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TO COMPARE THE EFFECTS OF INTRATHECALDEXMEDETOMIDINE AND FENTANYL AS ANADJUVANT TO ROPIVACAINE IN ORTHOPAEDIC LOWER LIMB SURGERIES

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Keywords:
Dexmedetomidine,fentanyl, isobaricropivacaine, spinal anaesthesia.

Abstract

Introduction: Spinal Anaesthesia is the preferred mode of anaesthesia for lower limb surgeries. Adjuvants to 0.5% Ropivacaine may enhance the duration and quality of analgesia.

Aim: To compare the efficacy of intrathecal dexmedetomidine and fentanyl as an adjuvant to isobaric ropivacaine in orthopaedic lower limb surgeries.

Materials and Methods: After informed consent,150 patients of ASA Grade I & II of age group 18-65 years of either sex, normal coagulation profile undergoing orthopaedic lower limb surgeries under spinal anaesthesia were randomly divided into 3 groups of 50 patients each. Group I: Intrathecal administration of 3 ml of 0.5% isobaric Ropivacaine with 0.5 ml Dexmedetomidine (5µg) [total of 3.5ml]. Group II: Intrathecal administration of 3 ml of 0.5% isobaric Ropivacaine with 0.5 ml Fentanyl (25µg) [total of 3.5ml]. Group III: Intrathecal administration of 3 ml of 0.5% isobaric Ropivacaine with 0.5 ml of normal saline [total of 3.5ml]. Patients were observed for onset and duration of sensory and motor blockade, haemodynamic changes, duration of analgesia, sedation and adverse effects.

Results: Demographic profile was comparable in the groups. The onset of anaesthesia was shorter in Groups I and II as compared with the control Group III, but it was shorter in Group I than in Group II. The duration of sensory and motor block was prolonged in Group I and II as compared with the control Group III, but it was longer in Group I than in Group II. The duration of postoperative analgesia was prolonged in Groups I and II than in Group III, and it was prolonged in Group I than in Group II. Sedation scores were found to be statistically significantly higher in group I as compared to group II and control group III.

Conclusion: Dexmedetomidine and fentanyl were effective adjuvants to ropivacaine when used in spinal anaesthesia in patients undergoing lower limb surgery. Intrathecal dexmedetomidine is associated with faster onset of sensory and motor blockade and prolonged motor and sensory block with haemodynamic stability, greater sedation and greater duration of postoperative analgesia as compared to fentanyl or alone ropivacaine

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Introduction

Spinal anaesthesia is a commonly used technique in anaesthetic practice for gynaecological, lower abdominal, pelvic, and lower limb surgeries. Lower limb surgeries could be performed under local, neuraxial and general anaesthesia, but neuraxial block is the preferred method. Spinal anaesthesia is a simple and economical method which offers rapid onset of action, reliable surgical anaesthesia and good muscle relaxation with small dose of local anaesthetics. Regional anaesthesia has several advantages over general anaesthesia due to which it is the preferred technique for lower abdominal & lower limb surgeries.

Ropivacaine was introduced into clinical practice in 1996, and has consistently demonstrated an improved safety profile over bupivacaine with a reduced CNS and cardiotoxic potential, together with wide clinical utility at different doses and for wide range of indications. Ropivacaine was approved for a new route of administration, the intrathecal route, in European union in February 2004.[1] Clearance of ropivacaine is higher than that determined for Bupivacaine & its elimination half time is shorter. Higher clearance of ropivacaine offers advantage over bupivacaine in terms of systemic toxicity.[2]

In view of the reduced toxic potential, ropivacaine has a definite edge over bupivacaine in regional anaesthetic techniques. However, the advantages of ropivacaine may be offset by its limited duration of action, slower onset of block and lesser duration of postoperative analgesia[3,4] In order to improve the quality of blockade, prolong the duration of analgesia, and reduce the required dose of local anaesthetics, appropriate adjuvants are commonly used with local anaesthetics for spinal anaesthesia.[5,6]Addition of adjuvantsalso reduce the incidence of side effects caused by the use of high-dose of local anaesthetics, such as late and severe bradycardias, hypotension, nausea, and vomiting, It has been found that many drugs, such as opioids (morphine, fentanyl, and sufentanil), α2 adrenergic agonists (dexmedetomidine and clonidine), magnesium sulfate, neostigmine, ketamine, and midazolam, can be used as adjuvants for intrathecal local anaesthetics to improve the quality of spinal anaesthesia.[7]

