ORIGINAL RESEARCH PAPER

Anaesthesiology

Dexmeditomedine as spinal adjuvant with Ropivacane 0.75% in lower limb and lower abdominal surgeries for post-operative analgesia.

KEY WORDS: Dexmedetomidine, Ropivacaine, spinal anesthesia.

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ABSTRACT

Aim: To evaluate the efficacy of Dexmeditomedine as spinal adjuvant with Ropivacane 0.75% in lower limb and lower abdominal surgeries for post-operative analgesia.

Methods: Sixty patients undergoing elective abdominal and lower limb surgery of ASA grade I and II, between the age group 18 to 50 were included in the study. All patients were given spinal anaesthesia and were randomly divide into two groups . Group R- patients receiving 3ml of 0.75% isobaric Ropivacaine

Group D patient receiving 3 ml of 0.75% isobaric Ropivacaine plus 5 microgram preservative free Dexmeditomedine.

All Patients in both groups were assessed for sensory block (onset, extent, regression and duration of block), motor block (onset, degree and duration using modified Bromage scale,) and monitored for hemodynamic .

Results: The total duration of post operative analgesia in group R was 241.23 ± 55.98 minutes, while it was 481.9 ± 38.891 minutes in group D. Statistically significant difference was found in this respect in both the groups and group D having longer duration of post - operative analgesia (p -value <0.0001) than group R..

Conclusion : 5 mcg Dexmeditomedine effective and safe adjuvant to spinal Ropivacaine in surgical procedure requiring longer duration.

INTRODUCTION

since the introduction of spinal anasesthesia in 1898 by Dr. August Bier, who described the intrathecal administration cocaine1, spinal anasesthesia is preferred over general anasesthesia, particularly in surgical producers of lower abdomen and lower limbs[2].

Ropivacaine produces a greater degree of differential block at low concentration and a property of producing frequency dependent block offers considerable clinical advantage in providing analgesia with minimum motor blockade.[3]

Ropivacaine is long anaesthetic with high pka and low lipid solubility, and it is considered to block sensory nerves to greater extent than mother nervers.[5] Ropivacaine is less cardiotoxic and neurotoxic than bupivacaine[6].

The use of intrathecal Ropivacaine does not affect the spinal cord blood flow hence it does not produce neurotoxic effects.[7] An isobaric solution has slower onset of action than a hyperbaric one of equal volume, but a more extensive motor block.8The duration of anaesthesia is related to concentration of the drug used and hence the action is dose- dependent.9 Ropivacaine is available in different concentrations such as 0.2%, 0.5%, 0.75% and 1%.

Our concern is using Dexmeditomedine as an adjuvant with Ropivacaine which Provides better intra operative hemodynamic, condition as well as prolonged post operative analgesia with minimal side effects Dexmeditiomedine is a highly selective a2 adrenergic agonist which has been used for premedication and as a adjuvant to general anesthesia. It reduces upload and inhalational anesthetic requirement. Interathecal alpha2 agonist are found to have antinociceptive action both somatic and visceral pain.

Our study describes the use of intrathecal Dexmeditomedine with Ropivacaine in lower limb and lower abdominal surgeries. The purpose of this study is to compare intrathecal isobaric Ropivacaine with combination of isobaric Ropivacaine with Dxmeditomedine to study two segment regression of spinal blockade and duration of analgesia which is defined as the time from intrathecal administration of Dexmeditomedine to first request for supplemental analgesia by patient. Post operative cumulative analgesic consumption and maximum visual analogue scale (VAS) of pain score have been evaluated as secondary outcome)

MATERIAL AND METHODS

Study was carried out sixty patients aged 18 to 50 yrs (BMI<35), both male and female, of ASA grade I and II posted for lower limb and lower abdominal surgeries.

Patients were randomized in 2 groups with 30 patients in each. After approval from hospital ethics committee, informed consent was taken from patients for the procedure. A detailed history and thorough general and systemic examination was done and patients having respiratory, cardiovascular disease, bronchial asthma, History of allergic reactions to drug or food are excluded from study.

Detailed History was taken for Epilepsy, Hypertension, Diabetes, and tuberculosis. All routine investigations like hierogram, TLC, DLC, coagulation profile and urine examination performed prior to surgery. patients were kept NBM for 6 hours prior to the procedure. All patient received tablet diazepam 0.2mg/kg. orally the night before surgery. one arrival in the operation room patients were proeloaded with ringer lactate solution at 15 ml/ kg. All patients were monitored with automated non invasive blood pressure, pulse oximetry and electrocardiogram. Position of table was kept horizontal. Patient was given sitting position and under all aseptic precautions lumbar puncture was performed with spinal needle of either 23 or 25 gauge at L-3 L-4,or L-4, L-5 inter space. After ensuring free flow of clear cerebrospinal fluid the desired drug was injected. Patient was randomized on the basis of sealed envelop technique to received one of the following in to the

subarachnoid block.

