side effects were noted.

Results: Post-hoc bonferroni test was used for intercomparison of mean HR and MAP and significant difference was observed between them. The mean onset of Sensory Block was 3.51$\pm$0.50, mean Time to achieve maximum height of block (Minutes)was 10.63$\pm$0.59, Time to onset of regression at the level of L1 (minutes) was 187.45$\pm$22.61, mean Motor Block-Time to modified Bromage score 3 was 6.12$\pm$0.84 and Motor Block - Time to complete recovery (minutes) was 173.14$\pm$34.26. The mean Time to complete analgesia (in minutes) was 401.06$\pm$16.91 and mean Time to effective analgesia (in minutes) was 415.25$\pm$16.70.

Conclusion: The present study concludes that addition of dexmedetomidine with Ropivacaine provides faster onset of sensory/motor block.

1. Introduction

Spinal anaesthesia is currently more popular than ever because of the properties of a faster onset, effective sensory and motor block, adequate muscle relaxation and profound analgesia during the operative as well as during the early post-operative period, simply by injecting a small amount of local anaesthetic drug directly into cerebrospinal fluid (CSF) in subarachnoid space. The biggest challenge for this technique is controlling the spread of the local anaesthetic through out the CSF, to provide suitable extent and degree of block for the surgery to be done but without producing extensive spread unnecessarily and so risk of complications might be increased.[1]

The commonly used local anaesthetic agents for the regional anaesthesia are lidocaine and bupivacaine. Ropivacaine (newer amide local anesthetic) has proved to be less lipophilic than bupivacaine and is therefore less likely to produce neurotoxicity and cardiotoxicity. Moreover due to less lipophilicity, it does not penetrate large myelinated motor fibres to a great extent resulting in a lesser degree of motor block.[2,3]

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Preservative free isobaric/plain Ropivacaine was recently approved for intrathecal administration for surgery and according to recent studies, plain Ropivacaine could also produce sufficient analgesia for surgery.[4,5] Hence, its shorter duration, faster recovery of motor function and lower toxicity profile have been identified as a potential benefit for lower limb surgeries of shorter duration.

For improving the quality of regional anaesthesia for better sensory and motor block, few haemodynamic side-effects, better post-operative analgesia and preventing local anaesthetic toxicity, many pharmacological agents have been used with local anaesthetics called as neuraxial adjuvant. Therefore, studies have been carried out to elucidate the efficacy of hyperbaric Ropivacaine, using adjuvants like clonidine, fentanyl or dexmedetomidine with isobaric Ropivacaine.[6] Intrathecal dexmedetomidine has been used in the dose of 3 mcg,5 mcg,10 mcg and 15 mcg along with bupivacaine, and in the dose of 5 mcg as an adjuvant to Ropivacaine alone.[7]

Alpha (α)-2-Adrenergic receptor (AR) agonists are currently being the focus of interest because of their sedative, analgesic, perioperative sympatholytic, anesthetic -sparing, and hemodynamics-stabilization properties. Dexmedetomidine, a newer and highly selective $\alpha 2$ adrenergic agonist has evolved as a panacea for various applications and procedures in the perioperative and critical care settings. It possess all these properties but lacking respiratory depression, making them a useful and relatively safer adjunct for the diverse clinical applications.[7] The stable hemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful adjuvant. Based on earlier studies, it was found that Dexmedetomidine produces prolonged postoperative analgesia with minimal side-effects when added to Ropivacaine in epidural and caudal anesthesia.[8]

Since, only limited literature is available where Dexmedetomidine's efficacy as an adjuvant to Ropivacaine in spinal anesthesia had been explored, so the present study was conducted to explore the efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in terms of duration of sensory and motor block, post-operative analgesia and side effects in orthopedic surgeries.

2. Materials and Methods

After obtaining Intitutional Ethical Approval, study was conducted in Department of Anaesthesiology, TMMC & RC, TMU, Moradabad which is a tertiary care hospital in Moradabad.

This was a clinical trial done on 50 patients undergoing spinal anaesthesia for lower limb orthopaedic surgery. The study was conducted during the period from January 2016 to December 2016.