Dexmedetomidine, a selective α2 adrenergic receptor agonist, has been shown to be a better adjuvant of local anaesthetics for neuraxial blocks, [8,9,10] although clonidine is the first clinically used intrathecal α2-adrenoreceptor agonist.[11]Owing to its selective alpha 2‐adrenergic agonistic action, Dexmedetomidine offers prolongation in sensory‐motor blockade and enhanced analgesic effects in spinal anesthesia.[9] Literature supports its usage over a dose range of 3–15 μg with hyperbaric Bupivacaine, while up to 5 μg with isobaric Ropivacaine.[12-15] Dexmedetomidine is a good adjuvant to spinal Bupivacaine, to produce prolonged block and excellent quality analgesia with minimal side effects.[16] Intrathecal alpha2receptor agonists are found to have antinociceptive action for both somatic and visceral pain.[17]

The addition of lipophilic opioids such as sufentanil and fentanyl have been shown to enhance the analgesic potency of ropivacaine for spinal anaesthesia. The addition of fentanyl to ropivacaine for spinal anaesthesia has been shown to prolong the duration of analgesia in the early postoperative period and reduce the amount of local anaesthetic required to perform a sufficient dermatome spread and block intensity. This reduction in local anaesthetic requirements reduces the intensity and duration of motor blockade and allows patients to ambulate faster.[18]

There are limited studies on intrathecal isobaric ropivacaine-fentanyl combination for postoperative analgesia in lower abdominal and lower limb surgeries. In view of few comparative studies between ropivacaine-dexmedetomidine and ropivacaine-fentanyl combinations for spinal anaesthesia, this study has been designed to compare the effects of intrathecal ropivacaine with dexmedetomidine versus ropivacaine with fentanyl in orthopaedic lower limb surgeries.

Materials and Methods

This prospective, randomized, double blind and comparative study was conducted after obtaining ethical committee clearance at Government medical college Patiala. It included 150 patients of ASA Grade I & II of age group 18-65

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years of either sex undergoing orthopaedic lower limb surgeries under spinal anaesthesia in Rajindra Hospital, Government Medical College, Patiala.

Our exclusion criteria were patient's refusal, any spine abnormality, altered coagulation profile, allergy to local anaesthetic, recent myocardial infarction, significant aortic stenosis, patients with neurological disorders, cardiac or respiratory system failure, any major hepatic or renal problem and skin infection at the site of block.

A written informed consent was obtained from each patient after explaining the technique prior to inclusion in this study in their own vernacular language.

Preanaesthetic evaluation which included detailed clinical history from patient, general physical examination, baseline pulse rate, blood pressure, respiratory rate and systemic examination which includes cardiovascular, respiratory and central nervous system examination and basic lab investigations was done in all the patients and they were explained in detail about the procedure of the spinal anaesthesia during the preanaesthetic visit.

Each patient was kept fasting for at least 6 hours preoperatively. Patients were given tab ranitidine (150mg) HS and tab lorazepam (1mg) HS before surgery.

Patients were randomly allocated in 3 equal groups of 50 patients each. In Group I,patients received 3 ml of 0.5% isobaric Ropivacaine with 0.5 ml Dexmedetomidine(0.5µg) [total of 3.5ml].In Group II, patients received 3 ml of 0.5% isobaric Ropivacaine with 0.5 ml Fentanyl(25µg) [total of 3.5ml]. In Group III, patients received 3 ml of 0.5% isobaric Ropivacaine with 0.5 ml of normal saline [total of 3.5ml].

