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Original Research Paper

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STUDY OF DEXMEDITOMIDINE AS AN ADJUVANT TO ISOBARIC ROPIVACAINE FOR POST OPERATIVE ANALGESIA IN LOWER ABDOMINAL AND LOWER LIMB ORTHOPEDIC SURGERIES.

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ABSTRACT

Background: Knowledge and use of adjuvant drug has rendered neuraxial analgesia more effective in the management of both acute and chronic pain. -2 agonists have both analgesic and sedative properties when used as adjuvant in regional anaesthesia.

Aim: To study the effects of intrathecal dexmedetomidine added to isobaric ropivacaine for surgeries under spinal anesthesia.

Materials And Methods: A prospective, randomized, double blind study was conducted on 50 patients of American society of Anaesthesiologists physical status I,II , aged between 18 to 60 years, weighing between 50 to 120 kg posted for lower limb orthopedic and lower abdominal surgeries under spinal anaesthesia.The patients were randomly allocated into two groups of 25 each to receive either 3 ml of inj Ropivacaine 0.75% with Inj.dexmeditomidine (5 μg) 0.05 ml in group RD or 3 ml of inj. Ropivacaine 0.75% with Normal saline 0.9%, 0.05 ml in group RN. The onset time of sensory block and motor block, duration of surgery,total duration of sensory and motor blockade and duration of post-operative analgesia, visual analog scale score, vital parameters, and adverse effects compared between these two groups.

Results: The mean duration of surgery in group RN was (89.40 ± 14.74 min) and in group RD was (95.40 ± 19.31 min),The mean onset time of complete sensory and motor bock in group RN was longer (4.66 ± 0.59 min and 10.01 ± 1.83 min) compared to group RD (4.08± 0.59 min and 8.27 ± 1.19 min),total duration of sensory and motor block in group RN was shorter (109.36 ± 11.41 min and 300.8 ± 29.28 min) as compared to group RD (125.24 ± 15.90 min and 329.6 ± 26.05 min),The mean duration of analgesia was longer in group RD(426.80 ± 27.19 min) as compared to group in RN (400.80 ± 37.18 min).All results were statistically significant ($P < 0.001$). Pulse rate in all the patients was maintained in normal range during the observation period. Mean pulse rate was 76.53±42.69/min in group RN and 76.92±3.28/min in group RD. Average mean systolic and diastolic pressure were 119.70 ± 4.13; 78.25±3.1 mm Hg in group RN and 119.60±5.20; 77.79±3.39 mmHg in group RD.No significant side effects were observed in any of the two groups.Shivering is observed in one patient of group RN.Nausea and vomiting were observed in two different patient of group RD.

Conclusion: To conclude, 5 microgram dexmedetomidine seems to be an attractive alternative as an adjuvant to spinal ropivacaine in surgical procedures, especially those requiring long time. This combination (ropivacaine and dexmedetomidine) provides very good quality of haemodynamic stability. It has excellent quality of postoperative analgesia with minimal sideeffects.

KEYWORDS : Analgesia, Dexmedetomidine,Ropivacaine,Subarachnoid block.

INTRODUCTION

Postoperative pain is considered a form of acute pain due to surgical trauma with an inflammatory reaction and initiation of an afferent neuronal barrage.

Postoperative pain is both distressing and detrimental for the patient. The pain causes the patient to remain immobile, thus becoming vulnerable to DVT, pulmonary atelectasis , muscle wasting and urinary retention.[1]

Since the introduction of spinal anaesthesia by **BIER IN 1898**, it's widely used regional anaesthetic technique for lower abdominal, lower limb orthopedic and gynaecological surgeries. The ensuing nerve block ensures the patient's well being, while motor block facilitates the surgeon's work. It also provides good analgesia in immediate post operative period.

The **ROPIVACAINE,** a new amide local anaesthetic(LA) with similar LA properties as **BUPIVACAINE**, is the first single-enantiomer LA to be produced commercially. Animal studies have demonstrated that intrathecal **ROPIVACAINE** has little effect on spinal cord blood flow and produces similar sensory block as an equivalent dose of **BUPIVACAINE,** with reduced degree of motor block.

The low lipid solubility of **ROPIVACAINE** leads to greater sensory-motor differentiation by blocking sensory nerve fibres more readily than motor fibres. Early recovery of motor function is associated with decreased incidence of venous thrombo embolism and shorter hospitalization.[2-3]

DEXMEDETOMIDINE is highly selective α2- **agonist.** More potent and faster than **CLONIDINE.** It has analgesic, sedative, antihypertensive, and anaesthetic-sparing effects and have been widely used for ICU sedation with hemodynamic stability. Intrathecal α2 agonists have antinociceptive action for both somatic and visceral pain.[4]

The aim of our study was to evaluate and compare the effect of Dexmedetomidine as an adjuvant to isobaric ropivacaine 0.75% and Inj. Ropivacaine 0.75% alone in subarachnoid block on the duration of analgesia,onset times and durations of sensory and motor block and patient's satisfaction.