Group R - 3ml volume of 0.75 % isobaric Ropivacaine and
Group D - 3ml volume of 0.75% isobaric ropivacaine with 5microgram dexmeditomedine.

Injection was given over approximately 10-15 second, patient was made supine. All patients were given oxygen by transparent face mask at flow rate of 5 lit/ min.

Sensory block Assessment :
Sensory level was determined by pinprick using 24 Guage hypodermin needle. Onset of analgesis was defined as time interval from completion of subarachnoide injection i.e. 'O' time to loss of pinprick sensation at knee joint (L1). Maximum sensory dematomal level was tested by pinprick in mid clavicle line every minute until the level stabilized for two consecutive tests. Afterwards sensory level was tested every 15 minutes until two - segment regression and up to complete sensory recovery to see the '' Duration of Anaesthesia'' Complete sensory recovery was defined as return of sensation of great toe (S1) Time taken to achieve maximum sensory level, two segment regression and complete sensory recovery was noted.

Following operation the patients were interrogated every 15 min for pain at operation site, systemic narcotic analgesics were not given until patient demanded analgesic for pain. Time taken from the administration of subarachnoid anesthetic drug to the time parent first demanded analgesics drug for pain was noted i.e. considered as the duration of effective analgesia.

Degree of analgesia as per BROMAGE PR-(1964) Scale was graded as
I- Required the general anesthesia for completion of surgery.
II- Pain that required addition of analgesic drug.
III- Mild discomfort but did not required systemic analysis.
IV- No Discomfort at all during the procedure.

Motor block Assessment :
The onset of motor block was defined as the time from the injection of drug in subarachnoid space till the patient was unable to raise the extended legs.

Grade -0 -No motor block.
Grade I - inability to raise the extended leg.
Grade II- Inability to flex the knee, able to flex the ankle.
Grade III- Inability to flex the ankle, complete motor block.

Recovery from motor block was recorded every 15 min. Recovery of motor block was defined as the ability of patient to flex the ankle but unable to flex knee. Duration of motor block was calculated from 'O' time up to recovery of motor block.

Analysis of data was performed using students unpaired t-test (for finding the significance of difference between means of two independent samples) chi-P value less than 0.05 was considered to be significant.

Post Operative Pain Assessment :
Post operatively pain score was recoded by using visual Analog score (VAS), between 0 and 10.

0- no pain
1,2,3 mild pain
4,5,6-moderate pain
7,8,9 -severe pain and
10 -worst pain.

initially every 1 hourly for 2 hours, than every 2 hourly for next 8 hours and then every 4 hours till 24 hours. Injection diclofinac 75mg intramuscular was given as rescue analgesia when VAS more than 4. Follow up was carried out also for post- operative headache as well as post- operative pain and dysesthessias in buttocks, thigh or lower limb.

OBSERVATION AND RESULTS

Table No.1.

DEMOGRAPHY AND BASELINE PARAMETER

Sr. No.	Parameter	Group D (n=30)	Group R (n=30)	P-value
1.	**Age (years)** 20 21-30 31-40 41-50 >50 Mean SD	3(10%) 11(36.7%) 7 (23.3%) 9 (30%) 0 33.60 9.737	5(16.7%) 11 (36.7%) 11 (36.7%) 3 (10%) 0 30.10 8.044	**0.1765**
2.	**Sex** M F	25(83.3) 5 (16.7)	27 (90) 3 (10)	**0.7065.**
3.	**Weight (kgs)** Mean SD	64.93 5.977	65.83 5.173	**0.5353**
4.	**Height (cm)** Mean SD	162.0 6.481	162.1 6.033	**0.9345**
5.	**ASA grades** I II	22(73.33%) 8 (26.7%)	22 (73.3%) 8 (26.7%)	**1.0000**

The average age in Ropivacaine 0.75% group was 30.10 ±8.044 years and that in ropivacanine 0.75% with Dexmeditomedine group was 33.60 ±9.737 years. Both the groups were comparable with respect to mean age and no statistically significant difference was found (P value 0.1345) All patients included in the study ranged between 18-50 years of age: howerer, both the groups were comparable with respect to age groups with no statistical significance.