In the operating room, after attaching routine monitors (electro-cardiogram, noninvasive blood pressure, pulse oximeter), baseline BP(systolic, diastolic and mean), heart rate, respiratory rate and peripheral oxygen saturation(SpO_2) were recorded before intrathecal injection(marked as time 0). Intravenous access was secured with 18G cannula. All patients were preloaded with 15ml/kg of Ringer's lactate solution. The patient was positioned in left lateral position or sitting position. Under all aseptic precautions, parts were cleaned & draped and L3-L4 space was identified. The study medication was prepared and subarachnoid block was given at the L3-L4 interspace with a 23G Quinke's spinal needle and 3.5 mL of the study drug solution [consisting of 3 mL of 0.5% isobaric ropivacaine with 0.5 mL Dexmedetomidine (group I) or 0.5mL fentanyl (group II) or 0.5 mL normal saline (group III)] was injected intrathecally at rate of 0.2ml/second as per the group allocation. The subarachnoid block was administered by the anaesthetist who was notinvolved in the study to ensure blinding of the anaesthetist. Both patients and observers were blinded to the drugs given. Patients were immediately placed in supine position. Oxygen was provided via venturi mask at the rate of 4 Litre/min,

Blood pressure (systolic, diastolic and mean), heart rate, respiratory rate and peripheral oxygen saturation(SpO_2) were continuously monitored and recorded at 5, 10, 15, 20, 25 and 30 minutes after the injection, and subsequently every 15 minutes. Hypotension (defined as systolic blood pressure of less than 90 mmHg or less than 20% of baseline blood pressure) was treated with intravenous fluid initially (250 mL boluses repeated twice) and intravenous mephentermine 5mg, if required. Bradycardia (defined as heart rate of less than 60) was treated with intravenous injection 0.6 mg atropine sulphate.

The following parameters were observed perioperatively

Onset of sensory block : Sensory block was assessed by pin prick method. The level of sensory blockade was assessed every 2min until the level stabilized for four consecutive tests. The onset of sensory blockade(defined as the time from the injection of intrathecal drug to the absence of pain at the T10 dermatome) was recorded.

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Onset of motor block: Onset of complete motor blockade(time taken from the injection to failure to raise the lower limb on command)was recorded. Onset of motor blockade was assessed at 5min intervals till 15 min according to the Modified Bromage Scale[19]:

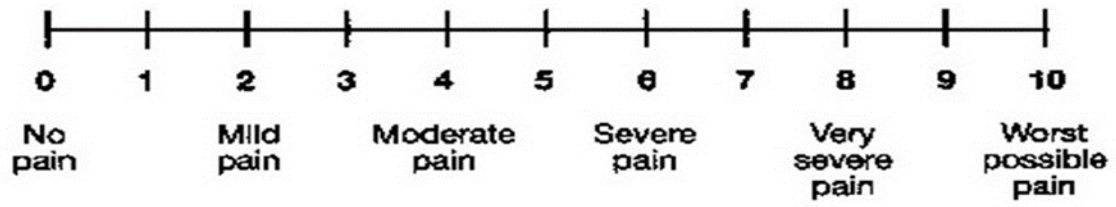
- 1.Complete block (unable to move feet or knee)
- 2.Almost complete block (able to move feet only)
- 3.Partial block (just able to move knees)
- 4.Detectable weakness of hip flexion while supine(full flexion of knees)
- 5.No detectable weakness of hip flexion while supine
- 6.Able to perform partial knee bend

Duration of sensory and motor block: The duration of sensory blockade (two segment regression time from highest level of sensory blockade) was recorded. Duration of motor blockade (time required for motor blockade to return to Bromage's grade 6 from the time of onset of motor blockade) was recorded.

