

Comparative Study of Dexmedetomidine and Fentanyl As Adjuvants to Ropivacaine for Epidural Anaesthesia in Orthopedic Replacement Surgeries

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ABSTRACT

Introduction: Epidural anaesthesia has advantages like flexibility in adjusting the block intraoperatively, in case of prolonged surgery ability to provide postoperative analgesia via use of epidural catheter, so it is a popular and versatile anaesthetic technique. The present study aims at comparing the hemodynamic, duration of block, sedative, and analgesic effect of fentanyl and dexmedetomidine when combined with ropivacaine.

Material and methods: After approval from the ethical committee, the study was conducted on patients presented to Department of Anaesthesiology and Critical care, Maharani Laxmi Bai Medical College Jhansi, UP. 100 patients of both gender aged 40-80 years, ASA physical status I and II who underwent orthopaedic replacement surgeries were allocated randomly into two groups: Group I: (RD) 15ml ropivacaine(0.75%) with 50mcg Fentanyl. Group II: (RF) 15ml ropivacaine (0.75%) with 50 mcg Dexmedetomidine. Besides cardio-respiratory parameters and sedation scores, various block characteristics were also observed which included time to onset of analgesia at T10, maximum sensory analgesic level, time to complete motor blockade. At the end of study, data was compiled systematically and analyzed using IBM SPSS 21. Value of $P < 0.05$ is considered significant.

Results: The demographic profile of patients was comparable in both the groups.

Time Onset of sensory block at T10

Ropivacaine and Dexmedetomidine Group I [RD] 9.36 ± 0.802

Ropivacaine and Fentanyl Group II [RF] 11.44 ± 0.907) complete motor blockade

Group I [RD] 17.66 ± 1.611

Group II [RF] 24.98 ± 0.880 ,

Mean duration of motor blockade

Group I [RD] 231.78 ± 10.414 ,

Group II [RF] 190.42 ± 8.795

Mean height of block

Group I [RD] T5

Group II [RF] T6

Mean duration of motor block (min)

Group I [RD] 231.78 ± 10.414

Group II [RF] 190.42 ± 8.795

DURATION OF ANALGESIA

Group I [RD] 383.50 ± 21.291

Group II [RF] 273.96 ± 18.289

Sedation scores-better in the Group I Ropivacaine and Dexmedetomidine [RD].

Conclusion: Our study concluded that Dexmedetomidine is better as an adjuvant than Fentanyl for epidural anaesthesia because of intense analgesia, better quality of motor block and prolong post op analgesia, along with higher sedation scores and insignificant side effects.

Keywords: Dexmedetomidine, epidural anesthesia, fentanyl, orthopaedic replacement surgery, ropivacaine

INTRODUCTION

Fidel Pages described a lumbar epidural in abdominal surgery in 1921.

Achile Dogliotti¹ described the —loss of resistance technique to locate epidural space in 1931, Tuohy's catheter technique(1945), used for continuous spinal anaesthesia to lumbar epidural anaesthesia by Curbello² in 1949.

We used ropivacaine 0.75% as local anesthetic agent in the study. In comparison to bupivacaine, ropivacaine is known to have lesser cardiotoxicity³⁻⁴ and motor blockade⁵⁻⁶, with similar pain relief⁶⁻⁷ at equivalent analgesic doses. The addition of an adjuvant increases the effectiveness of a local anesthetic and intensifying the sensory blockade causes reduction in dose of local anesthetic agents.

Fentanyl is partial agonist (μ) on opioid receptor. Its main site of action is the substantia gelatinosa on the dorsal horn of spinal cord. It blocks fibers of nociceptive impulses.⁷ Dexmedetomidine is a selective-2 agonist which provides sedation, anxiolysis, hypnosis, analgesia and sympatholysis a major advantage of its higher selectivity compared with clonidine for α_{2A} receptors.⁸⁻⁹

MATERIAL AND METHODS

After approval from the ethical committee of the institution, the study was conducted on patients presented to Department of Anaesthesiology and Critical care, Maharani Laxmi Bai Medical College Jhansi, UP, INDIA.

Selection of cases

Patients underwent replacement surgeries of both genders age ranging from 40 to 80 years belonging to American Society Of Anaesthesiologist (ASA) grade 1 or 2 were screened in all 100 patients.

