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Original Research Article

A COMPARATIVE STUDY OF FENTANYL AND DEXMEDETOMIDINE FOR EPIDURAL ANALGESIA FOR LOWER LIMB ORTHOPEDIC SURGERY – A PROSPECTIVE DOUBLE-BLIND STUDY

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ABSTRACT

Background: Epidural adjuncts to local anesthetics have a synergistic effect and are frequently used. This study compared the analgesic efficacy & side effects of 50mcg Fentanyl and 50mcg Dexmedetomidine with 0.75% epidural ropivacaine in lower limb orthopedic surgery. **Method**:This prospective randomized double-blind study was conducted on 70 patients of ASA Grade I & II in the age range 20-65 yrs. The patients were randomly divided into two groups Group I (n=35) and Group II (n=35). Group I- received Fentanyl 50 mcg 1ml as an adjuvant to Ropivacaine 0.75% 15 ml. Group II – received Dexmedetomidine 50mcg 1ml as an adjuvant to Ropivacaine 0.75% 15 ml. The Groups were compared for hemodynamic parameters, the onset of sensory block & motor block, total duration of analgesia, and side effects. **Results:** The demographic & hemodynamic variables at baseline were comparable. The onset of sensory block was quicker in Group II (10.35 ± 0.375 min) in comparison to group I (12.21±0.234 min)with the difference being statistically significant ($p< 0.05$). The onset of motor blockade was quicker in Group II (14.73±0.33 min) compared to group I (18.32±0.37min) with the difference being statistically significant ($p< 0.05$). The duration of analgesia was statistically significantly prolonged in Group II (383.4 ±18.45min) as compared to Group I (278.6 ± 16.756 min). Few incidences of bradycardia, hypotension & dry mouth were observed in Group II and nausea & vomiting in Group I with no statistically significant difference. **CONCLUSION :** Dexmedetomidine as an adjuvant to 0.75% epidural Ropivacaine offered a better alternative to Fentanyl & provided an early onset of sensory & motor blockage, deeper sedation levels, longer duration of analgesia postoperatively, comparable hemodynamic variables, and fewer side effects in lower limb orthopedic surgeries.

Keywords: Dexmedetomidine, Fentanyl, Ropivacaine, epidural analgesia.

INTRODUCTION

Epidural anesthesia is the most commonly used technique in providing perioperative & post-operative analgesia. It can be placed at various levels of vertebrae and provides a hemodynamically stable course. It stands as an integral & desirable anaesthetic technique in lower limb orthopedic & abdominal surgeries since there is minimal postoperative discomfort & pain with early postoperative mobilization **(1).**

Bupivacaine as a local anaesthetic (LA) has long been used in providing epidural anesthesia. Bupivacine used in high dosage carries the risk of LA toxicity & altered hemodynamic responses with severe cardiovascular (CVS) and central nervous system (CNS) toxicity **(2).** Newer amide LA drug Ropivacaine stands as an alternative drug of choice with a longer duration of action, a lesser propensity of motor block postoperatively, and minimized CVS & CNS toxicity. There is a faster reversal of sodium ion channel blockage, after cardiac action potential with Ropivacaine **(3)**

Studies done by Chitra et al **(4)** & Bajwa et al **(5)** have proven addition of adjuvants to LA provides faster onset, prolongs, and intensifies the sensory blockade with advantages of reducing the dosage of LA in turn minimizing the associated adverse effects of those drugs. Various LA adjuvants have been used to date like epinephrine, neostigmine, ketamine, fentanyl, and dexmedetomidine. Some of these carry a greater risk of serious side effects like if epinephrine is accidentally injected i.v. or neurotoxicity with ketamine if inadvertently injected in cerebrospinal fluid, also opioids may cause nausea, vomiting, itching, confusion with respiratory depression. **(5)**

Limited studies are found in the literature comparing the adjuvant action of fentanyl & Dexmedetomidine with epidural Ropivacaine. Thus, this study was designed to compare the drugs Fentanyl and Dexmedetomidine as an adjuvant to Ropivacaine in epidural anaesthesia for lower limb orthopedic surgeries in terms of onset of complete sensory and motor blockade, total duration of analgesia, hemodynamic variables, and adverse effects.

