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Research Article

DEXMEDETOMIDINE AS INTRATHECAL ADJUVANT TO 0.75% ISOBARIC ROPIVACAINE IN LOWER LIMB ORTHOPAEDIC SURGERY

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A R T I C L E I N F O

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A B S T R A C T

Background and Aim– Adequate post-operative pain relief should be a critical part of management of anaesthesia. Ropivacaine produces a short duration of motor blockade which is useful for early mobilisation of patient and hospital discharge but postoperative analgesia is a crucial concern with Ropivacaine. So, our point of interest is of administering an adjuvant with Isobaric Ropivacaine which provides improved intraoperative hemodynamic parameters along with extended post-operative analgesic effects with the least side effect profile. Thus our aim was to evaluate and compare the efficacy of analgesia following intrathecal administration of isobaric ropivacaine with or without dexmedetomidine in lower limb orthopedic surgeries.

Methods - Study was carried out on 60 patients belonging to American Society of Anaesthesiologists grade I and II, aged between 15 to 60 years, including either gender and they were randomly assigned to one of the two groups: Group RN: 2.5 ml isobaric Ropivacaine 0.75% (18.75 mg) with 0.5 ml normal saline (NS). Group RD: 2.5 ml isobaric Ropivacaine 0.75% (18.75 mg) with 5µg of Dexmeditomidine in 0.5 ml NS. Time to reach peak sensory level, the sensory and motor regression times and duration of sensory and motor blockade were noted. Duration of analgesia, Hemodynamics and side effects were recorded.

Results – Time to onset of sensory block and motor block was early in group RD as compared to group RN. Duration of sensory and motor blockade was prolonged in group RD. The mean regression time to S1 segment was prolonged in group RD and the duration of analgesia was significantly increased in group RD compared to group RN.

Conclusion– The addition of Dexmedetomidine 5µg intrathecally to 0.75 % isobaric ropivacaine seems to be a superior adjuvant with an increased duration of motor and sensory blockade and an increased post-operative analgesia with a negligible side effect profile.

INTRODUCTION

Adequate post-operative pain relief should be a critical part of management of anaesthesia. Incomplete post-operative pain alleviation may cause clinical and psychosomatic changes that may escalate the morbidity and mortality as well as increase the health-care monetary burden, in addition to lowering the quality of life post-operatively.[1] The most commonly used drug for subarachnoid block is Bupivacaine which has side effects like cardiovascular toxicity, neurological toxicity and more chances of hemodynamic changes.[2] Ropivacaine is a first single enantiomer specific compound, which has a decreased risk of toxicity to the cardiovascular system, the central nervous system and has faster recovery of motor function.[3]Ropivacaine produces a short duration of motor blockade which is useful for early mobilisation and hospital discharge but postoperative analgesia is a crucial concern with Ropivacaine. So, our point of interest is of administering an adjuvant with Isobaric Ropivacaine which provides improved intraoperative hemodynamic parameters along with extended post-operative analgesic effects with the least side effect profile. There are various non-opioids such as alpha-2 agonists and opioids that are used as adjuvants to intrathecally used local anaesthetics to improve the overall characteristics of the blockade.[4] Furthermore, it is cardio-protective, neuro-protective, and has minimal effect on the respiratory system.[5] With the understanding of pharmacological properties and drug interactions we designed a double blinded prospective randomised controlled study at our institution for the patients receiving subarachnoid block who were posted for surgeries involving the lower limb. We are conducting this particular study with the aim to evaluate the outcome of adding Dexmeditomidine 5µg to 0.75% Isobaric Ropivacaine 18.75mg on characteristics of the block and hemodynamic parameters in patients posted for lower limb surgeries.

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METHODS

The study was conducted at Dr. D Y Patil Medical College, Hospital and Research Centre with ethical approval from the institution.Study was carried out on 60 patients belonging to ASA (American Society of Anaesthesiologists) grade I and II, aged between 15 to 60 years, including either gender, scheduled for elective lower limb orthopaedic surgical procedures under spinal anesthesia. After obtaining informed written consent from patients in their own understandable language, theywererandomly assigned to one of the two groups:

Group RN: 2.5 ml isobaric Ropivacaine 0.75% (18.75 mg) with 0.5 ml normal saline (NS). Group RD: 2.5 ml isobaric Ropivacaine 0.75% (18.75 mg) with 5µg of Dexmeditomidine in 0.5mlNS. Patients with pre-existing cardiovascular disease (IHD, hypertension, valvular heart disease), deranged liver functions or renal functions, Patients with any Neurological and psychiatric disorders, Patients with any contra indication for neuraxial blockade, Patients posted for emergency procedures, History of allergy to any of the drugs being used under study and Unwilling patients were excluded from the study.