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A thorough preanaesthetic check up was done including the history and physical examination, airway examination. All the necessary investigations were done.

Exclusion Criteria

Patient refusal

Any contraindication to epidural anaesthesia.

Patient with diseased or deformed spine.

Patient's with history of diabetes, hypertension, cardiac disease, COPD, coagulation abnormalities or any other severe systemic illness or allergic to amide type of local anaesthetics.

Patient who had history of lower back surgery.

Informed consent was taken for study.

Allocation of Study Groups:

The study was divided into two groups.

Group I - (n=50) 15ml ropivacaine(0.75%) with 50mcg Fentanyl (1 ml). Total volume = 16 ml

Group II - (n =50) 15ml ropivacaine (0.75%) with 50 mcg Dexmedetomidine (1 ml) Total volume = 16 ml

Drug preparation

Dexmedetomidine available as 100 mcg/ml so 50mcg made by adding 0.5 ml NS in 0.5ml Dexmedetomidine.

Fentanyl 50mcg/ml, 1ml (50mcg).

Anaesthetic technique:

After shifting the patient to OT the procedure was explained. Monitor was attached and all vitals HR, SBP, DBP, MAP, SPO2 as baseline values. Then 18G of IV canula was inserted, hydrated with 10ml/kg body weight of RL solution. The patient was placed in sitting position flexing the neck to open up the lumbar vertebral space.

With all aseptic precautions, at space L₃-L₄ a small skin wheal was raised with 2% lignocaine. The Tuohy Epidural needle was used of 18G, 3 -3.5 inches long, with blunt bevel with gentle curve of 15-30 degree at the tip. 18G tuohy needle was inserted into the skin then supraspinous ligament, then into the interspinous ligament, which is encountered at a depth of 2-3 cm until distinct sensation of increased resistance was felt as the needle passed through the ligamentum flavum,

at this point the needle stylet was removed and the plastic syringe was attached into the hub of the needle. The loss of resistance technique will be used by filling syringe with 2ml of air. The needle was advanced, millimetre by millimetre, with rapidly repeating attempts at injection. As the tips of needle just enter the epidural space there is a sudden loss of resistance and injection, syringe was removed and catheter was introduced via the needle. The catheter has markings showing the distance from its tip and should be advanced to 15cm at the hub of the needle to ensure that sufficient length of the catheter has entered the epidural space. The needle was removed, Epidural catheter was secured. Test dose 3ml of 2% lignocaine with epinephrine was administered.

STATISTICAL ANALYSIS

We analysed distributed data by using t- test and categorical data by chi square test. Continuous data were recorded as mean and standard deviation, whereas categorical data were recorded as number of patients and percentage which was analysed using IBM SPSS statistics 20.0 software ,P<0.05 was considered statistically significant.

RESULTS

Median Level of sensory block was T6 in Group I [RD] and T5 in Group II [RF].

Mean time for sensory level at T10 was found to be significantly lower (p<0.0001) in Group I [RD] (9.36±0.802 min) as compared to Group II [RF] (11.44±0.907 min).

complete motor blockade

[RD] 17.66 ± 1.611

[RF] 24.98 ± 0.880,

Onset of sensory block was faster in Dexmedetomidine than Fentanyl Hemodynamic parameter HR, SBP, DBP, MABP, SpO2, at different time intervals between in both groups were comparable and statistically insignificant.

Dexmedetomidine and Fentanyl, both provided perioperative haemodynamic stability in epidural Dexmedetomidine provide sedation score 3 and 4, in most of cases as compare Fentanyl in which score was 2 in most of case which was statistically significant.

Time of onset of sensory block at level (min)	Group I [RD]	Group II [RF]
Number of subjects	50	50
Minimum time (min)	8	10
Maximum time (min)	11	13
Mean±SD	9.36±0.802	11.44±0.907
p value	0.0001 (S)	

Table-1: Time of onset of sensory block at level T10 (min) in study group

Time to achieve the complete motor block (min) in study group	Group I [RD]	Group II [RF]
Number of subjects	50	50
Minimum time (min)	15	22
Maximum time (min)	23	25
Mean±SD	17.66±1.611	24.04±0.880
p value	0.0001 (S)	

