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Comparison of Intraoperative and Post-Operative Outcome between Intrathecal Ropivacaine and Ropivacaine with Dexmedetomidine for Lower Limb Surgeries

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Abstract: ***Use of intrathecal adjuvant such as Dexmedetomidine has gained popularity with the aim of prolonging the duration of block, provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects. The aim and objective of the study was to compare the hemodynamic, sensory, and analgesic potentiating effects of intrathecally administered dexmedetomidine when combined with ropivacaine. Materials and Methods: prospective randomized double blind study, 60patients of ASA I and II in the age groups of18-60 years of either sex under going lower limb surgeries .The patients were randomly allocated into two groups of 30 (Group A)each to receive intrathecally with 3cc of 0.5%Ropivacaine with 0.5ml sterile water and (Group B)3ccof 0.5%Ropivacaine with 5µg of Dexmedetomidine in 0.5ml sterile water. The hemodynamic changes time of onset and duration of sensory blockade, time of first analgesic request postoperatively were recorded.Results: The demographic profile of patients was comparable in both the groups.Patients in Group B had a significantly longer sensory block than patients with in Group A. The mean time of sensory regression to S2 was (323±31 min) in Group B and (191±15 min) in Group A. The time for rescue analgesia was significantly longer in Group B (376.37±20.60min) as compared to Group A (210.8±16.83MIN). Conclusion: Dexmedetomidine as an adjuvant to Ropivacaine is associated with prolonged sensory, hemodynamic stability, prolonged postoperative analgesia.***

Keywords: Dexmedetomidine, Ropivacaine, Intrathecal, Lower limb

1. Introduction

Neuraxial blockade (spinal or epidural) is the preferred mode of anesthesia for lower limb surgeries.

Spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection as from catheter in situ, less failure rates and cost-effectiveness, but has the drawbacks of shorter duration of block and lack of postoperative analgesia.

Ropivacaine is a longacting regional anesthetic that is structurally related to bupivacaine. It is a S(−) enantiomer, unlike bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles[1].

Ropivacaine is a better substitute to bupivacaine for day care procedure since it is less cardiotoxic, exhibits lesser degree of motor blockade, shows quicker recovery and lesser degree of hemodynamic disturbance.

Various neuraxial adjuvants have been used intrathecally like clonidine,fentanyl,morphine to improve the quality and duration of the spinal anesthesia along with better postoperative analgesia. The most commonly used agents have been opioids, such as morphine, fentanyl. However addition of opioids has been associated with undesirable side effects like respiratory depression, pruritis, nausea and vomiting.

Dexmedetomidine, is a novel and highly selective α-2 adrenoceptor agonist, having antinociceptive action for both somatic and visceral pain.It is under evaluation as a neuraxial adjuvant as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects.

It reduces blood pressure and heart rate dose dependently and sedative effects.It reduces opioids and inhalational anesthetic requirements [2].

2. Aims and Objectives

To assess the analgesic and hemodynamic effects of intrathecal administration of ropivacaine with dexmedetomidine in elective lower limb surgeries

3. Materials and Methods

The study was carried out in the department of Anesthesiology, Father Muller medical college, Mangalore as a randomized prospective double blinded study of 60 patients from September 2015 to December 2016.

Sixty patients aged between 18 years and 60 years of physical status ASA grade 1 and ASA grade 2 who fulfilled the inclusion and exclusion criteria undergoing lower limb surgeries under spinal anesthesia lasting more than 30 minutes were included in the study after ethical clearance from the college ethical committee. Each patient was visited

preoperatively and the procedure explained and written and informed consent obtained.
Based on previous studies and statistical formula with simple random sampling technique, they were allocated into 2 groups of 30 patients each by a computer generated randomization table to receive the study drugs as follows:

Group A (n=30):3cc of 0.5%Ropivacaine with 0.5ml sterile water to a total volume of 3.5ml

Group B(n=30): 3cc of 0.5%Ropivacaine with 5µg of Dexmedetomidine made upto 0.5ml and added to above solution and total volume made to 3.5ml.

Each patient was visited preoperatively and the procedure explained and written and informed consent was obtained.

All the routine investigations required for pre-operative evaluation and the proposed surgery was done. All the patients were premedicated with tablet Ranitidine 150 mg and T.Diazepam 10 mg overnight of surgery. Patients were allowed for a period of absolute fasting of at least 8 hours.