The study participants were selected as per the inclusion and exclusion criteria:

2.1. Inclusion criteria

1. ASA I & II patients of either sex
2. Age between 18-60 years

2.2. Exclusion criteria

Patients not given consent, infection at the injection site, prior history of spine surgery, hypovolemia, coagulopathy, spinal deformities, increased intracranial pressure, indeterminate neurologic disease, communication problems, known hypersensitivity to local anesthetics and opioids are excluded from our study

2.3. Sample size calculation

A sample size calculation was performed using the standard deviation of the time to the first request for analgesics. To detect a 30 min difference in the mean duration of the first request for analgesics (two sided- alpha error of 5% and beta error of 20%), 23 subjects were required. After factoring in attrition rate of 10%, the minimum sample size required was calculated to be 30 subjects. The present study was performed on 50 patients.

2.4. Anaesthetic technique

All patients were examined in PAC Clinic/bed side for fitness of anaesthesia as per department protocol. In this study, all patients received an intrathecal injection of 22.5 mg Ropivacaine (3ml Ropivacaine 0.75%) & 5μg dexmedetomidine i.e. 0.5 ml. Commercial preparation of dexmedetomidine containing 50 μg /ml, which were be diluted upto 5 ml with normal saline and 0.5 ml was taken. Anaesthesia plan was discussed and con sent for spinal anaesthesia was taken. Night before surgery every patient was given lorazepam 1mg orally.

On the day of surgery, standard monitoring devices was attached, and venous access was secured in the operating room. PR and MAP were measured with an automatic, non-invasive device. SpO_2 was continuously monitored using pulse oximeter throughout surgery. Oxygen was administered via Hudson mask at the rate of 2-4 l/min until the end of surgery. Before starting anaesthesia, all patients were pre-medicated with i.v. ondansetron 0.1mg/kg body weight and preloaded with lactated Ringer's solution 15-20 ml/kg body weight. Thereafter i.v. fluids were administered to replace operative blood loss.

After infiltrating the skin at the puncture site with lidocaine 2%, lumbar puncture were performed in the sitting position with a 25-gauge Quincke spinal needle, using a midline approach at the L_{3-4} inter vertebral space. Identification of the intended inter-vertebral space was done by noting the location of the L_4 spinous process on Tuffier's line (line connecting the superior aspects of the iliac crests). Correct needle placement were identified by

free flow of cerebrospinal fluid and confirmed by aspiration and reinjection of cerebrospinal fluid before and after the administration of the study drug solution, 3ml Ropivacaine with 0.5ml Dexmedetomidine (0.5 mcg). The study drug was injected over 15-20 seconds. After the injection of the spinal medication, the patients were placed supine immediately at the end of injection, the time of which was recorded as 'zero'." After confirming the loss of sensation at T_{10} dermatome Surgeons were asked to go ahead with the incision.

The level of sensory block was evaluated by loss of pinprick sensation to 23 G hypodermic needle. The test was performed every 2 minutes till loss of discrimination to pinprick sensation and C_{5-6} in the upper limb was used as baseline point for normal sensation to compare. Assessments continued at 30 minutes intervals following the completion of surgery until normal sensation returned. The degree of motor block in the non-operative leg were assessed using a modified Bromage score. Time to modified Bromage grade 3 & Time to complete recovery, in minutes, was recorded.

Assessment of motor block was done continuously at 30 minutes interval until normal motor function returned.

Onset time to T10 - was defined as the " interval from intrathecal administration to the point where patient is unable to perceive pinprick sensation at T_{10} dematomal level."

Time to achieve maximum height of block – was defined as "the interval from intrathecal administration to the maximum height achieved in terms of dermatomes where patient is unable to perceive pinprick sensation".

Time to onset of regression at L_1 - was defined as "the interval from intrathecal administration to the point of resolution of the sensory block at the level of L_1 dermatome when the patient starts perceiving pinprick sensation".

Time to modified Bromage grade 3 - was defined as "the interval from intrathecal administration to the point where patient is unable to move his feet or ankle joint".

Time to complete recovery of motor block- was defined as "the interval from intrathecal administration to the point of complete resolution of the motor block" i.e. to the point where the Bromage score were be back to zero and patient starts to move his legs and feet freely.

2.4.1. Haemodynamic changes

a) **Pulse Rate (PR)-** Bradycardia (pulse rate less than 50 per minute) was treated with i.v atropine 0.5 mg bolus, if symptomatic.

b) **Mean Arterial Pressure (MAP) -** was calculated according to the following formula:-

Hypotension was labelled when systolic blood pressure became less than 90 mmHg and was treated with i.v. fluids and i.v.mephentermine 6mg bolus.

c) **SpO2-** was calculated on Hudson mask @ 2-4l/min.

Decrease in arterial oxygen saturation, SpO2 <90% was considered significant.

1. Duration of analgesia: The time when patient started to feel pain and request for postop erative rescue analgesia was made.

