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AN EVALUATION OF DEXMEDITOMIDINE ADDED TO INTRATHECAL ROPIVACAINE IN LOWER LIMB ORTHOPAEDIC SURGERIES

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ABSTRACT **Aim:** To evaluate the onset and duration, hemodynamic changes, post operative analgesic requirements and sedation when dexmeditomidine is added to intrathecal ropivacaine in lower limb orthopaedic surgeries. **Methods:** In this randomised, double-blind, case control study, 50 patients about to undergo elective lower limb orthopaedic surgery were randomly allocated into two groups. Group R where 3ml of 0.75% Ropivacaine plus 0.5ml of normal saline was given intrathecally and Group D where 3ml of 0.75% Ropivacaine plus 5µgm of Dexmedetomidine in 0.5 ml of normal saline was given intrathecally. The onset and duration of block, hemodynamic changes, post operative analgesic requirements and sedation were observed. Results were analysed statistically using student's t test to determine the p value and significance of the observations. **Results:** In the dexmedetomidine group the onset of sensory block was significantly fast compared to the ropivacaine group (3.52+1.66 minutes vs 5.04+1.43 minutes) with statistically insignificant changes in heart rate, mean arterial pressure and SpO2. The time to two segment regression showed significant variation with the dexmedetomidine group taking 116.4+4.07 minutes for regression compared to 78.8+7.8 minutes by the ropivacaine group. **Conclusion:** Dexmedetomidine provides fast onset, prolonged duration and stable hemodynamics which make it an effective alternative to other adjuvant agents used with intrathecal ropivacaine.

KEYWORDS : : Dexmeditomidine, Subarachnoid block, Ropivacaine, Surgical anaesthesia

INTRODUCTION

Lower limb orthopaedic surgeries are most commonly done under spinal anaesthesia but post operative pain relief is a major problem when only local anaesthetic drugs are used. A number of adjuvants such as clonidine, midazolam, opioids and others have been studied to prolong the effect of spinal anaesthesia.

The addition of opioids to local anaesthetic solution causes pruritus, nausea, vomiting, urinary retention and respiratory depression. Clonidine added to intrathecal local anaesthetic agents can cause hypotension, bradycardia and sedation in a dose dependant manner.

Dexmedetomidine, an imidazoline derivative, is 1600 times more selective for $\alpha_2$than $\alpha_1$receptors and with a plasma elimination half life of about 2 hours. As a neuraxial adjuvant drug, it provides stable hemodynamic conditions with good intraoperative and postoperative analgesia and minimal adverse effects.

AIM OF THE STUDY

The purpose of this study was to evaluate the following parameters when dexmedetomidine was added to intrathecal ropivacaine in lower limb orthopaedic surgeries:

- Onset and duration of sensory block
- Hemodynamic changes
- Postoperative analgesic requirement
- Sedation

MATERIALS AND METHODS

After getting approval from the Institutional ethical committee, the study was conducted in fifty patients undergoing elective lower limb orthopaedic surgeries under spinal anaesthesia. The patients were randomly allocated into two groups of 25 each by sealed envelope technique.

Inclusion criteria

ASA I&II
Age between 23 to 68 years
The exclusion criteria included
Local infection,
Bleeding disorder,
Heart block,
Hypertension and
ASA III and IV patients.
Uncooperative patients

All patients were thoroughly examined preoperatively. Informed written consent was obtained and the procedure was explained. They were allocated into the following groups.

Group R: 3ml of 0.75% Ropivacaine plus 0.5ml of normal saline.
Group D: 3ml of 0.75% Ropivacaine plus 5µgm of Dexmedetomidine in 0.5 ml of normal saline.

On arrival in the operating room, the patients were preloaded with lactated ringer's solution at 15ml/kg. No premedication was given to the patients on the previous night and on the day of surgery. Blood pressure, oxygen saturation, and ECG were monitored in all patients. Under strict aseptic precautions, spinal anaesthesia was performed using 25G Quinke's needle at L3-4 or L4-5 interspace in sitting position. Immediately after performing the subarachnoid block all patients were placed in supine position.

THE FOLLOWING PARAMETERS WERE OBSERVED

(A) SENSORY BLOCK

Sensory block was assessed by loss of pinprick sensation to 23G hypodermic needle in the midaxillary line bilaterally. Sensory level was tested every 2 minutes until the highest level had stabilised for four consecutive tests. Following parameters were recorded from the time of injection of the drug into the intrathecal space.

