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EPIDURAL DEXMEDETOMIDINE WITH ROPIVACAINE IN PATIENTS UNDERGOING LOWER LIMB SURGERY : COMPARISION BETWEEN TWO DIFFERENT DOSES.

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ABSTRACT

Background: This study is carried out to determine the optimal dose of dexmedetomidine that should be added to epidural ropivacaine to improve the quality of motor and sensory block.

Method: Group A received 0.5mcg/kg while Group B received 1mcg/kg of dexmedetomidine along with ropivacaine and various haemodynamic parameters and side effects were noted.

Result: Quality of block was better with 1mcg/kg of dexmedetomidine with acceptable haemodynamics and side effects.

Conclusion: Optimal dose of epidural dexmedetomidine is 1mcg/kg.

KEYWORDS : Dexmedetomidine, Ropivacaine, epidural.

INTRODUCTION

Epidural anesthesia is commonly used technique for providing peri-operative surgical anesthesia as well as postoperative analgesia in lower abdominal and limb surgeries.[1] But many a times to achieve desired effect, invariably large volumes of local anaesthetics are used leading to deleterious consequences. To overcome this problem adjuvants like ketamine, clonidine, opioids, and midazolam are commonly used to improve the duration and quality of analgesia of neuraxial blockade and decrease risk of systemic toxicity by decreasing the dose of LA.[2,3]

Alpha 2-adrenergic receptor agonists have been the focus of interest for their sedative, analgesic, peri-operative sympatholytic, anesthetic-sparing, and hemodynamic-stabilizing properties.[4] Dexmedetomidine is a highly selective α-2 adrenergic agonist with affinity eight times greater than that of clonidine.[5,6,7,8,9,10] At present, dexmedetomidine, although approved for intravenous use only, has been successfully used in neuraxial block in experimental and clinical studies with less side effects. [9,11] However, the study of dexmedetomidine is scarce and the optimal dose of epidural dexmedetomidine with ropivacaine for surgery is still uncertain. The present double-blind prospective randomized study was designed to investigate the effect of adding different dose of epidural dexmedetomidine to ropivacaine during lower limb surgery.We compared quality of block in view of onset and duration of motor and sensory block, hemodynamic responses , duration of postoperative analgesia and side effects, if any.

MATERIAL AND METHOD

After approval of institutional ethical committee, a written informed consent was taken and sixty patients were randomly selected for elective lower limb surgery under epidural anesthesia.

Patients between 18 to 60 years of age (male/female), American society of anesthesiologists (ASA) grade I and II class, undergoing lower limb surgery, and with normal sensory and motor function of affected limb were enrolled in this study. Patients with hypersensitivity to study drugs, local pathology at the site of injection, ASA Class III or above, pregnant, lactating mothers, patients with chronic pain or on long-term analgesics, patients on anticoagulants or having bleeding disorder, and body mass index (BMI) >30kg/m2 were excluded from study.

All patients underwent preanaesthetic checkup (PAC) and were kept nil per oral as per the fasting guidelines. The patients were randomly divided into two predefined groups of 30 each.

Group A- 0.5% Ropivacaine(14 ml) + inj. Dexmedetomidine 0.5 mcg/kg (in 1 ml 0.9% saline) Group B- 0.5% Ropivacaine(14 ml) + inj. Dexmedetomidine 1 mcg/kg (in 1 ml 0.9% saline)

To reduce subjective and objective bias, the study wasdesigned in a way that anesthetist doing the procedure, patient, surgeon and observer were not aware of group allocation.

All patients were given 150 mg oral ranitidine and 0.25mg alprazolam tablet as premedication a night prior to surgery. In the operative room, identity of the patient, fasting status, consent and PAC were confirmed. After reassuring the patient, monitoring was applied and base line values of HR, SBP, DBP and MAP, RR, SpO2 were noted. IV cannulation using 18G iv cannula was taken in the contralateral upper limb and Lactate Ringer solution was started. Oxygen was administered at the rate of 4-5 L/min via Hudson's mask.

Under strict aseptic precautions and after local infiltration of 2ml (2%) Lidocaine, lumber epidural anesthesia was given in sitting position at the level of L3-L4/L4-L5 interspace by using 18 G Touhy's needle and location of epidural space was confirmed by loss of resistance technique. A test dose of 3 ml of 2% lignocaine with 1:200000 adrenaline solution was administered. After 4-6 minutes of test dose and excluding intravascular or intrathecal injection, 15 ml study solution was administered according to study group.