Time to complete analgesia was defined as the " interval from intrathecal injection to the point where patients first started to feel pain".

Time to effective analgesia was defined as "the interval from intrathecal injection to the point where patients demanded rescue analgesics for pain relief ".

2. The occurrence of Side Effects including nausea, vomiting, pain, bradycardia, hypotension, sedation or any other side effects were also be recorded. Hypotension (SBP <90 mm Hg or >30% fall from the baseline value) was treated by injection mephentermine 6 mg IV and an extra bolus of 100 ml of Ringer lactate. Bradycardia (HR <50 beats/min or >30% decrease from the baseline value) was treated with IV atropine (0.5 mg). Sedation was assessed with a four point verbal rating scale (1= no sedation, 2 =light sedation, 3=somnolence, 4=deep sedation).

Criteria for discharge from post-op recovery room shall include stable vital signs, with no nausea/vomiting.

2.5. Statistical analysis

"Statistical analysis was performed using SPSS version 21.0 software (SPSS, Chicago, IL, USA). Nominal data (such as gender, Age Groups) was presented as number and percentages. Continuous data (such as age, duration of effect, and duration of motor and sensory block) was expressed as mean, standard deviation and range. *Repeated meausre*s *ANOVA tes*t with post-hoc bonferroni test was used for the comparison of the mean values at different time intervals. P-value of 0.05 was as considered as statistically significant".

3. Results

Demographic profile of the study group is listed in Table 1.

The comparison of mean PR was done between different time intervals using the Repeated measures ANOVA test. There was a significant difference in mean PR between different time intervals.

The inter-group comparison of mean PR was done between different time intervals using the Post-hoc bonferroni test. The mean PR was significantly more after spinal injection and After 3 minutes than After 6 minutes, After 9 minutes and After 12 minutes than Pre-operatively than After 15 minutes, After 30 minutes, After 45 minutes, After 60 minutes, After 75 minutes, After 90 minutes than After 120 minutes, After 150 minutes, After 18 0 minutes and After 240 minutes

The mean PR was significantly more After 105 minutes and After 210 minutes in comparison to After 45 minutes,

Table 1: Demographic Profile (mean SD)

Variable	mean±SD	SEM
Age(years)	37.88±7.63	2.47
Weight(kg)	69.45±9.65	3.36
Height(cm)	165.37±7.59	2.92
Sex(M:F)	40:10	
Duration of surgery (min)	106.32±19.21	3.61

Table 2: Mean Pulse Rate

	PR	Mean	Std. Deviation	F-value	p-value[a]	Post-hoc comparisons[b]
1.	Pre-operative	87.86	4.12			
2.	After spinal injection	92.67	5.41			
3.	After 3 minutes	91.45	5.14			
4.	After 6 minutes	90.00	3.67			
5.	After 9 minutes	89.92	5.31			
6.	After 12 minutes	89.69	3.82			
7.	After 15 minutes	87.63	5.11			
8.	After 30 minutes	87.43	7.76	6.448	< 0.001*	2, 3 > 4, 5, 6 > 1, 7, 8, 9, 10, 11, 12, 14, 15, 16, 18 13, 17 > 9, 14, 18
9.	After 45 minutes	87.14	2.94			
10.	After 60 minutes	87.88	3.94			
11.	After 75 minutes	87.75	4.19			
12.	After 90 minutes	87.43	3.53			
13.	After 105 minutes	90.31	5.13			
14.	After 120 minutes	85.67	3.63			
15.	After 150 minutes	87.75	4.19			
16.	After 180 minutes	87.43	3.53			
17.	After 210 minutes	90.31	5.13			
18.	After 240 minutes	85.67	3.63			

[a] Repeated measures ANOVA test [b] Post -hoc bonferroni test * Significant difference

After 120 minutes and After 240 minutes

The comparison of mean MAP was done between different time intervals using the repeated measures ANOVA test. There was a significant difference in mean MAP between different time intervals.

The inter-group comparison of mean MAP was done between different time intervals using the Post-hoc bonferroni test. The mean MAP was significantly more pre-operatively and After 240 minutes than After 60 minutes, After 75 minutes, After 90 minutes, After 120 minutes, After 150 minutes and After 180 minutes than After 45 minutes than After spinal injection, After 3 minutes, After 6 minutes, After 9 minutes, After 12 minutes, After 15 minutes, After 105 minutes and After 210 minutes.