- Highest level of sensory block
- Time taken to reach the highest level
- Time to two segment regression and
- Time to sensory regression to S2 dermatome

(B)POSTOPERATIVE ANALGESIA

Postoperatively, pain scores were recorded by using Visual Analogue Score (VAS) between 0 and 10 (0 = no pain, 10 = the most severe pain), initially every hour for 2 hours, then every 2 hours for next 8 hours and then after every 4 hours till 24 hours. Injection diclofenac 75mg intramuscular was given as rescue analgesia when VAS ≥4. It was repeated after 12 hrs. If patients again complained of break through pain Inj. Tramadol 100 mg was given intramuscularly. All patients were followed up for the next one week by a blinded anaesthesiologist. They were asked about the presence of headache, back pain, as well as pain, numbness and tingling sensation in the lower extremities.

© SEDATION.

Sedation was assessed with a four-point verbal rating scale
1 = No sedation
2 = Light sedation
3 = Somnolence
4 = Deep sedation

STATISTICAL TOOLS

Kruskul Wallis chi-square test was used to test the significance of difference between quantitative variables and Yate's chi square test for qualitative variables. A 'p' value less than 0.05 is taken to denote significant relationship

OBSERVATION AND RESULTS

All 50 patients in two groups completed the study without any exclusion. We did an inter group analysis and the results were as followed. Of the 50 patients 25 belonged to Group R (ropivacaine) and other 25 categorized as Group D (ropivacaine with dexmedetomidine). Data were presented as range, mean, standard deviation. The probability value 'P' of less than 0.05 considered statistically significant.

Table 1: HAEMODYNAMIC VARIABLES

Parameter	Mean Arterial Pressure		Pulse Rate	
	Group D	Group R	Group D	Group R
Range	75 – 92	74.5 -103.95	63 – 91.8	63.2 – 93
Mean	81.5	83.8	75.8	75.6
SD	3.7	7.0	7.1	7.1
'p'	0. 3458 Not significant	0.9438 Not significant		

Table shows the distribution of hemodynamic variables between the two groups and p value is not statistically significant.

Table 2: SPO2

Parameter	SPO2	
	Group D	Group R
Mean	99	99
SD	-	-

There was no difference between the two groups regarding spo2

EFFICACY OF THE TWO DRUGS

Table 3: Time of onset of sensory block

Parameter	Time of onset of sensory block (in minutes)	
	Group D	Group R
Range	2 – 6	4 – 8
Mean	3.52	5.04
SD	1.66	1.43
'p'	0. 0021 Significant	

In table 3 onset of sensory block in the two groups were depicted. P value is statistically significant .The time of onset of sensory block was faster in group D (3.52 ± 1.66) when compared with group. R 5.04 ± 1.43.

Table 4: Peak level of Sensory Block

Peak level of Sensory Block	Number of cases in			
	Group D		Group R	
	No.	%	No.	%
T2	2	8	2	8
T4	7	28	4	16
T6	14	56	17	68
T8	2	8	2	8
Total	25	100	25	100

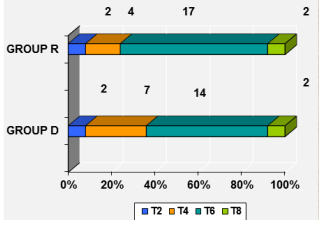

Table 5: Time to two segment regression

Parameter	Time to two segment regression (in minutes)	
	Group D	Group R
Range	90 – 140	70 – 100
Mean	116.4	78.8
SD	14.7	7.8
'p'	0. 0001 Significant	

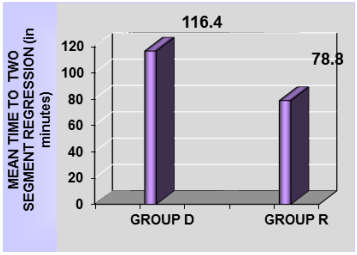

Table shows the distribution of time to two segment regression between the two groups. In group D the time to two segment regression was prolonged (116.4 ±14.7) when compared with group R (78.8± 7.8) and it is statistically significant.

Parameter	Time to regression to S2 Dermatome (in minutes)	
	Group D	Group R
Range	390 – 490	230 – 290
Mean	451.6	252.8
SD	29.6	16.5
'p'	0. 0001 Significant	

Table 6: Time to sensory regression to S2 Dermatome

Parameter	Time to first rescue analgesic (in minutes)	
	Group D	Group R
Range	375 - 500	215 – 255
Mean	456.2	236.6
SD	28.7	12.9
'p'	0. 0001 Significant	

Table shows the time to sensory regression to s2 dermatome in the two groups. In group D time to sensory regression to s2 dermatome is 451.6 29.6minutes and in group R 252.8 16.5 minutes. This is statistically significant.