After detailed preanesthetic check-up, all the patients were kept fasting for a period of at least 6 hours prior to surgery. In the operation theatre, IV access was secured with 20-gauge cannula. Monitoring devices were attached (heart rate, pulse oximeter, ECG, non-invasive BP). Baseline parameters were recorded. The subjects were pre-loaded with 10 ml/kg Ringer lactate and maintained on IV fluids throughout the procedure. Lumbar Puncture was performed in sitting position using 26 gauge Quincke's spinal needle in L3-L4 Intervertebral Space. The anaesthesiologist who administered the drug and the observer were blinded to the study. Sterile syringes containing 3 ml of total volume of the drug were loaded by another anaesthesiologist not participating in the study. Heart rate, blood pressure, SPO_2 were recorded every 5 minutes for 30 min following subarachnoid block and every 15 minutes for the next hour and hourly there after till surgery finishes. Oxygen 4L/min was administrated through a face mask. Hypotension defined as a decrease in mean arterial pressure more than 20% from baseline or less than 60 mm Hg was treated with incremental intravenous (IV) doses of mephentermine 6 mg and boluses of IV fluid as required. The incidence of adverse effects such as nausea, vomiting, shivering and hypotension was recorded. The sensory dermatome level was assessed by pin prick method. The motor blockade was assessed according to the modified Bromage ScaleBromage 0- Patient able to move hip, knee and ankle. Bromage 1- Patient unable to move hip, but able to move knee and ankle. Bromage 2- Patient unable to move hip and knee but able to move the ankle. Bromage 3- Patient unable to move hip, knee and ankle. Onset of sensory and motor block- Time to reach theT-10 Dermatome and to reach the Bromage 3 level. Duration of sensory and motor block-Time to regression to dermatome S1 and time to reach Bromage 0 was noted in post-operative care unit. Sedation was assessed by using Modified Ramsay sedation scale. Postoperatively, the pain score was recorded by using visual analogue pain scale (VAS) between 0 and 10 (0 = no pain, 10 = severe pain).Data will be statistically described in terms of mean (±SD), frequencies (number of cases) and percentages when appropriate. Comparison of quantitative variables between the study groups was done using unpaired t-test while Man Whitney test was used for ordinal variables like sedation score and VAS score. For comparing categorical data, Chi square test was performed. A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel 2007 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 21.

RESULTS

Table 1 Demographic Parameters

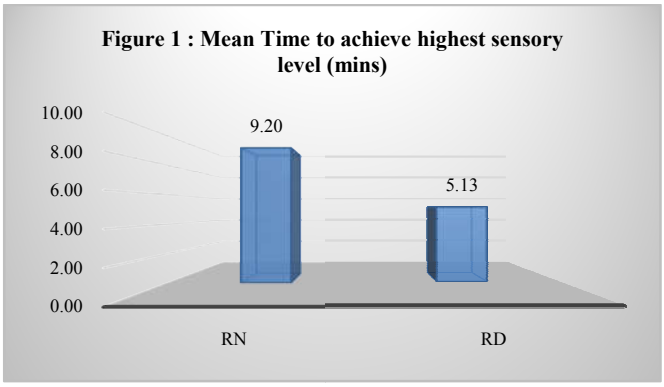
Parameters	Group RN		Group RD		P Value
Age (years)	41.67 ± 11.65		38.07 ± 10.01		0.20, NS
Weight (kgs)	58.73 ± 5.73		57.27 ± 6.34		0.35, NS
Gender	Male 63.3%	Female 36.7%	Male 66.7%	Female 35%	1.00, NS
ASA	I 43.3%	II 46.7%	I 56.7%	II 53.3%	0.84, NS

Both the groups were similar pertaining to their Age, Weight, American Society of Anaesthesiologists Physical status and Gender (Table 1).