The mean Sensory Block Onset time to T 10 (Minutes) was 3.51±0.50, mean Time to achieve maximum height of block (Minutes) was 10.63±0.59, mean Sensory Block - Time to onset of regression at the level of L1 (Minutes) was 187.45±22.61, mean Motor Block - Time to modified Bromage score 3 (minutes) was 6.12±0.84 and Motor Block - Time to complete recovery (minutes) was 173.14±34.26.

The mean Time to complete analgesia (in minutes) was 401.06±16.91 and mean Time to effective analgesia (in minutes) was 415.25±16.70.

A sedation score of 0 was found among 1 (2.0%) patients, score 1 was found among 2 (4.0%) patients, score 2 was found among 12 (24.0%) patients and score 3 was found among 35 (70.0%) patients.

4. Discussion

Regional anesthesia is considered to be gold standard technique as it is known to provide complete and dynamic anesthesia. The benefits include suppression of stress response by sympatholytic activity, stable hemodynamics along with reduced cardiac morbidity, reduction in pulmonary complications due to active physiotherapy and early mobilization, less blood loss and reduced thromboembolic complications after surgery. [9,10]

The results of the present study showed that spinal Ropivacaine with Dexmedetomidine significantly prolongs the duration of sensory and motor block with better quality of analgesia postoperatively.

The action of local anesthetics and $\alpha 2$ adrenergic agonists is complimentary accounting for their analgesic properties. The prolongation of motor block may be the due to the binding of $\alpha 2$ adrenergic agonists to the motor

Table 3: Mean Arterial Pressure

	MAP	Mean	Std. Deviation	F-value	p-value[a]	Post-hoc comparisons[b]
1.	Pre-operative	97.61	2.42	8.662	< 0.001*	
2.	After spinal injection	87.12	7.97			
3.	After 3 minutes	86.68	8.69			
4.	After 6 minutes	87.64	7.76			
5.	After 9 minutes	88.28	8.66			
6.	After 12 minutes	87.48	7.58			
7.	After 15 minutes	86.60	7.35			1, 18 > 10, 11, 12, 14, 15, 16 > 9 > 2, 3, 4, 5, 6, 7, 8, 13, 17
8.	After 30 minutes	88.52	6.68			
9.	After 45 minutes	91.84	6.73			
10.	After 60 minutes	95.14	4.33			
11.	After 75 minutes	95.94	4.39			
12.	After 90 minutes	97.16	4.53			
13.	After 105 minutes	87.94	7.98			
14.	After 120 minutes	98.32	3.67			
15.	After 150 minutes	95.94	4.39			
16.	After 180 minutes	97.16	4.53			
17.	After 210 minutes	87.94	7.98			
18.	After 240 minutes	99.18	0.87			

[a] Repeated measures ANOVA test [b] Post -hoc bonferroni test * Significant difference

Table 4: Block characteristics

	Mean	Std. Deviation	SEM	Minimum	Maximum	Range
Sensory Block Onset time to T 10 (Minutes)	3.51	0.50	0.07	3	5	2.00
Time to achieve maximum height of block (Minutes)	10.63	0.59	0.08	10	12	2.00
Sensory Block - Time to onset of regression at the level of L1 (Minutes)	187.45	22.61	3.17	150	240	90.00
Motor Block - Time to modified Bromage score 3 (minutes)	6.12	0.84	0.12	5	7	2.00
Motor Block - Time to complete recovery (minutes)	173.14	34.26	4.80	150	400	250.00

Table 5: Time to complete and effective analgesia

	Mean	Std. Deviation	SEM	Minimum	Maximum	Range
Time to complete analgesia (in minutes)	401.06	16.91	2.37	350	430	80.00
Time to effective analgesia (in minutes)	415.25	16.70	2.34	380	450	70.00

Table 6: Side effects

	Present (%)	Absent (%)	Total
Nausea	8(16%)	42(84%)	50
vomiting	8(16%)	42(84%)	50
bradycardia	0	50	50
hypotension	2(4%)	48(96%)	50
shivering	8(16%)	42(84%)	50

Table 7: Sedation score

Sedation score	Frequency	Percent
0	1	2.0
1	2	4.0
2	12	24.0
3	35	70.0
Total	50	100.0

neurons in the dorsal horn.[4,5] The use of Dexmedetomidine as an epidural adjuvant by various authors have not ed its synergism with local anesthetics without no additional morbidity.[11,12]

