Comparative Study of Efficacy of Two Different Doses of Epidural Dexmedetomidine (0.6µg/kg and 1µg/kg) with 0.75% Ropivacaine for Inguinal Hernioplasty

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ABSTRACT

Introduction: Epidural anaesthesia is one of the most common regional anaesthetic technique used for lower abdominal and lower limb surgeries. Various adjuvant are being used with ropivacaine for prolongation of intra operative and post-operative analgesia in epidural block. Dexmedetomidine, the highly selective α2 adrenergic agonist is a new neuraxial adjuvant gaining popularity.Dexmedetomidine has dose dependent action when used intrathecally and not much studies have been conductedto determine the efficacy of different doses of dexmedetomidine in epidural anaesthesia.So in our study we selected two different doses of dexmedetomidine(1 and 0.6µg/kg)to determine the efficacy with ropivacaine.Aim of the study was to evaluatethe efficacyof two different doses of dexmedetomidine(0.6µg/kg and 1µg/kg)as an adjuvant to to ropivacaine 0.75% in epidural anaesthesia for elective inguinal hernioplasty surgeries.

Materials and methods: One Hundred Patients scheduled for elective inguinal hernioplasty under epidural anesthesia participated in this study. They were assigned into two groups: Group A (n = 50), 15ml of 0.75% ropivacaine plus 0.6µg/kg Dexmedetomidine given and in Group B (n = 50), 15ml of 0.75% ropivacaine plus 1 µg/kg of Dexmedetomidine given. The Following variables were studied: onset of sensory and motor block, duration of sensory and motor block, maximal dermatomal level of analgesia.

Results: Group B had rapid onset of sensory and motor blockade ($p<0.05$), prolonged duration of sensory, motor block ($p<0.05$), and determine more intense motor block ($p<0.05$), greater sedation scores compared group A.Side effects like hypotension and bradycardia were observed more with group B but it was not stastically significant.There was no difference in the maximal dermatomal level of analgesia.

Conclusion: Epidural Dexmedetomidine at 1 µg/kg as an adjuvant to 0.75% Ropivacaine is associated with prolonged sensory and motor block, hemodynamic stability, more intense motor block and greater sedation scores when compared to dexmedetomidine 0.6 µg/kg with Ropivacaine.

Keywords: Dexmedetomidine, Ropivacaine, Epidural block

INTRODUCTION

Epidural anaesthesia is one of the most popular regional anaesthesia technique used for lower limb and lower abdominal surgeries. The advantages of epidural anaesthesia being it[1,2], provides good surgical anaesthesia and can meet the extended duration of surgical needs, provides post operative analgesia, reduces the incidence of hemodynamic changes.

Different local anaesthetics are tried for epidural anaesthesia[3], most popular in India being Lidocaine and Bupivacaine. The drawback of lidocaine is its intermediate duration of action and the drawback of bupivacaine is the increased incidence of fatal cardiac toxicity after accidental intravascular injection, because of narrow cardiovascular collapse/central nervous system toxicity (cc/cns).[4] For this reason, there has been a search for alternative drugs with desirable blocking properties of bupivacaine but with a greater margin of safety. Ropivacaine and levobupivacaine are the newer long acting amide local anaesthetics which have a wide margin of safety compared to bupivacaine, with all its advantages.[4]

Recently Ropivacaine has been introduced, since Ropivacaine has all the advantages of bupivacaine with less cardiac toxicity[5], it appears that it may be an ideal local anaesthetic for epidural anaesthesia. Various studies have found, Ropivacaine to be an effective local anaesthetic for epidural anaesthesia[6,7,8,9], Richard Arthur et al.[10] in their comparative pharmacokinetics of bupivacaine and ropivacaine have found that when applied directly to an isolated vagus nerve preparation, ropivacaine was less potent than bupivacaine in terms of conduction blocks of Aβ fibers, but ropivacaine blocked Aδ and C fibers to a greater extent than did bupivacaine. It is also found that lipid solubility of Ropivacaine is 2.9 compared with 3.9 of bupivacaine.[11] Hence, in our study ropivacaine was selected as the study drug.

The fear of surgery, strange surroundings of the operation

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theatre, the sight and sound of sophisticated equipments, the masked faces of many strange personale makes the patient panic to any extent.

Sedation, stable haemodynamics and an ability to provide smooth and prolonged post-Operative analgesia is the main desirable qualities of an adjuvant in neuraxial anaesthesia.

α-2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anaesthesia. Dexmedetomidine is a highly selective α_2 adrenergic agonist with an affinity of eight times greater than clonidine. Various studies have shown that the dose of clonidine is 1.5 – 2 times higher than dexmedetomidine when used in epidural route. The anaesthetic and the analgesic requirement get reduced to a huge extent by the use of dexmedetomidine because of its analgesic properties and augmentation of local anaesthetic effects as they cause hyperpolarisation of nerve tissues by altering transmembrane potential and ion conductance at locus ceruleus in the brainstem.[12] The stable haemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful pharmacologic agent.