Sedation: Grades of sedation during surgery were assessed by the Modified **Ramsay's Sedation Scale[20]:**

- 1 = anxious and agitated or restless, or both
- 2 = co-operative, oriented, tranquil
- 3 = responding to commands only
- 4 = brisk response to light glabellar tap or loud noise
- 5 = sluggish response to light glabellar tap or loud noise
- 6 = no response

Postoperative pain: Postoperatively, pain score i.e. VAS[21]was assessed 1 hourly for first 12 hours. The duration of complete analgesia (time from the intrathecal injection to the first pain report, VAS score > 0) and the duration of effective analgesia (time from the intrathecal injection to the first rescue analgesic requirement, VAS score > 3) was noted. Intramuscular diclofenac (75 mg) was administered as rescue analgesic.



Side effects: Patients were also assessed for side-effects like nausea, vomiting, hypotension, pruritis and bradycardia. All the data was analysed statistically.

Sample Size Calculation

The formula for determining sample size is given as:

$$n = \left(\frac{z_{\alpha/2} \cdot \sigma}{E}\right)^2$$

Where

n = Sample size

σ = Population standard deviation

E = Margin of error

z = The value for the given confidence interval

- The confidence level is estimated at 95%
- Standard deviation=8.64
- With a z value of .05, the confidence interval or margin of error is estimated at +/- 4

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- Assuming80 percent as power of the study, minimum sample size required for the study was calculated to be 49.

In our study 150 subjects were chosen

- n=50 in Group I
- n=50 in Group II
- n=50 in group III

Statistical Analysis

Descriptive statistics was done for all the data and were reported in terms of mean values and percentages. Suitable statistic tests of comparison were applied. Continuous variables were analysed with unpaired t- test. Categorical variables were analysed with help of t-test and Mann Whitney U-test wherever applicable after checking normality of data. Statistical significance was taken as p value <0.05. The data was analysed using SPSS version 22 and Microsoft excel 2007.

Results

In our study all the three groups were comparable in Age, Weight, sex and Mean duration of surgery(table 1).
On comparing the groups, we found that the mean onset time of sensory block was 153.58±7.70 secs in group I, 184.46±9.98 secs in group II and 202.12±16.05 secs in group III(table 2).The difference among the three groups was statistically significant (p value= 0.000) thereby showing that addition of dexmedetomidine and fentanyl decrease the time of onset of sensory block and that dexmedetomidine has faster onset of sensory block than fentanyl.

The mean time of onset of motor block in Group I was 443.12±24.11secs while it was 489.46±10.97 secs in Group II and 493.28±14.27 secs in group III(table 2) which was statistically significant between Groups I & II and between Groups I & III (p=0.000) but the difference was statistically non-significant between groups II and group III.(p=0.820). Thus, dexmedetomidine shortens the onset of motor blockade than fentanyl and control group.

The mean bromage scores in group I were 2.76±0.62, 1.00±0.00and 1.00±0.00 at 5 mins, 10 mins and 15 mins respectively. The mean bromage scores in group II were 3.10±0.61, 1.12±0.33 and 1.00±0.00 at 5 mins, 10 mins and 15 mins respectively. The mean bromage scores in group III were 4.48±0.51, 2.00±0.76 and 1.06±0.24at 5 mins, 10 mins and 15 mins respectively. The mean bromage score was found to be better in group I than group II and group III and the difference was found to be statistically significant between groups I and II and between groups I and III at 5 and 10 mins (p<0.005) while it was non-significant at 15 mins interval among all the three groups.

Total duration of sensory block in Group I was greater than in Group II and III(table 2).The difference was clinically and statistically significant (p=0.000) among all the three groups.

The mean total duration of motor block in Group I was 134.98±5.60 min while it was 96.96±7.27 min in Group II and 84.88±9.26 min in group III which was clinically and statistically significant (p =0.000) among all the three groups(table 2).

The sedation score was significantly higher in dexmedetomidine group than fentanyl and control groups(table 3 and figure 1).

The mean duration of effective analgesia noted in the dexmedetomidine group (group I) was 444.94±14.80min, and the fentanyl group (group II) recorded a period of 350.96±16.15min and control group (group III) recorded a period of 169.10±14.43 min as period of effective analgesia(figure 2).