MATERIALS & METHOD

This prospective randomised double-blind study included 70 patients belonging to the American Society of Anesthesiologist (ASA)physical status I and II in the age group 20-65 years of either sex, scheduled to undergo lower limb orthopedic surgeries under epidural anesthesia. Ethical clearance was taken from the institutional ethical board. The detailed nature of the study was explained to the patients & written consent was obtained.

Exclusion criteria: Patients with coagulation or neurological disorders, localized skin sepsis, morbid obesity, previous surgery of the spine, anticipated difficulty in regional anesthesia, drug allergy, gross spinal deformity, hemorrhagic diathesis, neurological disease, hepatic and renal diseases, pregnancy, psychiatric diseases, and unwillingness were excluded from the study.

Randomisation into groups: The patients were randomly divided into two groups Group I (n=35) and Group II (n=35).

Group I- received Fentanyl 50 mcg 1ml as an adjuvant to Ropivacaine 0.75% 15 ml

Group II – received Dexmedetomidine 50mcg 1ml as an adjuvant to Ropivacaine 0.75% 15 ml

Preanaesthtic evaluation a day prior to surgery was completed. Patients were notified to not consume liquids or solid foods at least 6 hrs prior to surgery. To calm the patients 0.25 mg tablet alprazolam was administered to the patients night before surgery. After shifting to the operating table, a multipara monitor was attached and baseline values of the vitals heart rate (HR), systolic (SBP) and diastolic blood pressure (DBP), mean arterial pressure (MAP)& partial pressure of oxygen (spO_2), respiratory rate & electrocardiogram (ECG) were recorded and monitored. Good intravenous access was secured and patients were well hydrated with ringer lactate solution. The patients were made to sit on operating table and assisted in lateral decubitus position maintained to open the lumbar intervertebral space The patient was draped and under aseptic conditions, using 2% lignocaine a skin wheal was raised at L 3 –L 4. Through the wheel 18 G Tuohy Epidural needle inserted passing through the skin, supraspinous ligament, interspinous ligament, at 2-3 cm depth until resistance felt at ligamentum flavum. Lumber space was identified using the loss of resistance to saline technique. After negative aspiration of blood & CSF, a test dose of 2-ml 2% lignocaine with epinephrine 1:200,000 was administered into epidural space. The study drug was handed to the blinded anesthesiologist by another anaesthetist and injected slowly into the epidural space.

Parameters monitored :

1. Assessment of sensory level – by pinprick method.

2. Time recorded for the achievement of sensory level T 10

3. Assessment of complete motor block – recorded time to achieve Bromage level 3

4. Hemodynamic Parameters – assessed at baseline, after administering block at,3,6,9,12,15 min after that an interval of 15 min.

24 hrs postoperative monitoring of sensory and motor block, postoperative analgesia, hemodynamic parameters, and side effects was done.

Statistical analysis: The data was put in an excel sheet, tabulated, and analysed using statistical software (SPSS version 22, IBM, India). Data were expressed as mean & standard deviation. *P*-value was noted at 95% confidence interval, $P < 0.05$ was considered significant.

RESULTS

The mean and standard deviation for age in Group I was 42.85 ± 5.61 yrs and in group II was 44± 8.41 yrs which was not statistically significant. No statistically significant difference in weight of patients in Group I (52 – 70 kg) and (50-75 kg) was observed.

Table I Haemodynamic parameters

Parameters at baseline	Group I	Group II	p-Value
SBP (mmHg)	133.24±8.25	131.57±11.03	>0.05
DBP (mmHg)	78.6 ± 8.54	80.67 ± 9.21	>0.05
Heart Rate(per min)	88.45±18.68	89.2 ± 12.89	>0.05
MAP	99.53 ± 8.87	100.50±10.95	>0.05
SPO2	97.65 ± 1.79	97.76 ± 1.68	>0.05
The average change in HR/min	6.8±2.5	8.5±3.7	>0.05
The average change in MAP (mm Hg)	8.4±.3.7	10.8±4.9	>0.05