MATERIALS AND METHODS

After approval of the institutional ethical committee, this prospective, double-blind, randomized trial was conducted on 50 patients of the ASA grade I and II of both genders, aged 18–60 years, scheduled for lower limb orthopedic and lower abdominal surgeries after obtaining written informed consent from each patient. Patients with negative consent, coagulopathy, infection at site of block, preexisting peripheral neuromuscular disease and allergy to any study drugs were excluded.

The patients were randomly allocated into two groups of 25 each . Group RD received 3 ml Ropivacaine 0.75% with

dexmedetomidine (5 μg) 0.05 ml and group RN received 3 ml Ropivacaine 0.75% with Normal saline(NS) 0.9%, 0.05 ml. A resident anesthesiologist, who wasn't involved in the study, prepared the syringes loaded with drugs for block and another anesthesiologist who performed the block and observed the patient thereafter was unaware of the contents of the loaded syringes for double blinding.

Method Of Study

Pre anaesthetic assessment was done with detailed history, general and systemic examination, airway assessment, spinal column examination.

One Day Before Surgery:

Details of study process including potential side effects and visual analogue scale(VAS) were explained to all patients and relatives.

The investigations were done in all patients of Haemoglobin, Urine analysis, Blood sugar, Blood urea, Serum creatinine, Coagulation profile, Blood grouping and Rh typing. ECG and chest x-ray for patients over 40 years of age.

Patient was shifted to the OT table,18-20G IV access was obtained on the fore arm and co-loaded with ringer lactate solution 10 ml/kg. The monitors connected to the patient included NIBP, ECG, and pulse oximetry. Under strict aseptic precautions lumbar puncture was performed with disposable Quincke's spinal needle (25G) in L3-L4 space. If spinal block failed at L3-L4, we changed the level to L2-L3.In case of failure at both levels the procedure was abandoned, general anaesthesia was administered and excluded from the study. Patients were monitored continuously. Fluid therapy was maintained with. ringer lactate infused according to hemodynamic volume status. HR, NIBP, SPO2, RR, ECG were recorded at 0, 2,5,10,15,30,45,60,75,90,105,120,150,180 min intraoperatively. Pain was assessed by VAS for every 4 hours till 24 hours post-operatively. Inj. Tramadol 2 mg/kg iv (max 100 mg) was given as a rescue analgesic when VAS score was ≥ to 4 (**Figure – 1**).

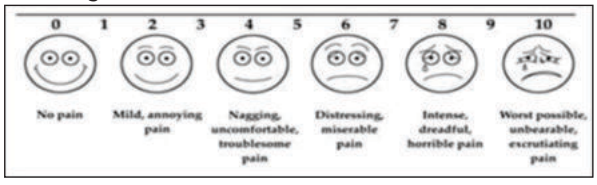

Figure 1: VAS Scale

RESULTS

Those patients were administered either 3 ml ropivacaine and 5 μg dexmedetomidine in group RD or 3 ml ropivacaine and 0.05 ml 0.9% NS intrathecally by subarachnoid block. The mean age of patients was 33.04±10.14 years in group RN and 36.44±10.34 years in group RD. Table - 1 shows all demographic data are insignificant.

Table 1: Demographic Data

Variable	Groups			
	RN		RD	
	Mean	SD	Mean	SD
Age(years)	33.04	10.14	36.44	10.34
Weight(kgs)	55.64	4.63	54.8	4.44
Gender(M/F)	20/5		19/6	

Table 2: Duration Of Surgery And Asa Grade

Variables	Groups			
	RN		RD	
	Mean	SD	Mean	SD
Total duration of surgery(min)	89.40	14.74	95.4	19.31
ASA Grade				
I (30%) ,n=15	8		7	
II (70%),n=35	17		18	

Table 2 shows the average duration of surgery was 89.40 ±14.74 min and 95.4±19.31 min in group RN and RD respectivelly. 30% (n= 15) of subjects belonged to ASA I and 70% (n=35) subjects belonged to ASA II.

Table 3: Variables

Groups	RN		RD	
Variables	Mean	SD	Mean	SD
Sensory block onset time(min)	4.66	0.59	4.08	0.56
Motor block onset time(min)	10.01	1.83	8.27	1.19
Total duration of sensory block(min)	109.36	11.41	125.24	15.90
Total duration of motor block(min)	300.8	29.28	329.6	26.05
Total duration of analgesia(min)	400.8	37.18	426.80	27.19

Table 3 shows the mean onset time of Sensory and motor block was 4.66±0.59 and 10.01±1.83 minutes in group RN and 4.08±0.56 and 8.27±1.19 minutes in group RD.Total duration of sensory and motor blockadge in group RN were 109.36±11.41 and 300.8±29.28 minutes respectively and in group RD were 125.24±15.90 and 329.60±26.05 minutes respectively.Total duration of analgesia was 400.8±37.18 minutes in group RN and 426.8±27.19 minutes in group RD.