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VAS scores were significantly lower in group I as compared to group II andcontrol group (figure 3). Our results showed that dexmedetomidine and fentanyl both cause reduction in VAS scores than control group hence providing better quality of postoperative pain than control group.

Table 1: Demographic profile

	Group I	**Group II**	**Group III**	**Group I vs II**		**Group I vs III**		**Group II vs III**	
Variable	Mean ±S.D.	Mean ±S.D.	Mean ±S.D.	p-value	S/NS	p-value	S/NS	p-value	S/NS
Age(in years)	37.52±11. 26	36.48±11. 96	39.42±13. 49	1.00	NS	1.00	NS	0.69	NS
Gender (M:F)	38:12	44:6	42:8	0.27	NS	1.00	NS	0.27	NS
Body weight (in kgs)	66.71± 6.21	68.66±6.49	65.68±7.30	0.56	NS	1.00	NS	0.10	NS

Table 2: Block Characteristics

	Group I	**Group II**	**Group III**	**Group I vs II**		**Group I vs III**		**Group II vs III**	
Variable	Mean ±S.D.	Mean ±S.D.	Mean ±S.D.	p-value	S/NS	p-value	S/NS	p-value	S/NS
Onset of sensory block(sec)	153.58±7.70	184.46 ±9.98	202.12± 16.05	0.00	S	0.00	S	0.00	S
Onset of motor block(sec)	443.12±24.11	489.46± 10.97	493.28 ±14.27	0.00	S	0.00	S	0.820	NS
Duration of sensory block(mins)	180.98±12.26	140.26± 5.03	116.16 ±10.49	0.00	S	0.00	S	0.00	S
Duration of motor block(mins)	134.98± 5.60	96.96 ±7.27	84.88± 9.262	0.00	S	0.00	S	0.00	S
Duration of effective analgesia(mins)	444.94±14.80	350.06 ±16.15	169.10± 14.43	0.00	S	0.00	S	0.00	S

S= significant
NS= non-significant

Table 3: Ramsay Sedation Score

Time-interval	**Group I**	**Group II**	**Group III**	**p-value I Vs. II**	**p-value I vs. III**	**p-value II Vs. III**
30 mins	2.28±0.45	2.02±0. 14	2.00±0.00	0.000*	0.000*	0.000*
60 mins	2.06±0.24	2.00±0. 00	2.00±0.00	0.096**	0.096**	1.000**
90 mins	2.00±0.00	2.00±0. 20	2.00±0.00	1.000**	1.000**	1.000**
120 mins	1.94±0.24	1.86±0. 35	1.98±0.14	0.372**	1.000**	0.065**

***** Significant
****** NonSignificant

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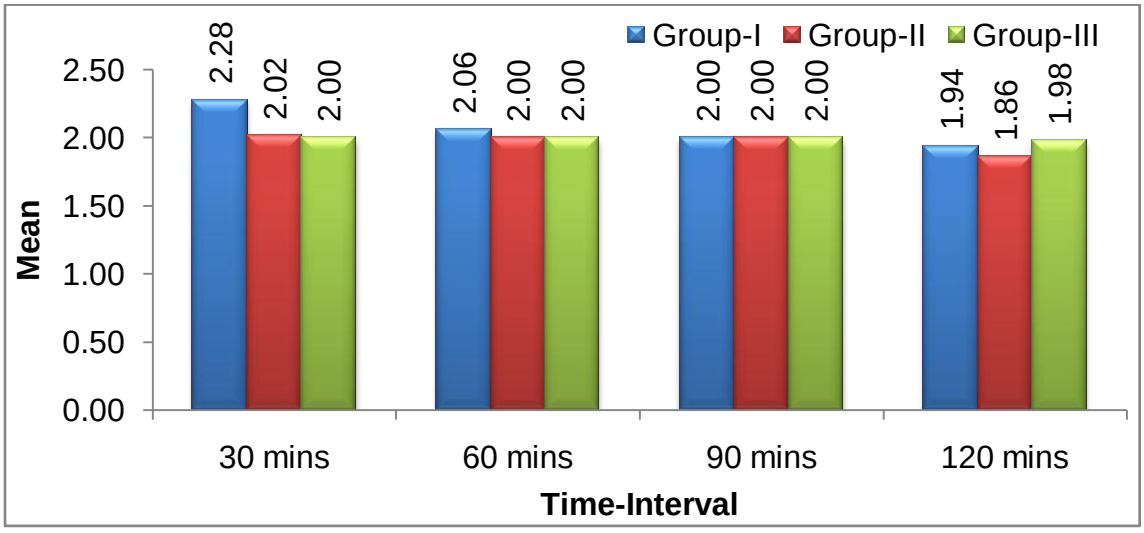