At baseline, the hemodynamic variables in both the groups were comparable with no statistically significant difference ($p > 0.05$) concerning HR, SBP, DBP, MAP, SpO_2, respiratory rate. Intergroup comparison showed no statistically significant difference in HR. The intragroup comparison showed a decline in HR which was not statistically significant ($p > 0.05$). Intergroup comparison showed no statistically significant difference in SBP at all time intervals. Intergroup comparison showed no statistically significant difference in DBP, MAP, SpO_2, respiratory rate at all time intervals ($p > 0.05$). (Table I)

Table II Characteristics of sensory & motor block

	Group I	Group II	P-value
Onset of sensory block (min)	12.21±0.234	10.35±0.364	< 0.05
The onset of motor block (min)	18.32±0.37	14.73±0.33	< 0.05
Total duration of analgesia (min)	278.6 ±16.756	383.4 ±18.45	< 0.001

The onset of sensory and motor blockade was quicker in Group II compared to group I with the difference being statistically significant ($p< 0.05$). The duration of analgesia was significantly prolonged in Group II as compared to Group I. This was statistically highly significant (p-value < 0.001) (Table II).

Intergroup comparison showed statistically no significant difference in the complication/ side effects. Few incidences of bradycardia, hypotension & dry mouth were observed in Group II and nausea & vomiting in Group I with no statistically significant difference. (Fig 1)

Intergroup comparison showed deeper levels of sedation in Group II as compared to Group I. At any time interval, SpO_2 levels were >90% in all the patients. No cases of respiratory depression and urinary retention were noted in the two groups.

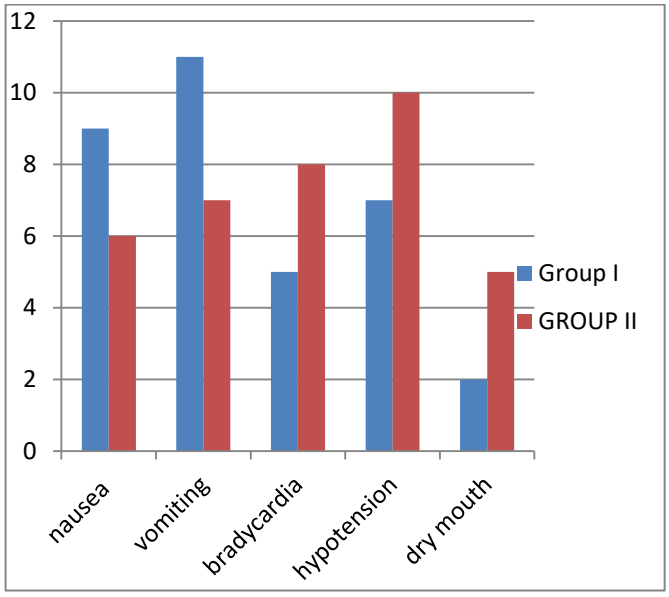

Fig 1 shows the presence of side effects and complications in Group I and Group II expressed as % on the y axis.

DISCUSSION

Epidural analgesia along with adjuvants have synergistic effects and provides superior analgesia and early rehabilitation as compared to local anesthetics used alone. Fentanyl has frequently been used as an adjunct with Ropivacaine in epidural anesthesia to achieve superior analgesia & perioperative anaesthesia but with fewer incidences of pruritis, urinary retention, nausea, vomiting, and respiratory depression. It mainly acts on the substantial gelatinosa on the dorsal horn of the spinal cord. Acting pre & post-synaptically blocks the fibers carrying nociceptive impulses. **(6)**

Dexmedetomidine, a selective alpha-2 adrenoreceptor agonist, acts on the spinal cord and has been proven to be an effective adjuvant to ropivacaine for regional and central neuraxial blocks. It provides sedation, anxiolysis, hypnosis, anti-anxiety, analgesia, and sympatholytic & hemodynamic effects by acting on both pre and post-synaptic sympathetic nerve terminal and CNS thereby decreasing the sympathetic outflow. Its side effects are hypotension & bradycardia which can be managed effectively.(7)

The present study compares the effect of adding fentanyl and dexmedetomidine to epidural ropivacaine in lower limb orthopedic surgeries. Group I- received Fentanyl 50 mcg 1ml as an adjuvant to Ropivacaine 0.75% 15 ml. Group II – received Dexmedetomidine 50mcg 1ml as an adjuvant to Ropivacaine 0.75% 15 ml (Total 16 ml).