Table 2 Block Characteristics

Block Characteristics	Group RN	Group RD	P Value
Time to attain highest sensory block	9.20 ± 2.16	5.13 ± 1.43	< 0.01*
Duration of regression to S1	184.50 ± 13.73	415.97 ± 18.72	< 0.01*
Motor Blockade Duration	133.07 ± 11.72	247.53 ± 13.48	< 0.01*
Duration of Analgesia	201.50 ± 12.13	431.00 ± 14.91	< 0.01*

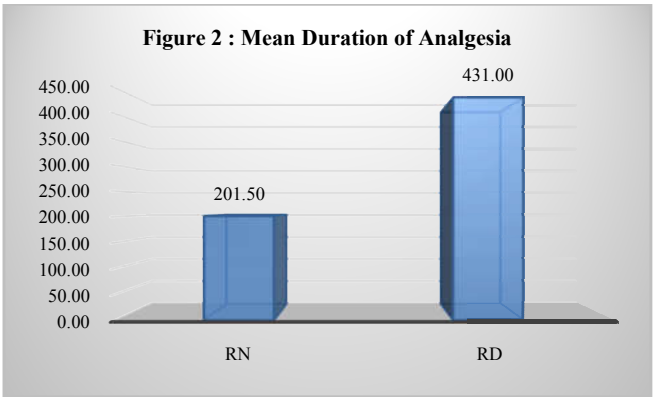
The mean time to attain highest sensory block was faster in group RD (5.13 ± 1.43 minute) whereas it was 9.20 ± 2.16 minutes in group RN and this difference was highly significant. (p < 0.01). (Figure-1)



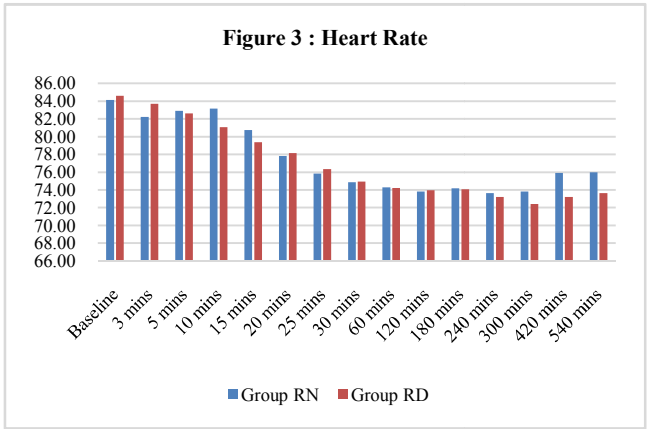
The time taken for sensory block regression to S1 dermatome was prolonged (415.97 ± 18.72 minutes) in group RD as compared to Group RN(184.50 ± 13.73 minutes). This result revealed a statistically significant difference between the two groups.

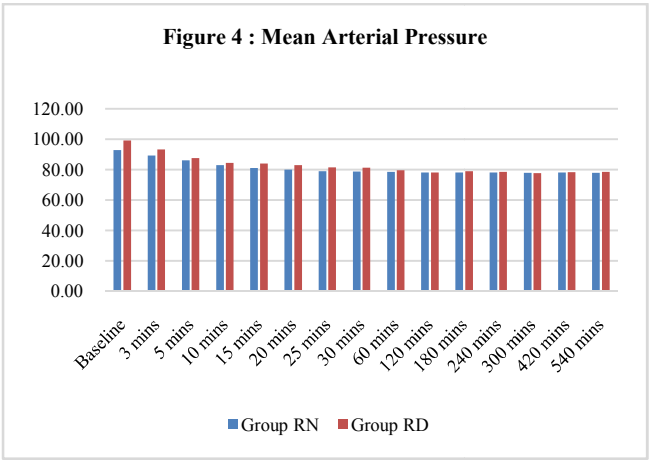
The mean motor blockade duration was 247.53 ± 13.48 minutes in group RD whereas it was 133.07 ± 11.72 minutes in group RN. So, the duration of the motor blockade was significantly longer in group RD when compared to group RN and this result was highly significant. (p < 0.01).

The duration of analgesia was much prolonged in group RD (431.00 ± 14.91 minutes) when compared to group RN (201.50 ± 12.13 minutes). This result was statistically significant with a p value < 0.01.(Figure 2)

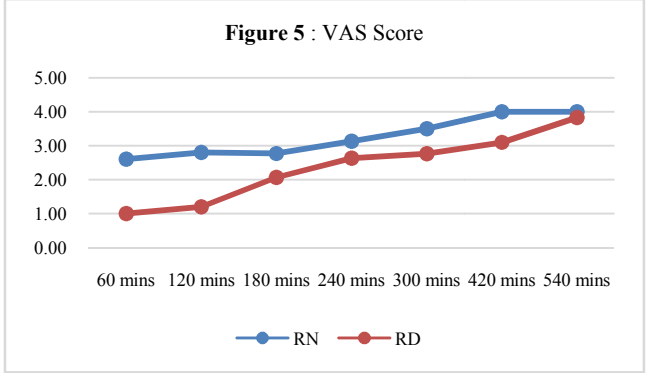


There was no statistical difference between the two groups in terms of hemodynamic parameters with respect to Heart Rate (Figure 3) and Mean Arterial Pressure (Figure 4).