On arrival in the operating room, intravenous line was secured with 18gor 20g intravenous cannula and patients were preloaded with lactate ringer's solution at 15ml/kg. Monitoring was done using automated multiparameter monitor. Vitals like, heart rate, non-invasive blood pressure, SPO2 was recorded.

The initial basal vital parameters were recorded before proceeding to sub-arachnoid block.

Under aseptic and antiseptic precaution, lumbar puncture was performed at L 3- 4 intervertebral space using midline approach with a 23G Quincke spinal needle in the sitting position and either of the study drugs was administered intrathecally using the randomization table. The study solution was prepared by a colleague not involved in the study to achieve blinding. After confirming free flow of CSF,the drugs were administered according to groups of 30 patients each as follows:

Group A (n=30):3cc of 0.5%Ropivacaine + inj. normal saline 0.5 ml

Group B(n=30): 3cc of 0.5%Ropivacaine + 5µg of Dexmedetomidine (0.5ml)

Immediately after completion of the block, patients were made to lie supine.

Oxygen was administrated through a mask if the pulse oximetry reading decreased below 90%. Hypotension defined as a decrease in systolic blood pressure by more than 30% from baseline or less than 80 mm Hg was treated with incremental intravenous doses of 6 mg of mephentermine and further intravenous fluid as required. Bradycardia defined as heart rate less than 50 beats per minute was treated with intravenous atropine 0.6 mg. Sensory testing was assessed by loss of sensation to pinprick with 23 G hypodermic needle.

The time of onset of sensory block,highest level of sensory block and duration of sensory block were recorded. Dermatomal levels were tested every 2 minutes until the highest level had stabilized for 4 consecutive tests.Testing was then done every 10 minutes thereafter until the two segment regression of the block occur.

Further testing was performed at 20 minutes intervals until recovery of S2 dermatome which was considered as duration of sensory block.

Patient's anxiety and sedation level was evaluated by Modified Ramsay Sedation Score as follows:

1. Patient is anxious, agitated or restless.
2. Patient is co-operative, oriented and tranquil alert.
3. Patient responds to Commands.
4. Asleep, but brisk response to light glabellar tap or loud auditory stimulus.
5. Sluggish response to light glabellar tap or loud auditory stimulus.
6. No response.

Postoperatively, pain scores was recorded by using Visual Analogue pain scale (VAS) between 0-10 (0= no pain, 10= the most severe pain), initially every 1 hour for 2 hours, every 2 hours for next 8 hours and then after every 4 hours till 24 hours.

Duration of analgesia was recorded when VAS >4 and was given injection Diclofenac 75mg IM as rescue analgesic.

4. Statistical Methods

Variables such as ASA status,sex,postoperative analgesia requirement and adverse effects were compared between groups by using chi square test. Parametric data were reported as mean ± standard deviation and analyzed by using student t-test. The comparison was studied using chi-square test or fischers exact test as appropriate.$p< 0.05$ was considered statistically significant.

5. Results

The groups were comparable with respect to demographic characteristics (Table 1).

Table 1: Demographic Data

Variable	Group A	Group B	P value
Age (Yrs.)	40.4±4.73	41.27±5.54	0.51
Sex (M/F)	22:08	18:12	0.273
Wt.	52.83±6.8	54.13±7.34	0.475
Mean Duration of Surgery	81.88±11.11	80.75±10.59	>0.05
ASA status 1/2	17/13	16/14	>0.05

There was no difference in onset of sensory block upto T10 dermatome in both groups. It was 3.53±1.1 in Group B and 3.60±1.2 min in Group A.there was no such significant difference between Group A and Group B in the highest level of block achieved and the time taken to reach highest level.

Two segment block regression was significantly slower with Group B(122.33±16.2 min) as compared to Group A(86.24±9.2 min) (p<0.001)
Time to two segment regression were significantly slower with Group B (p<0.001)

The duration of analgesia was376.37±20.60 min in Group B and 210.8±16.83 min in Group A. The difference was statistically significant p<0.001 (Table 2)

Table 2: Summary of Results

Variable	Group A	Group B	P value
Onset of sensory block (min)	3.60±1.2	3.53±1.1	>0.05
Time to highest sensory level (min)	11.4±1.48	11.2±1.62	>0.05
Time for two segment regression (min)	86.24±9.2	122.33±16.3	<0.001
Duration of sensory block (min)	202±30.11	336.17±40.81	<0.001
Time to first rescue analgesic (min)	210.8±16.83	376.37±20.60	<0.001