The demographic characteristics were comparable in both the groups and no statistically significant difference was noted thus eliminating selection bias.

In the present study, in Intragroup comparison, the heart rate showed a falling trend and stabilising around 60 min. Group II observed a statistically significant decrease in HR.

In the present study, comparable hemodynamic stability was observed within the two groups. Intragroup comparison observed a decline in SBP, DBP & MAP as compared to baseline in both Groups. Intergroup comparison revealed no statistically significant difference in DBP & MAP values. Group II observed a statistically significant decrease in SBP ($p < 0.05$) due to Dexmedetomidine-mediated sympatholytic and sympathetic neuroblockage. Similar results have been observed by Chitra et al **(4).** Stable hemodynamics is attributable to a low dose of LA & right selection of adjuvant dose.

In the present study, the meantime for the onset of sensory block to T10 dermatome was 10.35±0.364 min in Group II which was statistically significantly less than 12.21±0.234 min in Group I. This is in accordance with the study conducted by Sukhminder Jit Singh Bajwa et al **(5)** addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.52 ± 2.36 min) of sensory analgesia at T10 as compared to the addition of clonidine (9.72 ± 3.44 min) comparison ($P < 0.05$). Chitra et al 2017 stated the onset of sensory block to be significantly shorter in the dexmedetomidine group as compared to group fentanyl (7.93 ± 0.98 minutes & 9.76 ± 1.69 minutes respectively) **(4).**

In the present study, the meantime for the onset of motor block was 14.73±0.33 min in Group II which was statistically significantly less as compared to Group I (18.32±0.37 min). This is in accordance with the study conducted by Bajwa et al **(6)** and Sarabjit Kaur et al **(8).** In a study by Bang EC et al in which epidural anaesthesia was administered with ropivacaine with varying doses of fentanyl, the onset

of analgesia was shorter with the increasing dosage ($p<0.001$) **(9)**.

In the present study, the total duration of analgesia was 383.4 ±18.45 min in group II which was significantly higher as compared to 278.6 ±16.756 in group I. This is in accordance with the study done by Sarabjit Kaur et al where epidurally administered Ropivacaine with Dexmedetomidine prolonged the duration of sensory (535.18±19.85min) and motor block(385.92±17.719 min) with better quality of postoperative analgesia as compared to Ropivacaine alone **(8).** Same has been shown by Salgado et al**.(10)** (300 min) and Brown et al. **(11)** (220 ± 52 min). Elhakim M, et al 2010 have explained the synergistic effects of dexmedetomidine use with epidural ropivacaine and its association with reduced postoperative awareness and rescue analgesias **(12)**. Similar results have been shown by Chitra et al **(4)** total duration of sensory block was significantly longer in RD Group(413.33 ± 66.71) as compared to group FR (354.66 ± 66.88 minutes).

Superior sedative properties of dexmedetomidine have been demonstrated. Mathews Jacob et al concluded 0.5 mcg /bodyweight Dexmedetomidine to an optimal drug of choice showing required block characteristics, superior sedative properties with hemodynamic stability to be used as an adjuvant to epidural ropivacaine for orthopedic lower limb surgeries. A deeper level of sedation noted in Group II could be attributable to the hyperpolarisation of excitable cells in locus calculus **(13).**

Group I showed fewer incidences of nausea & vomiting as compared to Group II which was not statistically significant ($p > 0.05$). Group II showed a low proportion of bradycardia, hypotension, dry mouth & headache which was not statistically significant ($p > 0.05$). No respiratory depression was not noted in any of the groups. A study by Chitra et al (4) reported patients responded to loud sounds & physical stimuli in the Dexmedetomidine group as compared to the Fentanyl Group in which the subjects responded to verbal commands.

CONCLUSIONS

50mcg Dexmedetomidine as an adjunct to 0.75% epidural Ropivacaine offered a better alternative to 50 mcg Fentanyl & provided an early onset of sensory & motor blockage, deeper sedation levels, prolonged duration of sensory block, longer duration of analgesia postoperatively, comparable hemodynamic variables, and fewer side effects in lower limb orthopedic surgeries.

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