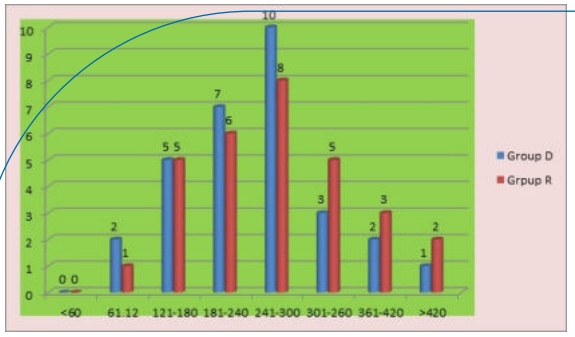
Three were 27 (90%) male and 3(10%) female patients in Ropivacaine 0.75% group and in Ropivacaine 0.75% with Dexmeditomedine group 25 (83.3%) were weight in Ropivacaine 0.75% group was 65.83 ±5.173 kg and that in Ropivacaine 0.75% with Dexmeditomedine group was 64.93 ±5.977 kg. both the groups were comparable with but no statistically signification difference was found (P value -0.5353) The mean height in Ropivacaine 0.75% group Dexmeditomedine group was 162.0 ±6.481 cm. both the groups were comparable with respect to mean height and no statistically signification difference was found (P value 0.9345).

TABLE NO.2 ONSET OF SENSORY BLOCK

Time (Seconds)	**Group D** (N=30)	**Group R** (N=30)	**P-Value**
<60	0(0)	0(0)	
61-120	2. (6.6)	1 (3.3)	
121-180	5 (16.6)	5 (16.6)	
181-240	7 (23.3)	6 (20)	
241-300	10 (33.3)	8 (26.6)	
301-260	3 (10)	5(16.6)	
361-420	2 (6.6)	3(10)	
>420	1 (3.3)	2(6.6)	
Mean SD	**2857.78**	**27185.2**	**0.2302**

In Ropivacine 0.75% group onset of sensory block was 241-300 seconds in 8 (26.7%) patients and in Ropivacaine 0.75% with Dexmeditomedine group it was 10 (33.3) patients hence there was no statistically significance in onset of sensory block in both the groups.

The mean onset of sensory block in Ropivacaince 0.75% group was 271 ±85.2 seconds while, it was 285 ±7.78 seconds in Ropivacaine 0.75% with Dexmeditomedine, group This difference was statistically not significant as similar onset of sensory block was found in both the groups (P-value 0.2302)



Onset of Sensory Block

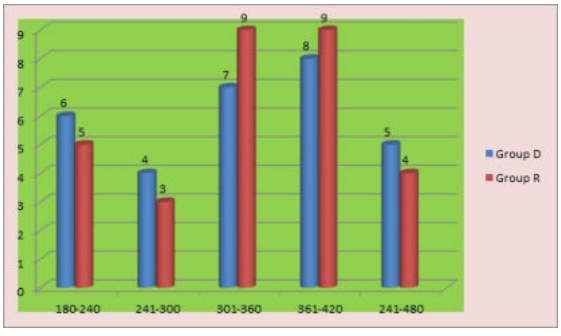
TABLE NO.3

TABLE NO.4 ONSET OF MOTOR BLCOK

Level	Group D (N=30)	Group R (N=30)	P-Value
180-240	6(20)	5(16.7)	**0.84441**
241-300	4(13.3)	3(10)	
301-360	7(23.3)	9(30)	
361-420	8(26.7)	9(30)	
241-480	5(16.7)	4(13.3)	
Mean SD	349.089.65	356.076.49	**<0.6438**

In Ropivaine 0.75% with Dexmeditomedine group, Onset of motor block was 301-420 seconds in 15 (50%) patients, while in Ropivacaine 0.75% group onset was similar 301-420 seconds in 18 (60%) patients. However, there no statistically significant difference found in both the groups.

The mean onset of motor block in Ropivacaine 0.75% with Dexmeditomedine group was 349.0



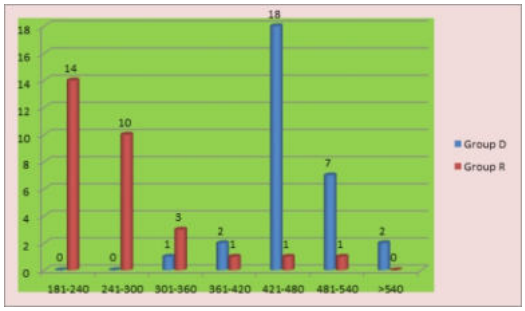
Onset of Motor Block

TABLE NO.5 TOTAL DURATION OF POST-OPERATIVE ANALGESIA

Level	Group D (N=30)	Group R (N=30)	P-Value
181-240	0(0)	14(46.6)	**<0.0001**
241-300	0(0)	10(33.3)	
301-360	1(3.3)	3(10)	
361-420	2(6.6)	1(3.3)	
421-480	18(60)	1(3.3)	
481-540	7(23.3)	1(3.3)	
>540	2(6.6)	0(0)	
Mean SD	481.938.891	241.2355.98	**<0.0001**