Table 4:Vitals

Groups	RN		RD	
Variables	Mean	SD	Mean	SD
HR/min	76.53	2.69	76.92	3.28
SBP mmHg	119.70	4.13	119.60	5.20
DBP mmHg	78.25	3.10	77.79	3.39

Table 4 shows mean pulse rate was 76.53 ± 42.69/min in group RN and 76.92±3.28/min in group RD.Mean systolic and diastolic pressure were 119.70 ± 4.13; 78.25±3.1 mm Hg in group RN and 119.60±5.20; 77.79±3.39 mmHg in group RD. Shivering was observed in one patient of group RN and nausea and vomiting were observed in two different patients of group RD.

Table 5 : VAS Score In Group RN

	VAS 0	VAS 1	VAS 2	VAS 3	VAS 4
8 hrs	15	10	0	0	0
12 hrs	4	14	7	0	0
16 hrs	0	3	15	7	0
20 hrs	0	0	4	17	4
24 hrs	0	0	0	11	14

Table 5 shows VAS score in group RN (number of patients) observed 4 hourly till 24 hours.

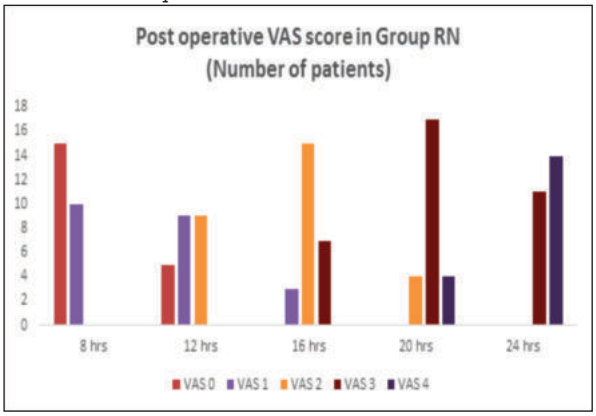

Chart 1: VAS Score In Group RN

Table 6 : VAS Score In Group RD

	VAS 0	VAS 1	VAS 2	VAS 3	VAS 4
8 hrs	25	0	0	0	0
12 hrs	18	6	1	0	0
16 hrs	0	15	9	1	0
20 hrs	0	4	13	7	1
24 hrs	0	0	7	14	4

Table 6 shows VAS score in group RD (number of patients) observed 4 hourly till 24 hours.

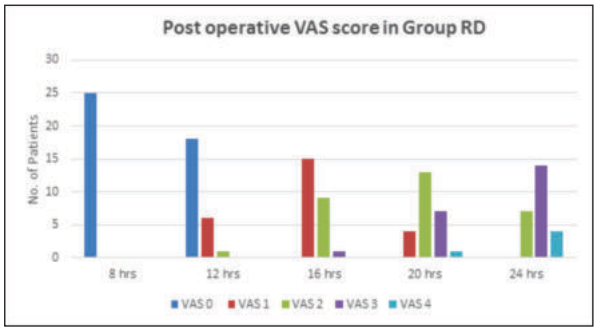

Chart 2: VAS Score In GROUP RD

The mean total duration of post-operative analgesia was shorter in **Group RN(400.8 min)** compared to **Group RD(426.8 min)**.The difference was **statistically highly significant (P<0.001).**The study reveals that duration of postoperative analgesia was longer and need of rescue analgesic was less in case of **Group RD** as compared to **Group RN.**

Post operative rescue analgesia is given when patient complained of pain at operative site for the first time, VAS ≥ 4 with Inj. Tramadol 2mg/kg intravenously.

DISCUSSION

In our study all demographic parameters are insignificant (**Table – 1**). Onset of sensory block is the time lapse between drug administration and loss of pin prick at T10 dermatome tested by hypodermic needle. Onset of motor block is the time lapse between drug administration and attainment of Bromage 3 scale.

In our study the mean onset time of complete sensory and motor bock in group RN was longer (4.66 ± 0.59 min and 10.01 ± 1.83 min) compared to group RD (4.08 ± 0.59 min and 8.27 ± 1.19 min)(**Table - 3**).

TAILAM TANMAYEE, P. RAGHUNATH, D. ANURADHA[4] in **2017** studied on 50 patient divided into two groups: group 1 (n=25) received 3 ml 7.5 mg/ml **ROPIVACAINE** with 0.05 ml 0.9% NS and group 2 (n=25) received 3 ml 7.5 mg/ml **ROPIVACAINE** with 5 μg **DEXMEDITOMIDINE** intrathecally in lower abdominal and lower limb orthopaedic surgery. They found mean time of onset of sensory block was 4.12 ± 1.69 min and mean time of onset of motor block was 10.12 ± 2.89 min.