Patients were placed in the supine position immediately after the epidural injection. Time of drug injection was noted. The patients were evaluated for onset of sensory and motor block every 2 min for first 30 min. HR, SBP, DBP, MAP, RR, SPO2 and sedation score were documented at every 5min for first 30 min and thereafter every 15min till end of surgery and then every 2hr till 20hrs. Bradycardia defined as heart rate < 60 beats/min and was treated with inj. atropine 0.6 mg intravenously. Hypotension defined as SBP < 20% of baseline value or < 90 mmHg and was treated with intravenous fluid and if needed inj. Mephentermine 3-6 mg in intravenously.

Following parameters were noted in study:

1. Onset of sensory block at T10. (time interval between the end of injection of study drug and the complete loss of cutaneous sensation)
2. Maximum sensory level achieved.
3. Time to achieve maximum sensory level.
4. Time to 2 segment dermatome regression from maximum sensory level.
5. Total duration of sensory block.
6. Onset of motor block. (time interval between the end of injection of study drug and Bromage grade 2)

7. Maximum grade of motor blockade achieved.
8. Total duration of motor block. (Time interval between injection of study drug and complete resolution of motor blockade to grade 0)
9. Time of requirement of 1st dose of rescue analgesia. (when VAS ≥ 4)
10. Sedation score by Ramsay sedation score.
11. Side effects, if any.

The sensory block was assessed by loss of sensation to pin prick in the midline with 25G hypodermic needle every 2 min interval till T10 dermatome was achieved and then every 5 min interval until no change in level occurred. Sensory block was assessed by using a 3-point scale:
Grade 0 - sharp pain on pin prick (normal sensation)
Grade 1 - loss of sensation of pinprick (analgesia)
Grade 2 - loss of sensation of touch (anesthesia)

Motor block was evaluated every 5 min for first 30 min and then every 15 min till the end of surgery by Modified Bromage scale:
Grade 0 - No block.
Grade 1 - Inability to move the hip but able to move knee and ankle.
Grade 2 - Inability to move hip and knee but can move ankle.
Grade 3 - No movement at all and unable to move hip, knee and ankle.

Sedation was assessed every 5 min for first 30 min and then every 15 min till the end of surgery by Ramsay sedation score:
Grade 1 - anxious, agitated or restless
Grade 2 - cooperative, oriented and tranquil
Grade 3 - reports to command only
Grade 4 - asleep but basic response to glabellar tap or loud auditory stimuli
Grade 5 - asleep but sluggish response to glabellar tap or loud auditory stimuli
Grade 6 - no response

Failure of block/Inadequate block was defined by no sensory or motor block even after 30 minutes of procedure. These cases were provided general anaesthesia and were excluded from study.

Surgical position was given after confirming sensory blockade T10 in all patients. Adverse effects like nausea, vomiting, shivering during the surgery were noted. Inj. Ondansetron 0.1mg/kg was given if patient had nausea or vomiting. If patient complained of pain intraoperatively, inj. Ketamine 0.5mg was given i.v. If pain still persisted, general anaesthesia was given and that patient was excluded from study.

Postoperatively, all hemodynamic parameters, level of sensory and motor block, sedation score and analgesia by VAS were evaluated. The patients were shifted to ward after complete recovery of motor block, stable vital parameters, no nausea/ vomiting , no pain or bleeding. End point of study was first requirement of rescue analgesia or VAS ≥ 4 whichever was earlier, and was treated by inj. Paracetamol 1gm infusion i..v.

Postoperative pain was assessed by visual analogue scale (VAS):
1- No pain
10 - Maximum possible pain

RESULTS

Table 1: Demographic Data

PARAMETER	GROUP A	GROUP B	P VALUE
Age (years)	37.5±11.38	36.7±10.47	0.179
Gender (M:F)	22:8	21:9	
Body wt. (kg)	70±11.10	65.8±12.13	0.184
Height (cm)	164.73±8.61	163±8.70	0.556
ASA status (I:II)	26:4	27:3	
Duration of surgery (mins)	125.3±14.3	122.66±15.18	0.483

Table 2 : Sensory and motor block characteristics

PARAMETER	GROUP A	GROUP B	P-VALUE
Onset of sensory block to T10 level (mins)	9.63±1.03	7.63±1.07	<0.001
Maximum level of sensory block	6.13±1.16	5.23±1.35	<0.001
Time to achieve max. sensory level (mins)	14.83±1.15	13.8±1.13	<0.001
Time for two segment regression (mins)	108.66±11.44	135.16±10.86	<0.001
Onset of motor block (mins)	23.12±5.27	18.66±5.77	<0.001
Duration of motor block (mins)	176.33±9.82	257.16±10.64	<0.001
Time for 1st dose of rescue analgesia (mins)	240.66±9.16	363.83±10.39	<0.001

Table 3 : Comparison of sedation score

SEDATION SCORE	GROUP A	GROUP B	P VALUE
1	0	0	NA
2	24 (80%)	5 (17%)	<0.0001
3	5 (17%)	11 (37%)	<0.001
4	1 (3%)	14 (47%)	<0.0001
5	0	0	NA
6	0	0	NA

