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The study of Ropivacaine With Dexmedetomidine Block Characteristics And Haemodynamic Changes In Patients Undergoing Spinal Anaesthesia For Lower Limb Orthopaedics Surgery.

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Abstract

Background: It is possible to achieve faster onset of spinal anesthesia, effective sensory and motor blocks, adequate muscle relaxation, and profound analgesia simply by injecting CSF directly into the subarachnoid space with a local anesthetic.

Aim and Objectives: This present study was conducted to see the efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in Patients Undergoing Spinal Anaesthesia For Lower Limb Orthopaedics Surgery.

Material and Methods: This observational study was done on 60 ASA I/II patients of age 20-60 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 are noted.

Results: Post-hoc bonferroni test was used for intercomparison of mean HR and MAP highly significant difference was observed. The mean onset of Sensory Block was 3.51±0.50, mean Time to achieve maximum height of block (Minutes)was 10.63±0.59, Time to onset of regression at the level of L1 (Minutes) was 187.45±22.61, mean Motor Block - Time to modified Bromage score 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.**Conclusion:** The present study concludes that addition of dexmedetomidine with Ropivacaine provides faster onset of sensory/motor block.

Keywords: Dexmedetomidine, Ropivacaine, Spinal Anaesthesia, Orthopaedics Surgery.

Introduction

Use of neuraxial blocks for orthopedic surgery has increased rapidly during the last few decades, with increasing demand for post-operative pain relief and also to decrease the need for intravenous anesthetic drugs during the post-operative period. Various adjuvants are being used with local anesthetics to prolong the duration of intra operative and postoperative analgesia and to minimize the adverse effects of high doses of local anesthetics.[1] The α2adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anesthesia.[2] Dexmedetomidine, a newer and highly selective α2 adrenergic agonist has evolved as a panacea for various applications and procedures in the perioperative and critical care settings.[3] The stable hemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful adjuvant.[4] 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.[5-8] Since only few studies are available where Dexmedetomidine's efficacyas an adjuvant to Ropivacaine in epidural anesthesia had been explored,[6-8]

Our study considering the fact that, most effective limited literature is available where Dexmedetomidine's efficacy as an adjuvant to Ropivacaine in spinal anesthesia were explored, so the present study was conducted to discover the efficacy of Dexmedetomidine as an adjuvant to Ropivacaine in terms of period of sensory and motor block, post-operative analgesia and side effects in orthopedic surgeries.

Materials and Methods

After obtaining Intitutional ethical Approval, this cross sectional observational study was conducted in indoor wards of department of Anaesthesiology, TMMC & RC, TMU, Moradabad that's a tertiary care health center situated in Moradabad and catering to Nursing homes and Hospitals of the region in addition to patients from complete of Moradabad and regions around Moradabad.

This was a clinical trial carried out on 50 patients undergoing spinal anaesthesia for lower limb orthopaedic surgery. patients with coagulation or neurological disorders, morbid obesity, pregnancy, deformity or previous surgical operation of spine, anticipated issue in local anesthesia, allergic reaction to the study drug and unwillingness were excluded from the study

Anaesthetic Technique:

All patients have been examined in % health center/bed aspect for fitness of anaesthesia as per department protocol. on this study, all patients obtained 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 have been be diluted upto 5 ml with normal saline and 0.5 ml have been taken.

Anaesthesia plan have been discussed and consent for spinal anaesthesia were taken. night time before surgical operation each patient were given lorazepam 1mg orally. on the day of surgical operation, standard monitoring devices were to be attached, and venous access were be secured inside the operating room. PR and MAP were measured with an automatic, non-invasive device. SpO2 were continuously monitored the usage of pulse oximeter for the duration of surgical procedure.Oxygen had been administered via Hudson mask on the price of 2 - 4 l/min till the surgical treatment ends.before beginning anaesthesia, all patientswere be pre-medicated with i.v.ondansetron 0.1mg/kg body weightand preloaded with lactated Ringer's solution 15-20 ml/kg body weight. Thereafter i.v.fluid have been administered to replace operative blood loss.

"After infiltrating the skin on the puncture site with lidocaine 2%, lumbar puncture were performed within the sitting position with a 25-gauge Quincke spinal needle, using a midline method on the L3-4 inter vertebral area. identity of the intended inter-vertebral area have been done by noting the region of the L4spinous method 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 showed by aspiration and reinjection of cerebrospinal fluid before and after the administration of the look at drug solution. The study drug were injected over 15-20 seconds. After the injection of the spinal medication, the patients were be placed supine immediately at the end of injection, the time of which had been recorded as '0'."