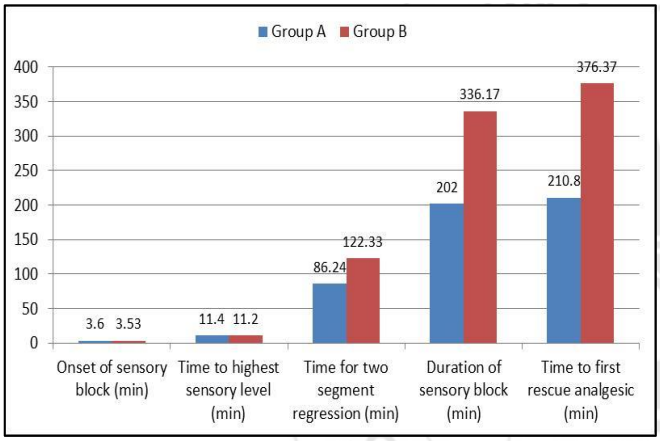

Chart 1: Graphical representation of Results

Side effects such as bradycardia, nausea and vomiting were not significant between the two groups and there was no neurological deficit (Table 3).

Table 3: Side Effects

	Group A	Group B	P value
Sedation	0	0	>0.05
Nausea	2	1	>0.05
Vomiting	3	2	>0.05
Hypotension	6	7	>0.05

6. Discussion

Various adjuvants have been tried with local anesthetics for sub arachnoid blockade. Dexmedetomidine, a selective α-2 adrenoreceptor agonistis highly specific with α-2:α-1 binding selectivity ratio of 1620:1.Thus decreasing unwanted side effects of α-1 receptors. Although it was first used as an intravenous sedative, it has been investigated as an anxiolytic,sympatholytic and analgesic properties related toα-2 adrenoreceptor binding [3].

It reduces opioid and inhalational anesthetic requirements, Intrathecal α-2 receptor agonists are found to have anti nociceptive action for both somatic and visceral pain

RajniGupta et al.[2] used intrathecal dexmedetomidine as an adjuvant and found it to be an attractive alternative as an adjuvant to spinal ropivacaine in surgical procedures, especially those requiring long time. It has excellent quality of postoperative analgesia with minimal side effects.

Al-Ghanem et al. in their study suggested that 5 mcg of dexmedetomidne seemed to be an attractive alternate as an adjuvant to spinal bupivacaine in surgical procedures [4].

Sarabijit Kaur et al. concluded that dexmedetomidine group was better as regards to prolonged duration of sensory block, postoperative analgesia with reduced doses of rescue analgesic required and better patient satisfaction score when used as an adjuvant to intrathecal local anesthetics[5].

Nalini A et al. found that on a comparative study between intrathecal ropivacaine and bupivacaine that due to shorter duration of motor blockade, with similar duration of sensory blockade, haemodynamics and height of blockade 0.5% isobaric ropivacaine is a better choice for ambulatory anesthesia[6].

Naithani Udita et al. assessed dose dependent effect of dexmedetomidine (3 mcg vs 5 mcg) as an adjunct to isobaric ropivacaine in spinal anesthesia[7]. They found third of their cases required analgesic supplementation. Both doses of dexmedetomidine produced a similar effect on block characteristic and postoperative analgesia; however, a dose of 5 mcg dose was associated with more hypotension and sedation.

In a study by Atul Kumar Singh (2012-2014), they evaluated the efficacy of two different doses of dexmedetomidine as an adjuvant to isobaric ropivacaine, intrathecally[8]. Time to achieve desired block was least in with Dexmedetomidine of 5µg and maximum in group Dexmedetomidine of 10µg. The sensory-motor blockade remained significantly prolonged in later group with Dexmedetomidine of 10µg.

In our study,we found out that the addition of 5mcg of dexmedetomidine intrathecally prolonged the sensory blockade with minimal side effects in patients undergoing lower limb surgeries and also provides excellent quality of postoperative analgesia with good hemodynamics

7. Conclusion

In conclusion, Demedetomidine 5 mcg as an adjunct to Ropivacaine is more superior to ropivacaine alone by shortening the onset time and prolonging the duration of effective analgesia thus reducing the requirement of rescue analgesia without affecting other parameters and complications of sub arachnoid blockade.

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