Table-2: Mean time to achieve the complete motor block (min) in study group

Mean duration of motor block (min)	Group I [RD]	Group II [RF]
Number of subjects	50	50
Minimum time (min)	201	170
Maximum time (min)	260	209
Mean±SD	231.78±10.414	190.42±8.795
p value	0.0001 (S)	

Table-3: Mean duration of motor block (min)

Duration of Analgesia (minutes)	Group I [RD]	Group II [RF]
Number of subjects	50	50
Minimum time (min)	340	240
Maximum time (min)	435	310
Mean±SD	383.50±21.291	273.96±18.289
p value	0.0001	

Table-4: Duration of analgesia (minutes)

Incidence of hypotension, bradycardia were found more in group I [RD]

Incidence of nausea and vomiting were found more in Group II [RF] but these side effects in both groups are statistically insignificant.

DISCUSSION

The present study was carried out on 100 patients ranging from 40-80 years of age, there was no significant difference in the age of patient among the two groups.

Anaesthesiologists are specialized clinicians to treat pain by adopting various techniques and drugs. Pain is a very unpleasant and distressful condition to the patient. If not treated it may result into various physiological changes, including rise in heart rate, blood pressure, restricted physical activity and sleepless nights. Attenuation of perioperative pathophysiology that occurs during the surgery through reduction of nociceptive input into the CNS and optimization of postoperative analgesia may decrease complications and facilitates patients recovery in the immediate postoperative period and after discharge from the hospital.

Many options are available for treatment of postoperative pain, including systemic (opioid and non opioid) analgesics and regional (neuraxial and peripheral) analgesic techniques. Neuraxial blockade specially caudal epidural blocks assume an integral role in the management of lower limb and orthopaedics replacement surgeries in patients as they are used not only to provide surgical analgesia but can be used in the postoperative period to provide effective pain relief.

We decided to use Ropivacaine in our study because in comparison to bupivacaine, it has a wider margin of safety, less motor blockade, less cardiovascular or neurological toxicity.

Opioid analgesics are for the treatment of postoperative pain but their use is associated with side effects like nausea, respiratory depression, pruritis and urinary retention,itching. In an effort to avoid the side effects seen with opioids and to find a good alternative to it, we decided to compare the effect of Dexmedetomidine.

(α -2 adrenoceptor agonist) with Fentanyl (a synthetic opioid) as adjuvant to ropivacaine in our study. Dexmedetomidine

have the following physiological properties: sedation, analgesia, it reduces the stress response to the surgery by reducing plasma catecholamine concentration, and prevents shivering via α_2 adrenoceptors in the central nervous system¹⁰.

The analgesic effect of the α_2 agonists is a complex issue¹¹. They can induce analgesia by acting at three different sites: in the brain and brainstem, spinal cord and in peripheral tissues. α_2 -adrenergic and opioidergic systems have common effector mechanisms in the locus coeruleus, representing a supraspinal site of action and activation of the descending medullospinal noradrenergic pathways or reduction of spinal sympathetic outflow at presynaptic ganglionic sites. Moreover, there is also significant interaction between opioids and α_2 agonists at the spinal cord level¹².

The antihypertensive effect of Dexmedetomidine results from stimulation of α_2 inhibitory neurones in the medullary vasomotor center (nucleus reticularis lateralis) of the brainstem.

Epidurally administered Dexmedetomidine decreases the electrical activity of preganglionic sympathetic nerves. Bradycardia is caused by an increase in vagal tone resulting from central stimulation of parasympathetic outflow and reduced sympathetic drive¹³. However in our study, in both the groups mean values heart rate and mean arterial pressure were lower than their respective baseline values.

Dexmedetomidine has unique sedative properties caused by hyperpolarization of excitable cells in the locus coeruleus¹⁴. On analysis of the demographic profile the age in both the groups, Age wise distribution of subjects in both the groups did not show an statistically significant difference (p=0.3749). Duration of surgery was also comparable in both groups.

Age wise distribution of study population

Patients underwent replacement surgeries of both genders age ranging from 40 to 80 years belonging to American Society Of Anaesthesiologist (ASA) grade 1 or 2 were screened in all 100 patients included in the study.