Figure 1: Ramsay Sedation Score

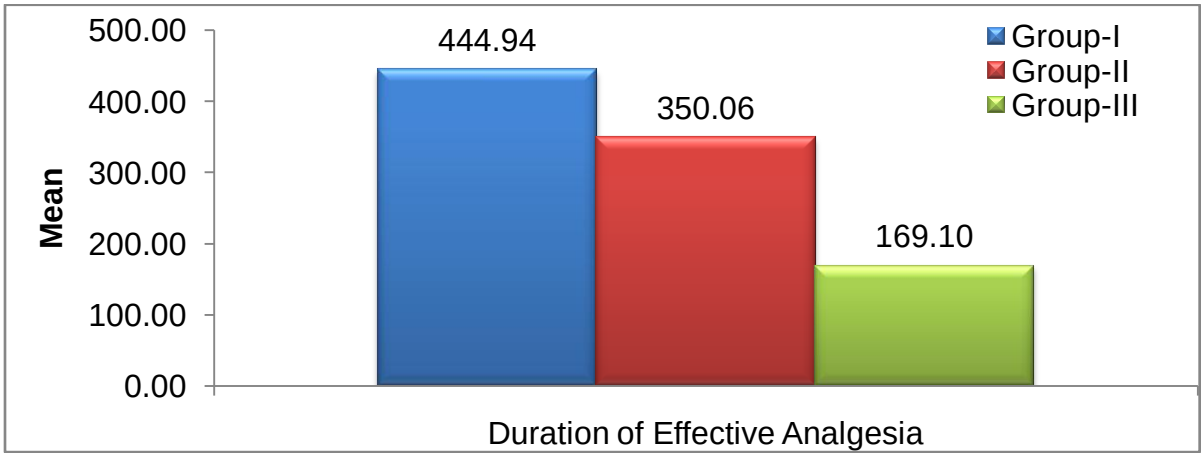

Figure 2: Duration of effective analgesia

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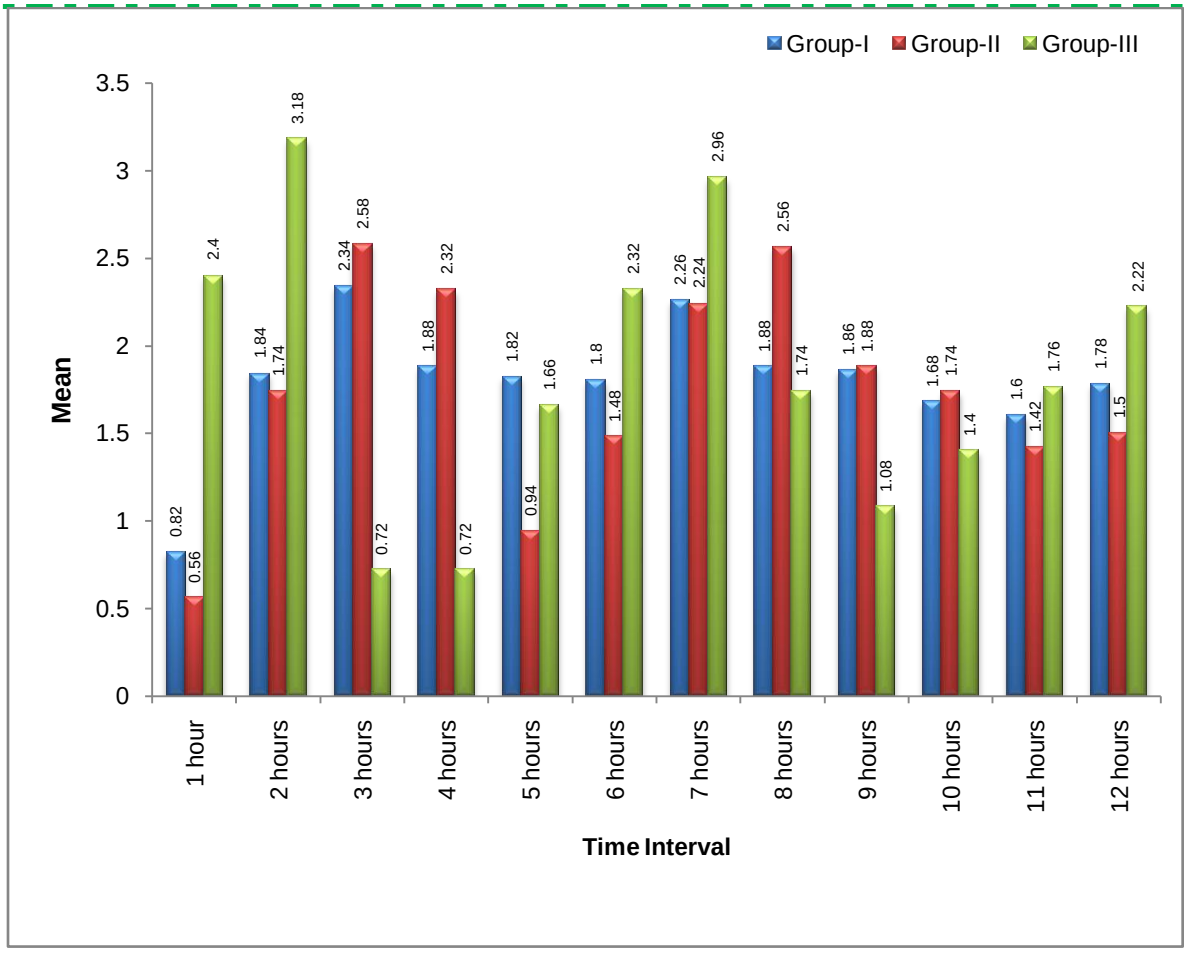

Figure 3:VAS scores

Discussion

Ropivacaine, a newer amide local anaesthetic, is considered to have a better tolerability profile for neuro-cardiovascular tissues and has emerged as an alternative to bupivacaine.[22] Hyperbaric ropivacaine though produces a more consistent nerve block than isobaric preparation, unavailability of commercial hyperbaric preparations have invited investigations on addition of adjuvant to isobaric ropivacaine to overcome its drawbacks.[23]Adjuvants from different pharmacological classes of drugs are used to enhance and prolong analgesia, and to lower dose requirements so as to reduce dose-dependent side-effects. In this present prospective randomized study, we compared the role of fentanyl and dexmedetomidine as adjuvants for intrathecal ropivacaine with an aim to compare their effect on onset & duration of sensory and motor blockade, various hemodynamic parameters like heart rate, blood pressure (systolic, diastolic and mean), SpO_2, respiratory rate and duration of postoperative analgesia.

On comparing the groups, we found that the mean onset time of sensory block was less in group I and group II than group III.The difference among the three groups was statistically significant thereby showing that addition of dexmedetomidine and fentanyl decrease the time of onset of sensory block and that dexmedetomidine has faster onset of sensory block than fentanyl. Our results were similar to study conducted by Saadalla et al[24]who found that the onset time of sensory block up to T10 dermatome was rapid in dexmedetomidine group (2.23 ± 1.05 min) and fentanyl group(4.12 ± 1.04 mins) in comparison with control group (6.44 ± 1.31 mins).Our study results were also

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similar to the study conducted by Ravipati et al [25]and El-Attar et al[26]where it was concluded that dexmedetomidine has significantly faster onset of sensory blockade compared with fentanyl when injected intrathecally.Our study results were contrary to that of Mahendru et al[14] who observed that the time of onset of sensory block was not significant in the groups receiving dexmedetomidine and fentanyl as adjuvants to intrathecal bupivacaine.