Considering the dose dependent action of intrathecaldexmedetomidine[13] we hypothesize that higher dose of dexmedetomidine used as an adjuvant in epidural anaesthesia with ropivacaine would result in better efficacy profile by further prolonging the sensory and motor blockade. Not much studies have been conductedto determine the efficacy of different doses of dexmedetomidine epidurally.So in our study we selected two different of dexmedetomidine (1 and 0.6µg/kg) to determine the efficacy with epidural ropivacaine.

MATERIALS AND METHODS

A study entitled"Comparative study of efficacy of two different doses of epidural Dexmedetomidine (0.6 and 1µg/kg) with 0.75% Ropivacaine for inguinal hernioplasty" was undertaken in Kempegowda Institute of Medical Sciences (K.I.M.S) hospital, Bangalore during the period October 2011 and July 2013. The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients.

One hundred patients, scheduled for various elective inguinal hernioplastysurgeries belonging to ASA class I and II were included in the study. The study population was randomly divided using computer generated randomization numbers into two groups with 50 patients in each group.

Group A (n = 50), 15ml of 0.75% ropivacaine plus 0.6µg/kginj Dexmedetomidine in 1ml of normal saline

Group B (n = 50), 15ml of 0.75% ropivacaine plus 1 µg/kg of injDexmedetomidine in 1ml of normal saline

Inclusion criteria for the study

- Adult patients aged between 18 to 65 years of both sex.
- Patients belonging to ASA class I and II posted for elective lower abdominal and lower limb surgical procedures.
- Weight > 50 kgs, Height 150-180cms

Exclusion criteria for the study

- Patient refusal for regional anaesthesia.
- Pregnancy and lactation.
- Patients posted for Emergency surgeries.
- Obese patient with BMI > 30.
- Patients having:
  - raised intracranial pressure
  - severe hypovolemia
  - bleeding coagulopathy
  - local infection
  - uncontrolled hypertension/ diabetis mellitus
  - neurological disorderand deformities of spine
  - cardiac disease
  - hepatic disease
  - allergy to local anaesthetics and dexmedetomidine

METHODS

A routine pre-anaesthetic examination was conducted on the evening before surgery.The patients were premedicated with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time on the previous night before surgery. They were kept nil orally 10 pm onwards on the previous night.

On the day of surgery, patient's basal pulse rate and blood pressure were recorded. A peripheral intravenous line with 18 gauge cannula after local anaesthesia was secured in one of the upper limbs. All the patients were preloaded with 500 ml of Ringer lactate 30 minutes prior to the epidural procedure. Multiparameter monitor was connected which records heart rate, non-invasive measurement of systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure(MAP), continuous electrocardiogram (ECG) monitoring and oxygen saturation (SPO_2).

With the patients in sitting position under aseptic precautions, epidural space was identified by loss of resistance technique to air using 18G Tuohy needle via the midline approach at either L2-3 or L3-4 inter spinous space. An epidural catheter was threaded and fixed at 3 cms inside the epidural space. A test dose of 3 ml of 2% lignocaine with 1:200000 adrenaline was injected through the catheter after aspiration. After ruling out intrathecal and intravascular placement of the tip of the catheter, study drug was injected in increments of 5 ml. The patients were turned to supine position after 1 min.

Assessment of sensory and motor blockade were done at the end of each minute with the patient in supine position after completion of the injection of 16 ml of the study drug, which is taken as the starting time. The onset time for sensory and motor block, the maximum level of sensory block, intensity of motor block and sedation score were recorded.Sensory blockade was assessed using a short bevel 22 gauge needle and was tested in the mid clavicular line on the chest, trunk and lower limbs on either side.

Motor blockade in the lower limbs was assessed using mod-

ified Bromage scale.

0 – able to perform a full straight leg raise over the bed for 5 sec

1– unable to perform the leg raise but can flex the leg on the knee articulation

2 – unable to flex the knee but can flex the ankle

3 – unable to flex ankle but can move the toes

4 – unable to move toes (total paralysis).

Measurements of blood pressure, heart rate, and oxygen saturation will be recorded every 5 minutes till the end of 1hour and then every 15 minutes till the end of surgery.

Sedation scoring as per (Five point scale):

Alert and wide awake	1
Arousable to verbal command	2
Arousable with gentle tactile stimulation	3
Arousable with vigorous shaking	4
Unarousable	5

Intraoperatively and postoperatively complications like fall in blood pressure, variation in heart rate were noted, treated and tabulated After the surgery, patients referred to the recovery room (PACU) post anaesthesia care unit where they remained until there was complete recovery of sensory and motor blockade. Epidural top up was given with 8ml of 0.2% inj.ropivacaine once the patient complains of pain. Postoperatively vital parameters will be recorded every 15 minutes, and also duration of sensory and motor blockade.

RESULTS

Table 1 shows the demographic data of the patient's studied. There was no statistically significant difference between the groups with respect to mean age, weight, height and gender.