Table 4 : Intraoperative complications

PARAMETER	GROUP A	GROUP B	P VALUE
Hypotension	5 (17%)	10 (33%)	0.126
Bradycardia	2 (7%)	3 (10%)	1.071
Nausea/vomiting	8 (27%)	3 (10%)	0.0616
Dry mouth	0	8 (27%)	0.0002
Respiratory depression	0	0	NA

DISCUSSION

In present study, we compared effects of two different doses of dexmedetomidine with ropivacaine in epidural anesthesia. The demographic profile in this study was comparable and did not show any significant difference between the two groups. We found that addition of dexmedetomidine in dose of 1mcg/kg to ropivacaine led to earlier onset and decreased time to achieve maximum sensory block in comparison to dose of 0.5 mcg/kg. These results are in concordance with other studies. Salgado et al [17] also noticed the onset of sensory block with dexmedetomidine was earlier than plain ropivacaine. Bajwa et al[18] suggested that mean onset of sensory block with dexmedetomidine was 7.12 ± 2.44 mins .

Maximum level of sensory block achieved by 1 mcg/kg dexmedetomidine group was T4- T6 which was comparatively higher than other group. These results were also similar to other studies.[17,18] Bajwa et al[18] observed in their clinical study that onset of sensory block with dexmedetomidine was significantly earlier than ropivacaine alone group. Onset of sensory block with dexmedetomidine was 7.12 ±2.44 mins which was quite similar to our study. Time to achieve maximum sensory level was also earlier with dexmedetomidine. Kaur et al [19] compared dexmedetomidine as an adjuvant to ropivacaine to ropivacaine alone in epidural anesthesia in lower limb surgery. Time of onset of sensory block, maximum level of sensory level and time to achieve maximum sensory level was significant earlier in dexmedetomidine group similar to our study.

In present study, there was significant earlier onset of motor block with significant prolonged duration in 1 mcg/kg dexmedetomidine group as compared to 0.5mcg/kg group. Similar results were documented by Bajwa et al[18] and Kaur et al. [19] Onset of motor block in our study was 18.66 ± 5.77 mins in 1 mcg/ kg dexmedetomidine group which was similar with results of Bajwa et al[18] (18.16±4.52). Onset time for 0.5 mcg/kg dexmedetomidine group was 23.12±5.27 mins in our study. Similar results were found with duration of motor block. Epidural use of 1 mcg/kg dexmedetomidine with ropivacaine in present study result in significantly delayed requirement of rescue analgesia as compared to 0.5 mcg/kg dexmedetomidine group (240.66 ± 9.16 mins in

group A and 363.83±10.39 mins in group B). Similar results were also observed by Salgado et al[17] and Kaur et al.[19]

Sedative effect of dexmedetomidine is mediated by inhibition of norepinephrine release from locus coeruleus due to activation of presynaptic α-2 adrenoceptors along with inhibition of adenylate cyclase. [19,20] Our study showed that 1 mcg/kg dexmedetomidine group has higher sedation score in comparison to other group which is similar with results of study by Bajwa et al.[18]. Dexmedetomidine does not decrease gut motility, hence it prevents intraoperative and postoperative nausea and vomiting while it is a common side effect of opioids like fentanyl.[21] In present study, commonly noted side effects were hypotension, bradycardia, nausea / vomiting, and dry mouth. There were no significant difference in side effects between both groups except dry mouth. 27% patients in 1mcg/kg dexmedetomidine group presented with dry mouth, while none of the patients in 0.5mcg/kg group experienced dry mouth (p=0.0002), but this side effect was easily managed by reassuring the patient and so was not of much concern. This was in accordance with the study done by Bajwa et al.[18]

In the present study all patients remained hemodynamically stable in both groups and incidence of bradycardia and hypotension was comparable at all measured intervals which confirms that 1mcg/kg dose of dexmedetomidine provides hemodynamically stable perioperative period.

None of the patients experienced excessive sedation or respiratory depression.

CONCLUSION

In this study, we found that both the groups achieved good effects with two different concentrations of dexmedetomidine were added to epidural ropivacaine, but 1mcg/kg group had earlier onset time of motor and sensory block, earlier achievement of maximum and complete blockade, prolonged sensory and motor blockade with good sedation score and postoperative analgesia. Both groups had comparable hemodynamic stability with tolerable side effects. Dexmedetomidine does not cause significant respiratory depression despite providing good sedation i.e. it has wide safety margins [13].

In summary, we could get the conclusion that 1mcg/kg of dexmedetomidine may be the optimal dose of epidural dexmedetomidine for patients undergoing lower limb surgery under epidural anaesthesia when combined with 0.5% ropivacaine.

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