After confirming the loss of sensation at T10 dermatome Surgeons have been be asked to go ahead with the incision.the level of sensory block was evaluated by loss of pinprick sensation. The test were performed each 2 mins until loss of discrimination to pinprick sensation and C5-6 inside the upper limb was used as baseline point for normal sensation to compare. assessments continued at half-hour intervals following the completion of surgical treatment until normal sensation returned. The degree of motor block within the non-operative leg had been assessed the use of a modified Bromage score[22]. Time to modified Bromage grade 3 & Time to complete healing, in mins, had been recorded.assessment of motor block was done continuously at half-hour interval till normal motor function returned.

Onset time to T10 - have been defined because the "interval from intrathecal management to the point wherein patient is not able to understand pinprick sensation at T10dematomal stage."

Time to gain most peak of block - had been defined as "the interval from intrathecal management to the most peak performed in phrases of dermatomes in which patient is not able to understand pinprick sensation".

Time to onset of regression at L1 - have been defined as "the interval from intrathecal management to the point of decision of the sensory block at the level of L1 dermatome while the patient starts perceiving pinprick sensation".

Time to changed Bromage grade 3 - had been defined as "the interval from intrathecal management to the point wherein patient is not able to move his feet or ankle joint".

Time to finish healing of motor block- were described as "the interval from intrathecal management to the point of complete decision of the motor block" i.e. to the point in which the Bromage score were be back to zero and patient starts to move his legs and feet freely.

1.Haemodynamic changes:-

a)Pulse rate (PR)-Bradycardia had been be considered while pulse rate will become less than 50 per minute and were be handled with i.v atropine 0.5 mg bolus, if symptomatic.

b)mean Arterial pressure (MAP) -were be calculated consistent with the following formula:-

Hypotension had been be considered while systolic blood pressure turns into less than 90 mmHg and had been be handled withi.v. fluids and i.v.mephentermine 6 mg bolus.

c)SpO2- have been be calculated on Hudson mask @ 2-4l/min.

lower in arterial oxygen saturation, SpO2 <90% had been be considered significant.

2. duration of analgesia: -

This have been be assessed by the time whenpatient started out to feel pain and request for postoperative rescue analgesia have been be made.Time to complete analgesia was defined as the "interval from intrathecal injection to

the point in which patients first started to feel pain".Time to effective analgesia was described as "the interval from intrathecal injection to the point wherein patients demanded rescue analgesics for pain relief".

3. **The prevalence of side effects:** including nausea, vomiting, ache, bradycardia, hypotension, sedation or some other side effects had been also be recorded.criteria for discharge from post-op recovery room shall include stable crucial signs, with no nausea/vomiting.

Statistical Analysis:

"All statistical analyses wasperformed 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 meausres ANOVA test* 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"

Results

Table No.1: Demographic profile of the study group

	Mean ± STD	SEM
Ages(years)	37.88 ± 7.63	2.47
Weight(kg)	64.26±11.935	2.98
Height (cm)	168.37±7.75	2.94
Sex(M:F)	40:20	
Duration of surgery (Sec)	108.32±19.45	3.65

Table No.:2 **Demographic Profile of PR (mean SD)**

	PR	Mean	Std. Deviation	F-value	p-value[a]	Post-hoc comparisons[b]
1.	Pre-operative	87.86	4.12	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
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			
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**

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 180 minutes and After 240

minutes.The mean PR was significantly more After 105 minutes and After 210 minutes in comparison to After 45 minutes, After 120 minutes and After 240 minutes.