14 (46.6%) patients in Ropivacaine 0.75% group had total duration of post -operative analgesia for 181-240 minutes while, 10(33.3%) patients had post -operative analgesia for 241-300 minutes. In Ropivacaine 0.75% with Dexmeditomedine group, 18 (60%) patients had total duration of post- operative analgesia for 421-480 minutes while, 7(23.3%) patients had duration of post -operative analgesia for 481-540 minutes. Statistically signification difference was found in both the groups and patients in Ropivacaine 0.75% with Dexmeditomedine group were having longer duration of post -operative analgesia.

The mean total duration of post- operative analgesia in Ropivacaine 0.75% group was 241.23



Total Duration of Post -operative Analgesia

INTRA AND POST OPERATIVE COMPLICATIONS

In Ropivacaine 0.75% Group, 2(6.6%) Patients had nausea and vomiting while in Ropivacaine 0.75% with Dexmeditomedine group, 1 (3.3%) patient had nausea and vomiting, It was successfully treated with inj. Ondensetron. No statistically significant difference was found in both the groups (P value-1.000).

Shivering was reported in 1(3.3%) patient and Hypotension was reported in 2(6.6) Patients in group R While only two patients of hypotension were found, and no patient was having shivering in group D. hypotension was managed successfully with bolus of IV fluids and inj mephentermine. No statistically significant difference was found in both the groups (P value-1.000).

Bradycardia was reported in 1 (3.3%) patient in Ropivacaine 0.75% with Dexmeditomedine group, which responded well to inj. Glycopyrolate while no one patient was having bradycrdia in Ropivacaine 0.75% group.

No statistically significant difference was found in both the groups (P -value 1.000)

There was no respiratory depression and no sedation in any patients of both the groups.

SUMMARY AND CONCLUSION

A prospective, randomized, single blind study title, Dexmed itomedine as spinal adjuvant with Ropivacaine 0.75% in lower limb and lower abdominal surgeries for post- operative analgesia, was undertaken .

Sixty patients undergoing elective abdominal and lower limb surgery of ASA grade I and II, between the age group 18 to 50 were included in the study.

All patients and their relatives were explained about the procedure and an informed consent was taken for it. A detailed history of any major disease and thorough physical examination was done. All routine investigations were done. They were kept nil mouth for 6 hours before surgery. No patient was premeditated and preloading was done with 10 ml/kg body weight intravenous Ringer lactate solution. All patients were given spinal anaesthesia under all aseptic precautions. The patients were randomly divide into two groups as follows.

Group R-patients receiving 3ml of 0.75% isobaric Ropivacaine
Group D patient receiving 3 ml of 0.75% isobaric Ropivacaine plus 5 microgram preservative free Dexmeditomedine.

All Patients in the two groups were assessed for sensory block (onset, extent, regression and duration of block), motor block (onset, degree and duration using modified Bromage scale,) and monitored for hemodynamic (pulse rate and arterial blood

opressure using non- pressure using non- invasive techniques, SPO2), side effects (nausea, vomiting, purities, hypotension, bradycardia, respiratory depression) and first need analgesics in post operative periods. the results of the present study were compared with other studies. There was no difference in age, weight and height in both groups. patients of both sexes were including both groups.

CONCLUSION

After a study on Dexmeditomedine as spinal adjuvant with Ropivacaine 0.75% in lower limb and Lowe abdominal surgeries for post- operative analgesia we concluded that,

1. There was no difference in onset of sensory and motor blockade in both the groups.
2. Maximum cephalic spread and time required to achieve highest deratomal level of sensory blockade was similar in both the groups.
3. Time required for two segment sensory regressions with Dexmeditomedine group was delayed significantly as compared to plane Ropivacaine group.
4. Duration of analgesia was longer (by 6-8hes) with Dexmeditomedine group as compared to plane Ropivacaine group.
5. Hemodynamic parameters like heat rate, blood pressure, oxygen saturation and respiratory rate remained stable throughout imtraopreative period with both the groups.
6. Incidence of nausea, bradycardia and hypotension was almost similar in both groups.

Any of these drugs does not cause side effects like sedation, dizziness, headache, and respiratory depression.

In conclusion, 5 mcg Dexmeditomedine seems to be an attractive alternative as an adjuvant to spinal Ropivacaine in surgical procedure requiring longer duration. It has excellent quality of post operative analgesia with minimal side effects. However, clinical studies to prove its efficacy and safety and varying dosages for supplementation of spinal local anaesthetic are recommended.

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