In our study,we found that dexmedetomidine shortens the onset of motor blockade than fentanyl and control.Our results were similar to the results of the study done by Safari et al[27] who found that the onset of motor block in the dexmedetomidine group was significantly lower than those of the fentanyl and control groups. Our results were contrary to the study done by Mahendru et al[14] who found that the onset times to reach T8 dermatome and Bromage3 motor block were not significantly different between the dexmedetomidine and fentanyl groups and concluded that intrathecal dexmedetomidine and fentanyl had no statistically significance with regard to the onset of motor blockade.

Total duration of sensory block in Group I was found to be greater than in Group II and III. Our results were similar to the study conducted by Ravipati et al[25] who concluded that intrathecal dexmedetomidine is associated with prolonged sensory block when compared to fentanyl similar to our results. Similarly Mahendru et al[14]and Gupta et al[28] also found that intrathecal dexmedetomidine had prolonged sensory block when compared to fentanyl.

The mean total duration of motor block was found to be higher in Group I than Group II and Group III .Our results were similar to the study conducted by Safari et al[27]where dexmedetomidine 5µg added to 12.5 mg of 0.5% hyperbaric bupivacaine (DEX group)was compared with 25µg fentanyl added to 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine (F group) and only 12.5mg of 0.5%hyperbaric bupivacaine(control group). It was found that the duration of motor block in the DEX group was significantly longer than those of the fentanyl (P = 0.014) and control groups (p = 0.005) similar to our study. However, duration of motor block was not significantly longer in the fentanyl group than the control (p = 0.081).This was contrary to our study where we found statistically significant difference in duration of motor block between group II and group III. Our results were also similar to the study conducted by Gupta et al[28]who concluded that intrathecal dexmedetomidine is associated with prolonged motor block when compared to fentanyl.

In our study, the sedation score was significantly higher in dexmedetomidine group than fentanyl and control groups. Our results were consistent with Naithani et al[29] who found statistically significant increase in sedation score with increasing dose of dexmedetomidine. Our results were similar to the results of study conducted by Varghese et al[30]who found that the mean scores in dexmedetomidine group were significantly higher than that of fentanyl and control groups at all the time intervals. Our results were contrary to the study done by Mohamed et al[31] who stated that there was no significant difference in sedation scores among dexmedetomidine and fentanylgroups which is in contradiction to our study, as dexmedetomidine group had significant sedation in our study.

The mean duration of effective analgesia noted in the dexmedetomidine group (group I) was higher than fentanyl group(group II) and control group(group III).Results of our study were consistent with the study carried out by Mohamed et al[31]in which it was found that the time of the first rescue analgesic requirement was significantly prolonged in the dexmedetomidine group (3.30 h) and the dexmedetomidine + fentanyl group (5.41 h) compared to the control group (0.233 ± 0.11 h). Our results were also similar to the study done by Varghese et al[30]whose results showed statistically significant increase in the duration of postoperative analgesia in group using dexmedetomidine as compared to group fentanyl.

Our results showed that dexmedetomidine and fentanyl both cause reduction in VAS scores than control group hence providing better quality of postoperative pain than control group. Our results were supported by the study

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conducted by Varghese et al[30] who found that the score was significantly low in dexmedetomidine group similar to our study.

Conclusion

In our study, we can conclude that dexmedetomidine and fentanyl are effective adjuvants to ropivacaine when used in spinal anaesthesia in patients undergoing lower limb surgery. Intrathecal dexmedetomidine is associated with faster onset of sensory and motor blockade and prolonged motor and sensory block with haemodynamic stability, greater sedation and duration of postoperative analgesia as compared to fentanyl or alone ropivacaine.

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