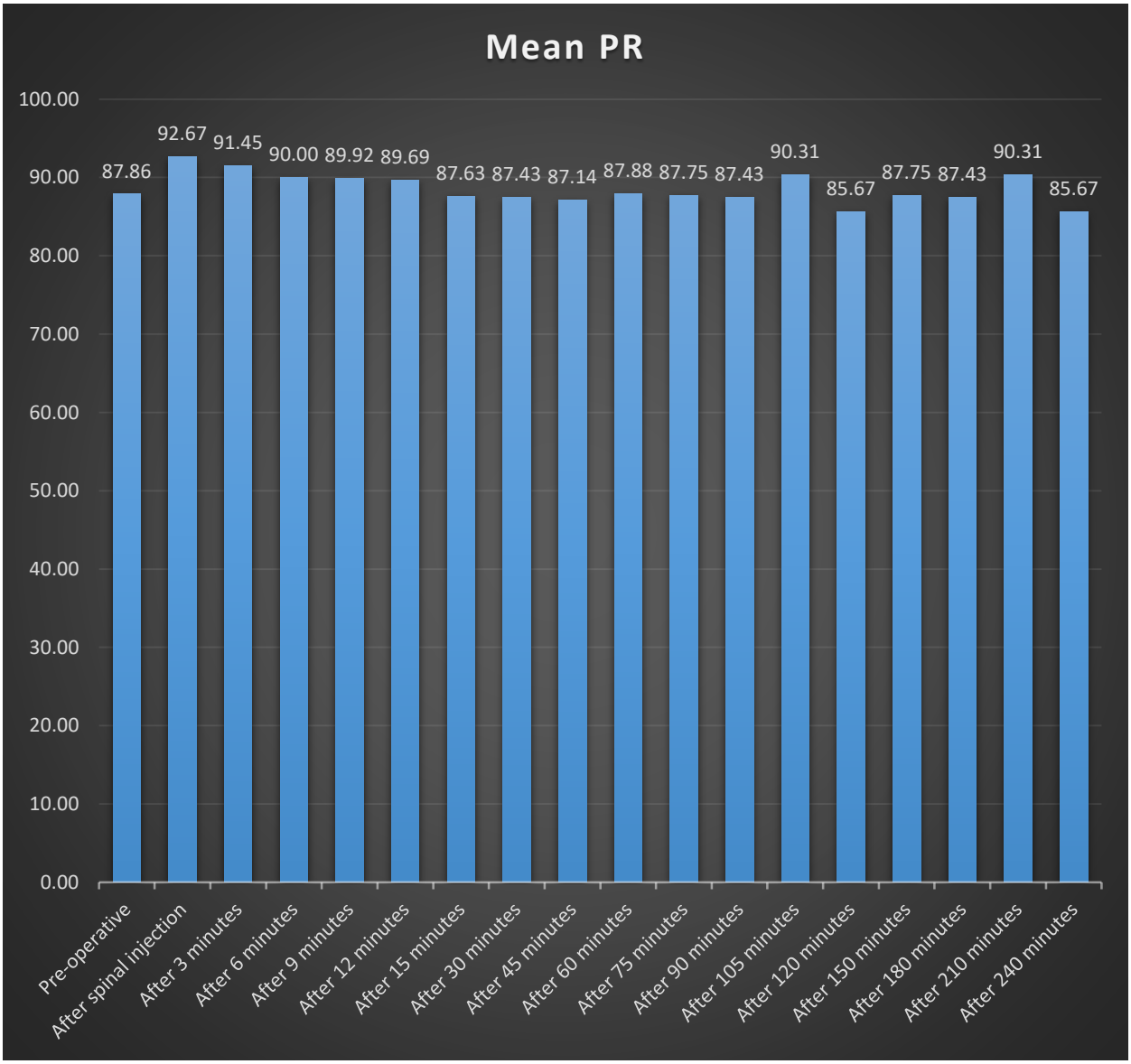

Table: No. 3: **Demographic Profile of MAP (mean SD)**

	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			
8.	After 30 minutes	88.52	6.68			
9.	After 45 minutes	91.84	6.73			
10.	After 60 minutes	95.14	4.33			1, 18 > 10, 11, 12, 14, 15, 16 > 9 > 2, 3, 4, 5, 6,
11.	After 75 minutes	95.94	4.39			
12.	After 90 minutes	97.16	4.53			

13.	After 105 minutes	87.94	7.98			7, 8, 13, 17
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**						

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.