VAS Score between group RN and RD was significant during the observation period between 120 minutes to 540 minutes The score was much lower in group RD at the predetermined intervals of time showing better post-operative analgesia in Dexmeditomidine group($P < 0.01$). (Figure 5)



Sedation as assessed by Ramsay Sedation Score was statistically significant during 10 minutes to 300 minutes of the observation period with a p value of less than 0.01. Group RD had better sedation scores that is the patients were more co-operative, calm and tranquil as compared to Group RN.

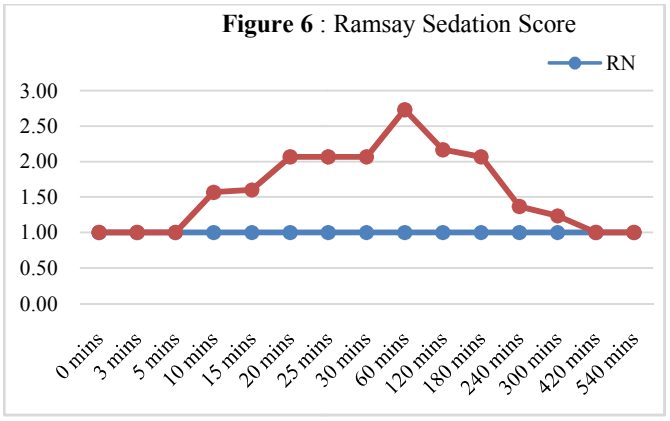
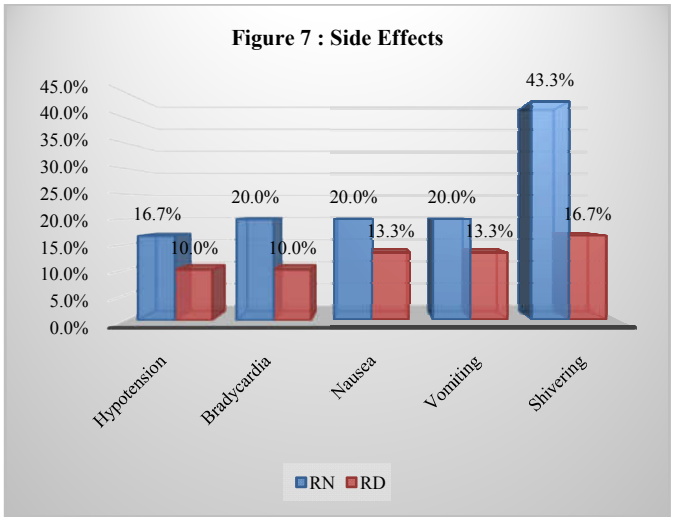


Figure 7 shows the incidence of side effects between the two groups. The incidence of shivering in Group RN was 43.3 % and in Group RD was 16.7 % and this statistical difference was significant in both the groups. ($p < 0.01$) The incidences of other side effects were insignificant



DISCUSSION

Ropivacaine is a novel pure amide local anaesthetic agent (S-enantiomer) with a wide margin of safety than Bupivacaine but with a lesser duration of motor and sensory action.[6] In studies where Ropivacaine was tried as a single dose spinal anesthetic drug, it produced variable block characteristics and significant number of patients needed general anesthesia for accomplishing the procedure. For this reason, various adjuvants are being added to the plain ropivacaine isobaric solution to prolong its motor and sensory blockade parameters and thus accomplish a better result.[7] Dexmedetomidine which is an adrenergicagonist specific to α2 adrenergic receptor is being utilized recently as an adjuvant to intrathecal drugs to increase the analgesic time duration and improve its quality.[5] The study showed that group RD required comparatively lesser time to achieve highest sensory block (5.13 ± 1.43 minutes) whereas group RN took approximately double the time (9.20 ± 2.16). Our results were concurrent with Mehmooda *et al*[8]study where he evaluated the addition of 10µg Dexmeditomidine to 3.5ml of hyperbaric bupivacaine and concluded that the time taken to achieve the maximum sensory

blockade was 6.2 ± 0.4 minutes in study class while it was 8.5 ± 0.5 minutes in the group which received only plain bupivacaine. It is also in accordance with Al-Mustafa *et al*[9] study in which they compared various doses of Dexmeditomidine added intrathecally to hyperbaric bupivacaine and they reported that the mean duration of sensory blockade required to get to the T10 dermatomal level was much lesser when compared to the group which received NS.