The mean Sensory Block Onset time (at the level of T10) was 3.51±0.50 minutes in the present study. This was quite similar to the studies by Gupta et al[7] for lower limb surgeries. But quite lesser than the studies by Soni, the mean time for sensory onset was 8.5±2.4 minutes, Arun Kumar et al the mean duration for the onset of sensory blockade to be 8.53±1.81 minutes and Babu et al, the mean duration for onset was 7.33±1.76 minutes for the spine surgeries. (However, the addition of dexmedetomidine was found to have a faster onset of sensory blockade in comparison to clonidine).[13,14]

In the current study, the mean time to achieve maximum height of sensory block was 10.63±0.59 minutes which was similar to the studies by Gupta et al for lower limb surgeries,[15] the mean time for achieving the maximum sensory block was 11.7±1.7 minutes, Subramanian R[16] et al, with time taken for peak sensory block time to be 10.7±2.41 minutes and Bajwa *et al*,[12] the time to reach maximum sensory level was 13.14 ± 3.96 minutes and Babu et al,[14] (11.66±2.05 minutes). However, in the study by Kaur et al,[17] the mean time taken to reach maximum sensory level was 21.63±4.17 minutes.

The maximum number of the patients reached the sensory level of T6 dermatome with few patients reporting upto T8 dermatome in the current study. This was similar to the studies by byBajwa *et al*.[11] and Kaur et al[17] with the maximum sensory level of Dermatome achieved to be T6.

The mean Time to onset of regression at the level of L1 was 187.45±22.61 minutes in our study which was more than the study by Gupta et al[7] for lower limb surgeries with a mean duration of 125.6±16.5 minutes.

In the present study, the mean Motor Block - Time to modified Bromage score 3 (minutes) was 6.12±0.84 minutes which was quite similar to the study by Swami et al[18] for supraclavicular brachial plexus block with a duration of 4.65±2.46 minutes. This was lesser when compared to the study by Soni,[19] the mean time for onset of motor block with Ropivacaine and dexmedetomidine combination was 11.3±1.6 minutes (but was better than the Ropivacaine alone and Ropivaciane in combination with clonidine).

The mean motor block time (Time to complete recovery) was 173.14±34.26 minutes in our study which was comparatively lesser in comparison to the studies by Swami et al for supraclavicular brachial plexus block, the mean duration of motor block being 472.24 minutes.

In the present study, the mean Time to effective analgesia (in minutes) was 415.25±16.70. This was found to be similar to the study by Babu et al for the spine surgeries[14] with a mean duration of analgesia to be 407.00±2.05 minutes, Swami et al[18] for supraclavicular brachial plexus block, the mean duration of analgesia was found to be 456.2 1±97.99 minutes and Gupta et al[7] the mean time of rescue of analgesia was 478±20.9 minutes.

Wu et al[20] also reported that the use of dexmedetomidine as a neuraxial adjuvant have been associated with reduced pain intensity postoperatively in the next 24 hours. There is an increase in the duration of postoperative analgesia was prolonged by approximatly 7 hours on an average. Additionally, neuraxial DEX have also been found to be associated with a significantly quicker onset of sensory block and prolonged duration of sensory and motor block.

The fast er onset of action of local anesthetics, speedy establishment of sensory and motor blockade, prolongation of the duration of analgesia; dose-sparing action of local anesthetics and stable cardiovascular parameters makes these agents a much more very effective adjuvant for regional anesthesia.[21,22]

Hypotension was reported by 2 (3.9%) patients in the current study. This was lesser than the study by

Subramanian R et al[16] Hypotension (systolic blood pressure $< 20\%$ of pre-operative value) was seen in 3 (10%) patients in group Ropivacaine with Dexmedetomidine.

Nausea and Vomiting was reported by 8 (15.7%) patients each in the present study. In the study by Kaur et al[17] three patients had nausea which was relieved without any intervention. In the study by Soni[19] and Bajwa et al[11] the incidence of bradycardia and hypotension was observed to be 2 and 9 patients respectively. Bajwa et al[11] reported urinary retention among 10% patients when Dexmedetomidine was used as an adjuvant to Ropivacaine.

Very few incidence of the side effects like respiratory depression, pruritus, headache, backache and vomiting were reported in our study which was quite similar to the other studies.[23]

5. Conclusion

The present study showed that intrathecal Dexmedetomidine with Ropivacaine significantly leads to early onset and prolongation in the duration of sensory and motor block with stable hemodynamics. However, more clinical studies to prove its efficacy and safety and varying dosages for supplementation of spinal local anaesthetics are recommended.

6. Source of funding

None.

7. Conflict of interest

None.

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