Table 2 shows the characteristics of sensory and motor block in both the groups. There was statistically significant difference between the groups with respect to the onset of sensory and motor block ($p<0.05$). There was significant prolongation of sensory block, motor block in group B compared to group A ($p = 0.000$).

Table 3 shows the maximum sensory level attained in both groups. 8 patients in group B had attained T5 level

Table 4 shows intensity of motor block in both the groups. 20 patients in group B had modified bromage scores 4 and 12 in group A

Table 5 shows sedation scores of two groups.group B had hiher sedation scores compared to group A and it was statistically significant ($p<0.05$).

DISCUSSION

In this study,the hypothesis that higher dose of dexmedetomidine used as an adjuvant in epidural anaesthesia with ropivacaine would result in better efficacy profile by further prolonging the sensory and motor blockade

In our study, the drugs selected for epidural anaesthesia were Ropivacaine and dexmedetomidine Ropivacaine, has structural similarity to bupivacaine. Without cardiotoxic effects of bupivacaine, has been introduced to Indian market recently. Dexmedetomidine has been studied by various authors as an adjuvant to epidural local anaesthetic.[14-21] Few studies have compared ropivacaine and dexmedetomidine for epidural anaesthesia in India.[18]

Presynaptic activation of alpha-2A adrenoceptor in the locus ceruleus inhibits the release of nor-epinephrine and results in the sedative and hypnotic effects.[22] In addition, the locus

	Group A	Group B	P Value
Age in years Mean±SD	32.19 ± 11.1	32.8 ± 10.12	0.962
Weight in kgs Mean±SD	58.64 ±5.17	56.10 ±6.11	0.27
Height in cms	170	169.3	0.825
Gender M/F	36/15	34/17	0.69

Table-1: Demographic data of the study subjects

	Group A	Group B	P-value
Mean time for Onset of sensory block (min)	5.26±1.49	2.51±0.62	0.012
Mean time for Onset of motor block (min)	11.22±3.28	9.24±0.56	0.031
Mean duration of sensory block (min)	359.30± 61.94	520.39 ± 20.21	0.000
Mean duration of motor block (min)	233.70± 15.36	362.24 ± 17.26	0.000

Table-2: Characteristics of sensory and motor block in both the groups

Max Sensory level	Group A (No.of patients)	Group B (No.of patients)	p-value
T5	0	8	
T6	31	35	
T8	17	6	0.010
T10	2	1	

Table-3: Maximum level of sensory blockade attained

	Group A	Group B	p-value
Bromage 2	3	0	<0.001
Bromage 3	35	30	0.35
Bromage 4	12	20	<0.001

Table-4: Grade of motor blockade

Sedation score	Group A	Group B	p-value
S1	12	0	
S2	33	15	
S3	5	29	0.001
S4	0	6	

Table-5: Sedation score

ceruleus is the site of origin for the descending medullospinal noradrenergic pathway, known to be an important modulator of nociceptive neurotransmission. Stimulation of alpha-2 adrenoceptors in this area terminates the propagation of pain signals leading to analgesia. Postsynaptic activation of alpha-2 receptors in the CNS results in decrease in sympathetic activity leading to hypotension and bradycardia.[23] Alpha -2 adrenoceptors present on primary afferent terminal (peripheral and spinal endings),in the superficial laminae of the spinal cord and within several brainstem nuclei have been implicated in the analgesia, supports the possibility of analgesic action of alpha agonist at peripheral, spinal and brainstem site.

According to the results, the demographic profile in the present study was comparable and did not show any significant difference($p>0.05$). We found that there was a significant difference in the onset of sensory and motor block with group B compared to group A.

It was found that,the total duration of sensory block was significantly prolonged in Group B (520.39 ± 20.21 min) which is in concordance with the results of Kaur S et al[24] (535min) as they had taken 20 ml of ropivacaine compared to Group A (359.30± 61.94 min).

Total duration of motor block (regression to Bromage 0) in Group B was 362.24 ± 17.26 min which is in concordance with the results of Kaur S et al[24] (385 min)as they had taken 20 ml of ropivacaine. Total duration of motor block in Group A was 259.80 ± 15.86 min.

There was also greater enhancement of the intensity of motor block and greater sedation scores with group B compared to group A. It provides better operative conditions and postoperative analgesia.

In group B,8patients attained T5 as the maximum sensory level attained. There was no significant difference between groups with regard to occurrence of hypotension and bradycardia at any time of the study.No side effects like pruritis,-vomiting,headache,backache, respiratory depression were reported in our study which was similar to other studies.[25,26] Addition of dexmedetomidine to ropivacaine provides better operating and haemodynamic conditions,with significant postoperative analgesia without increasing the morbidity. Hence higher doses of dexmedetomidine appears to augment the efficacy ofepidural ropivacaine.

CONCLUSION

Dexmedetomidine appears to augment the efficacy of epiduralropivacaine in a dose dependent manner without assosciated increase in adverse effects,

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