MCNAMEE et al.[5] in **2001** studied on 104 patients divided into two groups: group 1 (n=51) received 2.5 ml 7.5 mg/ml and group 2(n=53) received 2.5 ml 10 mg/ml intrathecal **ISOBARIC ROPIVACAINE** for total hip arthroplasty and demonstrated lower degree of motor block with 7.5 mg/ml compared to 10 mg/ml. The mean time for onset of sensory block at T10 dermatome was 2 min(range 1-25 min) in group 1 and 2 min (range 1-21 min) in group 2.

In our study total duration of sensory and motor block in group RN was shorter (109.36 ± 11.41 min and 300.8 ± 29.28 min) as compared to group RD (125.24 ± 15.90 min and 329.6 ± 26.05 min)(Table 3).Total duration of sensory block was assessed by time period from end of peak sensory level to pin prick at T10 and motor block was the time from unable to move feet and knees to just able to move feet only.

TAILAM TANMAYEE et. Al.[4] in **2017** studied on 50 patients divided into two groups: group 1(n=25) received 3 ml 7.5 mg/ml **ROPIVACAINE** with 0.05 ml 0.9% NS and group 2(n=25) received 3 ml 7.5 mg/ml **ROPIVACAINE** with 5 μg **DEXMEDITOMIDINE** in lower abdominal and lower limb orthopaedic surgery. They found mean duration of surgery was 94.4 min ± 34.4 min, mean total duration of sensory and motor block was 128.4 ± 15.7 min and 350 ± 50.4 min respectively.

SHAH A, ILA PATEL et al. [7]conducted study of 50 patients of ASA grade I,II undergoing lower limb and lower abdominal surgery. Mean time to achieve maximum sensory block was 11.7±1.7 min and mean time for total duration of sensory block was 125.6±16.5 similar to our study.

DHASMANA SATISH, SINGH VINITA et.al[6] studied on 50 patients of ASA grade I, II or III with intrathecal **ROPIVACAINE** 7.5 mg with **DEXMEDETOMIDINE** 5 g versus **ROPIVACAINE** 7.5mg with **CLONIDINE** 15 μg in TURP. The study showed mean total duration of sensory and motor block was 133.40 ± 14.20 min and 231±18 min respectively which is lower than our findings.This may be explained by the fact that they used lower dose of ropivacaine.

In our study mean total duration of post operative analgesia was longer in group RD (426.80 ± 27.19 min) as compared to in RN (400.80 ± 37.18 min)(Table 3).This was assessed from onset of sensory block to first rescue analgesic requested by the patient at VAS ≥ 4.

TAILAM TANMAYEE et.al[4]**,2017** studied on 50 patients. They found the mean total duration of post-operative analgesia was 400 ± 58 min.

NITISH KUMAR PARMAR, et. al, 2014 [8]conducted study on **120** female patients underwent vaginal hysterectomy under SA, were randomly allocated to receive either 3 ml 0.75% isobaric **ROPIVACAINE** + 0.5 ml NS(group R) or 3 ml 0.75% **ISOBARIC ROPIVACAINE**+ 5 μg **DEXMEDITOMIDINE** in 0.5 ml NS(group D).The total duration of analgesia was significantly prolonged with the addition of **DEXMEDETOMIDINE** as compared to **ROPIVACAINE** alone (370±38.75 min and 174.77±22.31 min) respectively.

SHAH A, ILA PATEL et al. [7]conducted study of 50 patients of ASA grade 1 and 2 undergoing lower limb and lower abdominal surgery.They found that the analgesic effect of **ROPIVACAINE** was potentiated by intrathecal **DEXMEDETOMIDINE**. The addition of 5 μg of intrathecal **DEXMEDETOMIDINE** prolonged the postoperative analgesic effect of **ROPIVACAINE** by approximately 8 hours which co related well with our findings.

COMPLICATIONS AND SIDE EFFECTS:

There was no incidence of headache,hypotension, bradycardia. There was no CNS and CVS toxicity seen in any group in our study.

Post-operative shivering in 1 patient of group RD was noted.

CONCLUSION

Based on the present clinical comparative study and a short review of past literature, I conclude that dexmedetomidine as an adjuvant to ropivacaine compared to ropivacaine alone in subarachnoid block for lower limb orthopaedic and lower abdominal surgery fastens the onset time for sensory & motor block and prolongs the duration of sensory & motor blocks with longer duration of postoperative analgesia, causes

decrease in need of rescue analgesic with no significant side effects.The intrathecal dexmedetomidine with ropivacaine has been shown to be a better drug in terms of cardiovascular and hemodynamic stability.

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