Table 7: Time to first rescue analgesic

Requirement in doses	Group D		Group R		'p'
	Mean	S.D.	Mean	S.D.	
Diclofenac	2.0	0	2.0	0	1.0 Not significant
Tramadol	0.2	0.41	0.52	0.51	0.0196 Significant

Table 8: Diclofenac and Tramadol doses required

Adverse effects	Group D		Group R	
	No	%	No	%
Hypotension	4	16	3	12
Bradycardia	1	4	1	4
Shivering	1	4	2	8
Vomiting	1	4	2	8
Total cases with adverse effects	6*	24	7*	28
Total cases without adverse effects	19*	76	18*	72
Total	25*	100	25*	100

* More than one adverse effect was present in one case in each group Adverse effects in each group were comparable.

DISCUSSION

We conducted a randomized, double-blind, case-control study to evaluate the postoperative analgesic efficacy of intrathecal dexmedetomidine 5 µg added to 0.75% ropivacaine in lower limb orthopaedic surgeries which was based on Rajni gupta et al, using dexmedetomidine as an intrathecal adjuvant for postoperative analgesia.

In our study, we used 3 ml of 0.75 % ropivacaine with 0.5 ml of normal saline or 5µg of dexmedetomidine in 0.5 ml of normal saline. We measured the time of onset of sensory block, peak level of sensory block, time to two segment regression, time to regression to S2 dermatome and the time to first rescue analgesia. All these were measured from the time of injection of subarachnoid block.

The affinity of dexmedetomidine to alpha 2 adrenergic receptors has been found to be 10 times more than that of clonidine. Moreover, Kalso et al. reported a 10:1 dose ratio between intrathecal clonidine and dexmedetomidine in animals. Kanazi et al in their study in humans found that 3µg of dexmedetomidine and 30 µg of clonidine will be equipotent. Al-Mustafa et al used dexmedetomidine intrathecally with bupivacaine in two different doses 5 µg or 10 µg and found that both the doses are safe to use in humans. So based on the previous studies we used 5 µg of dexmedetomidine intrathecally.

In our study we found that the time to two segment regression, time to sensory regression to S2 dermatome and the time to first rescue analgesia were prolonged in dexmedetomidine group than ropivacaine group. These results were comparable with the study of Rajni et al. In the present study, the time to two segment regression in dexmedetomidine group was 116.4 ±14.7minutes which was comparable with the study of Rajni et al (125.6 ±16.5minutes).

In our study, the time to sensory regression to S2 dermatome in group D is 451.6± 29.6 minutes which was comparable with the results of Rajni et al (468.3 ±36.8 minutes). The time to first rescue analgesia in group D is 456.2 minutes which is also comparable to Rajni et al (478.4 ±20.9 minutes).

The time of onset of sensory block was less in dexmedetomidine group compared to ropivacaine group and it is statistically significant. But rajni gupta et al in their study found no difference between the two groups. Al-Mustafa et al in their study found that addition of dexmedetomidine to intrathecal bupivacaine decreased the onset time of sensory block at the dose of 5µg and 10µg.

Ropivacaine acts by blocking sodium channels in the spinal cord, whereas the α2 -adrenergic agonist (dexmedetomidine) acts by binding to post-synaptic dorsal horn neurons and to the C-fibres in the presynaptic regions. The analgesic action of intrathecally administered α2 -adrenergic agonists is by decreasing the release of C-fibre neurotransmitters and by causing hyperpolarisation of neurons in the post-synaptic dorsal horn.

Al-Ghanem et al. in their study noted that the use of intrathecal dexmedetomidine to be associated with a decrease in blood pressure and heart rate. But in the present study, only one case of bradycardia and four cases with hypotension were noticed in the dexmedetomidine group and in the ropivacaine group, one case of bradycardia and three cases of hypotension were noticed. These adverse effects were comparable between the two groups. As compared to the study of Rajni et al, the incidence of hypotension is higher in our study and it may be due to more blood loss which is to be expected in orthopaedic surgeries.

Limitations in our study are we have used dexmedetomidine only in ASA I and II patients, but not in high risk patients with ASA physical status of III and IV. Intrathecal dexmedetomidine produces dose dependant effects on the quality of anaesthesia and analgesia but we used only a small dose of 5 µgm. We used dexmedetomidine in orthopaedic cases which is more prone for intraoperative bleeding and hypotension. So we are not able to quantify the incidence of hypotension caused by dexmedetomidine when injected intrathecally.

CONCLUSION

Dexmedetomidine added as an adjuvant to intrathecal ropivacaine results in fast onset and prolonged duration of sensory blockade. Additionally, the stable hemodynamic parameters and minimal sedation makes 5 µg of dexmedetomidine an effective alternative to other adjuvant agents used with intrathecal ropivacaine.

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