70% patients of group I is of age 61-70 year in group II 74%

in 61-70 years. Mean age in group I 62.14 ± 7.312 and group II 63.38 ± 6.580 (p value = 0.3749)

Surgical time (min) of distribution in study group

In group I minimum time 62 minute, maximum time 182. 90 and group II minimum time 92 minute, maximum time 182. Mean time of surgery in group I 111.60 ± 31.669 and group II 116.20 ± 20.527 (p value = 0.3909)

Time to Achieve the Sensory Level at T_{10}

We observed that Time to achieve sensory level at T_{10} was found to be significantly lower ($p < 0.001$) in Group II (11.44 ± 0.907 min) as compared to Group I (9.36 ± 0.802 min).

Sukhminder Jit Singh Bajwa et al (2011)¹⁵ Addition of Dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (8.52 ± 2.36 min) of sensory analgesia at T_{10} as compared to the addition of clonidine (9.72 ± 3.44 min) comparison ($P < 0.05$).

Arnab Paul et al (2017)¹⁶ found similar results with use of epidural Dexmedetomidine and Fentanyl with Ropivacaine.

Mean time to achieve the complete motor block (min) in Study group:

In our study, we observed that group I minimum time 15 minute, maximum time 23 minute and group II minimum time 22 minute and maximum time 25 minute.

Mean height of block achieved in group I 17.66 ± 1.611 and group II 24.04 ± 0.880 (p value = 0.0001).

Mean duration of motor block (min)

We observed that group I minimum time 201 minute, maximum time 260 minute and group II minimum time 170 minute and maximum time 209 minute.

Mean height of block achieved in group I 231.78 ± 10.414 and group II 190.42 ± 8.795 (p value = 0.0001)

Arnab Paul et al (2017)¹⁶ found similar results with use of epidural Dexmedetomidine and Fentanyl with Ropivacaine.

Hemodynamic parameters

Heart rate remained stable in the range of 56 to 88 /min in the group I and in range of 62 to 90 / min IN GROUP II. Mean arterial pressure (MAP) decreased from the baseline in both groups but never went below 65 mmHg. Significant hypotension and bradycardia were observed in group I (Dexmedetomidine with Ropivacaine) but manageable with intravenous atropine and ephedrine and this result was correlated with the study of Sukhminder jit singh bajwa, et al¹⁵.

Heart Rate

Heart rate of subjects of both the groups was statistically non-significant at all the above intervals except at 45 minutes. In Group I, change in heart rate from baseline was statistically significant at all the above time intervals upto 120 minutes except just before epidural block, after epidural block and at 135 minutes.

Similarly, in Group II change in heart rate from baseline was statistically significant at all the above time intervals upto 120 minutes except just before epidural block, after epidural block and at 135 minutes.

Mean Arterial Pressure

Mean arterial pressure of subjects of both the groups was statistically insignificant at all the above intervals.

Duration of Analgesia

In our study we observed that duration of analgesia was significantly higher ($p < 0.0001$) in Group II (383.50 ± 21.291 minutes) as compared to Group I (273.96 ± 18.289 minutes). Salgado PF at el¹⁷ Epidural Dexmedetomidine prolonged sensory and motor block duration time ($p < 0.05$) and postoperative analgesia ($p < 0.05$), and also resulted in a more intense motor block, I ($p < 0.05$).

Postoperative analgesia was prolonged significantly in RD group followed by the patient receiving Fentanyl.

Side Effects

In our study we observed that nausea and vomiting was found to be in higher proportion of subjects from Group I as compared to Group II.

None of the subjects from either of the groups had suffered with respiratory distress i.e. $SpO_2 < 90\%$. Hypotension, bradycardia and

urinary retention were found in higher proportion of Group II subjects as compared to Group I, but this difference was statistically insignificant.

Sedation

In our study we observed that Dexmedetomidine is popular sedative agent. group I 44% exhibited brisk response to light glabella tap or loud auditory stimulus in this category Group II result is 0%.

38% are responsive to commands only in group I and group II 16%. 18% are cooperative oriented and calm in group I and group II 84%. Sedation point was highly significant with administration of Dexmedetomidine.

CONCLUSION

Time onset of sensory block in Dexmedetomidine is faster, duration of complete motor block and analgesia is longer than fentanyl,

Therefore, it was concluded that Dexmedetomidine is better as an adjuvant to Ropivacaine than Fentanyl for epidural anaesthesia because of intense analgesia, better quality of motor block and prolong post op analgesia, along with higher sedation scores and insignificant side effects.

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