The duration of the sensory block regression to S1 in group RD was nearly two and a half times more as compared to group RN and it differs significantly This showed that the dexmedetomidine group took significantly more time for S1 segment regression. This was in accordance with the study done by Khageshwar *et al*[10] where he compared the efficacy of analgesia following the subarachnoid administration of clonidine or dexmedetomidine as an adjuvant to isobaric ropivacaine in patients undergoing surgeries of the lower limb. The analysis revealed a statistically significant difference amongst group R and D and group R and C. These values were also significantly different between group D and group C (P <0.05). Duration of sensory blockade was prolonged in group D when compared to group C.

There is a notable prolongation in the motor blockade duration in group RD with 247.53 ± 13.48 minutes when compared to group RN i.e. 133.07 ± 11.72 minutes. These results correlate with study done by Gupta *et al*[11] where they noted that dexmedetomidine when given intrathecally is linked with increased duration of sensory and motor block.

Eid Hea *et al*[12]observed that dexmedetomidine when administered intrathecally in two separate doses (10µg and 15µg) prolonged the analgesic and anaesthetic effects of intrathecal bupivacaine significantly in a dose-dependent approach. Shukla *et al*[13] conducted a study to evaluate the addition of 10µg dexmedetomidine(D) and 50mg magnesium sulphate(M) to 15mg hyperbaric bupivacaine and recorded the time of onset to reach peak motor and sensory level, the duration of regression for motor and sensory block, hemodynamic changes and side effects. They found that there is faster onset of anesthesia with increased analgesic duration in the group which was administered dexmedetomidine. Both these studies are in agreement with our study.

Visual Analogue Score between group RD and RN was significant during the observation period between 120 minutes to 540 minutes The score was much lower in group RD at the predetermined intervals of time showing better post-operative analgesia in Dexmeditomidine group. (P < 0.05) Our findings corresponded with the study conducted by Gupta *et al*[11] and they demonstrated that the pain score (VAS) was significantly reduced in Dexmeditomidine group in comparison to Fentanyl. Mehmooda *et al*(8) studied the addition of 10µg Dexmeditomidine to 3.5ml of hyperbaric bupivacaine where they concluded that the VAS score was low significantly in the Dexmeditomidine group during the time interval of 4 hours to 16 hours compared to the group which received plain bupivacaine.

The patients belonging to the dexmedetomidine group (RD) have scored sedation scores which were higher when compared to the group which received only ropivacaine (RN). The sedative effects for dexmedetomidine group of patients was quite notable and significant. This was in concurrence with the study done by Arati *et al*[14]where they observed that there was Grade lll sedation in Group D patients and Grade l and ll sedation in Group R patients. Dexmedetomidine produced better quality of sedation.

The incidence of shivering in Group RN was 43.4% and in Group RD was 16.7% which was significant statistically in the two groups (p<0.05). This had concordance with the study done by Eid Hea *et al*[12]where he evaluated and compared the efficacy of intrathecal administration of dexmedetomidine on the motor and sensory blockade characteristic and postoperative analgesic properties in 48 patients. They observed that the incidence of shivering was much lesser in the Dexmeditomidine groups when compared to the bupivacaine group. Our study had findings contrary to study done by Dolma *et al*[15] where they compared the of addition of dexmedetomidine to 0.75% isobaric ropivacaine for fracture neck of femur surgery where they reported that the side effects like shivering, vomiting, nausea were equally noted with similar occurrence in the two groups.

CONCLUSION

The addition of Dexmedetomidine 5µg intrathecally to 0.75 % isobaric ropivacaine seems to be a superior adjuvant with an increased duration of motor and sensory blockade and an increased post-operative analgesic duration with a negligible side effect profile.

Limitations

1. The study sample was small to extrapolate and draw further conclusive evidence.
2. Cost effectiveness of the study was not performed.
3. Only ASA Grade I and II patients were included.

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