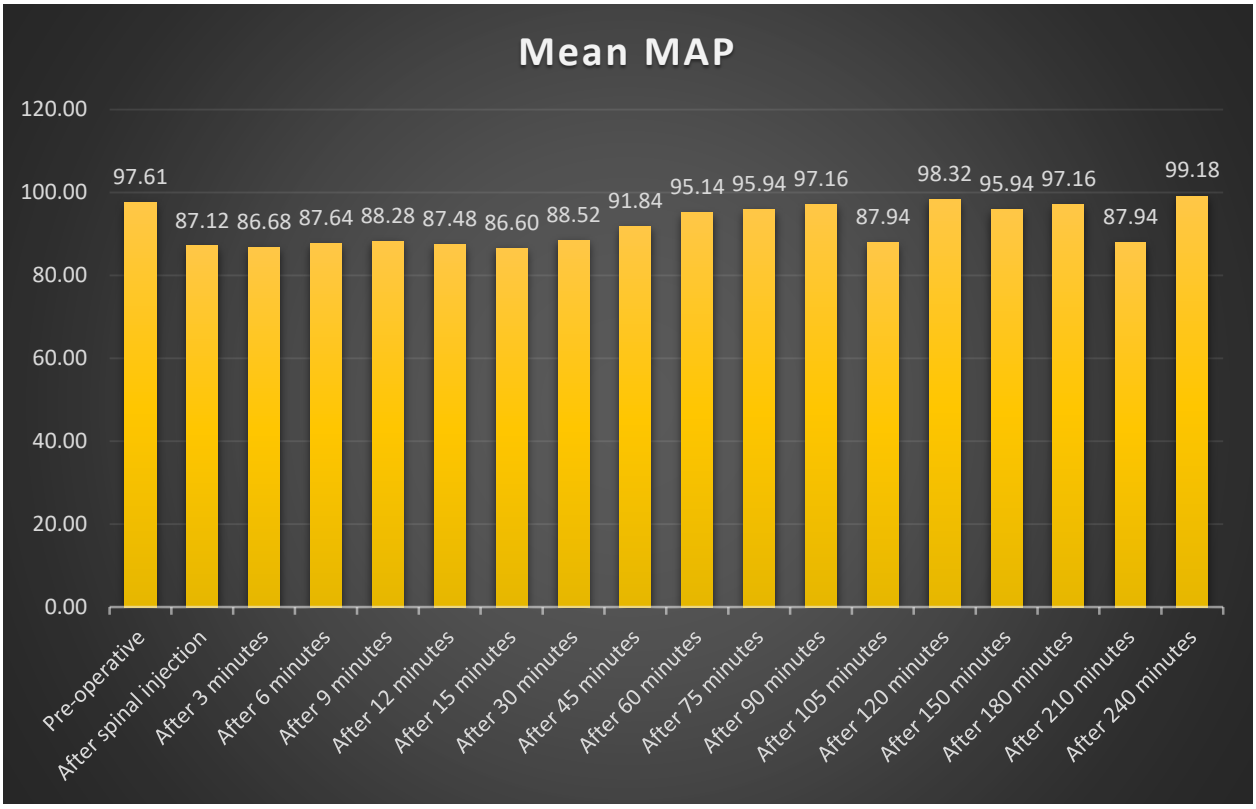

Table No. 4: Sensory block characteristics

	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

The mean Sensory Block Onset time to T 10 (Minutes) was 3.51±0.50, mean Time toachieve 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.

Table No. 5: 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

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.

Table No. 6: Side effects

	Nausea	**Vomiting**	**Bradycardia**	**Hypotension**	**Shivering**
Frequency	42	42	50	48	42
Percent	8	8	0	2	8
Total	50	50	50	50	50

Nausea was found among 8 (16.0%) patients.Vomiting was found among 8 (16.0%) patients.None of the patients reported bradycardia.Hypotension was found among 2 (4.0%) patients.Shivering was found among 8 (16.0%) patients.

Table No.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

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.

Discussion

Epidural anesthesia is considered to be gold standard technique as it is known to provide complete and dynamic anesthesia. The benefits of this 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 epidural Ropivacaine with Dexmedetomidine significantly leads to the prolongation in the duration of sensory and motor block with better quality analgesia postoperatively.The action of local anesthetics and α2 adrenergic agonists is complimentary which is accounting for their thorough analgesic properties. The prolongation of motor block may be the due to the bindingof α2 adrenergic agonists to the motor neurons in the dorsal horn.[4,5] The use of Dexmedetomidine as an epidural adjuvant by various authors have noted its synergism with local anesthetics without no additional morbidity.[11,12]

The amount of ropivacaine used in the present study was 20 ml which is considered to be adequate for the lower limb surgeries. Bajwa SJ et al,Bajwa et al, Salgado et al, Vieira et al and Katz et al also reported the use of 15-20 ml in their study.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 et al,[16] 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 456.21±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 DEX 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 approximately 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 faster 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 Bajwaet 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, pruritis, headache, backache and vomiting were reported in our study which was quite similar to the other studies.[23]

Strength and Limitations of the Present Study

There are a few limitations of the study. In the present study, only 20–60 years ages subjects participated in the research. Hence, in the feature, we would like to include an increase in a number of participants to reach a concrete conclusion. The present study was given an impact to understand about the that addition of dexmedetomidine with Ropivacaine provides faster onset of sensory/motor block.

Conclusion

The present study showed that epidural Ropivacaine with Dexmedetomidine significantly leads to the prolongation in the duration of sensory and motor block with better quality analgesia postoperatively

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