Original Research Article

Epidural ropivacaine with fentanyl versus ropivacaine with dexmedetomidine- A comparative prospective randomized control study in lower abdominal surgeries

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Abstract

Background: Epidural neuraxial blockade reduces frequent dosing of analgesics when especially an additive is added epidurally. Epidural ropivacaine provides lesses motor blockade and for lesser duration but it is less cardiac toxic. This prospective study is about comparing advantages and disadvantages of an epidurally given synthetic opioid, fentanyl or α2- agonist, dexmedetomidine when added with local anaesthetics ropivacaine in lower abdominal surgeries. **Aim:** To determine and compare the efficacy of epidural ropivacaine and fentanyl with epidural ropivacaine and dexmedetomidine. **Materials and methods:** This is a comparative prospective randomized control study, approved by institutional ethical committee. An individual informed consent was taken from all patients. All patients belonging to ASA grade 1 and 2, between age group of 18 to 50 years undergoing lower abdominal surgeries. Patients with contraindication for epidural anaesthesia, BMI >30 were excluded. Total 120 patients undergoing lower abdominal surgeries were divided into **Group I (60 Patients,** 0.75% Ropivacaine 18ml and Fentanyl 25µg epidurally**), groupII (60 Patients**0.75% Ropivacaine 18ml and Dexmedetomidine 50µg epidurally**). Discussion:** epidural block has advantage of extending analgesia to the postoperative period and has better hemodynamic profile.In this study we are comparing the adjuvants fentanyl and dexmedetomidine when administered with ropivacaine for epidural anaesthesia for infra umbilical surgeries**. Conclusion:** Addition of dexmedetomidine as an adjuvant to ropivacaine is better than fentanyl in providing sensory block, motor block and the analgesic effect with side effects that are easily manageable.

Key words: epidural, Ropivacaine, Fentanyl, Dexmeditomidine

Introduction

Epidural block provides a substantial amount of time to carry out surgical procedures and this becomes relevant in patients with increased risk of general anaesthesia. It provides a good post operative pain relief thus reducing the post operative morbidity and mortality and hence the duration of the hospital stay. When especially an additive is added epidurally, Epidural blockade reduces the frequent dosing of analgesics. Epidural can be used to block lumbar, thoracic as well as the cervical segments and thus can be used for a wide variety of surgeries. Commonly used local anaesthetics for epidural block are Lignocaine, levo-bupivacaine, bupivacaine and ropivacaine Epidural ropivacaine provides lesses motor blockade and for lesser duration but it is less cardiac toxic and also is 40% less potent when compared with bupivacaine. Ropivacaine, is available as 0.2%, 0.5%, 0.75% and 1% for neuraxial block. The onset of action is 15-20 minutes and the duration of action is 140-180 minutes for plain ropivacaine when epidurally administered in a volume of 20-30ml.The duration of action can be prolonged with an addition of an additive. Several drugs have been tried as an additive with the local anaesthetics like opioids, α2-agonists, midazolam, ketamine, neostigmine, gabapentin, tramadol, adenosine etc., with various outcomes.

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Adjuvents added to local anaesthetics will have their own side effects like bradycardia, hypotension, pruritus, urinary retension but, increase the density of motor blockade and good postoperative analgesic effect and postponing the time required for the first rescue analgesia. Addition of an adjuvant, reduces the dose of the local anaesthetics and saves us from the undesired effects of repeated dosing of analgesics postoperatively especially the opioids which can cause respiratory depression. This prospective study is all about comparing the advantages and disadvantages of an epidurally given synthetic opioid, fentanyl or the α2- agonist, dexmedetomidine when added with the local anaesthetics ropivacaine in lower abdominal surgeries.

Materials and methods

A comparative prospective randomized control study carried out in Alluri Sitarama Raju Academy of Medical Sciences, Eluru, in the Department of Anaesthesiology, was conducted on 120 patients undergoing lower abdominal surgeries selected randomly.

- The study was conducted between October 2020 - October 2021 at Alluri Sitarama Raju Academy of Medical Sciences, Eluru, after getting approved by the institutional ethical committeeAnd with informed consent.

Inclusion criteria

Males and females of age group 20-50 years and belonging to ASA I and II and undergoing lower abdominal surgery.

Exclusion criteria

- Patient's refusal
- Patients with contraindication for epidural anaesthesia

- Patients with contraindication for the specified drugs
- Obesity (BMI >30)

Procedure

The study was conducted in 120 patients randomly selected who were undergoing elective lower abdomen surgeries. The study is carried out after obtaining permission from the concerned authorities and consent from the patients. Patients satisfying the inclusion criteria are randomly allocated into 2 groups.

Group I - Patients receiving 0.75% Ropivacaine 18ml with fentanyl 25µg (0.25 ml)

Group II - Patients receiving 0.75% Ropivacaine 18ml with Dexmedetomidine 50 µg (0.5 ml)

Pre-anaesthetic work up

Consent form signed by the patient and a witness

Patient's condition and hemodynamic status recorded preoperatively.

Laboratory investigations:

- Complete blood count
- Random blood sugar (Fbsppbs if necessary)
- Renal function test
- Chest X-ray
- Electrocardiogram

After receiving the patient in the theatre, baseline pulse rate, and blood pressure (using NIBP), ECG and SpO2 are measured and intravenous crystalloids started.

Epidural techniques

- Strict aseptic precaution
- Patient in sitting position
- Skin infiltration with 2ml of 2%Lignocaine
- Epidural space is identified at L2-L3 space by loss of resistance to air technique.
- 18G Touhy's needle inserted and catheter is fixed at 4cm in the epidural space.
- Test dose of 3ml of 2% Lignocaine HCl with adrenaline 1:200,000
- I ntradural and intravascular placement of the catheter is ruled out and the study drug is given.

Drugs Used

- 0.75% Ropivacaine 18ml
- Fentanyl 25µg (for group I)
- Dexmedetomidine 50µg (for group II)

Intraoperative period

Assessment of sensory block

Bilateral pinprick method and loss of temperature sensation to alcohol swab is used to assess the sensory level of the blockade.

- T10 sensory block time is noted.
- Maximum level and the time for sensory block is noted.
- Time for two segmental dermatomal regression.
- Time for regression to L1 dermatome.
- Time of the pain onset is noted.
- Time of demand for the first rescue analgesics is noted(VAS >3)

Assessment of motor block:

Motor blockade is assessed by modified bromage scale. The following variables were noted:

- Onset to Bromage 3 (min)
- Regression to Bromage 0 (min)

Assessment of hemodynamic parameters

Continuous measurement of the following parameters every five minutes for the first one hour and every 10 minutes for the second hour and every 15 minutes there after intra-operatively and every 15 minutes postoperatively is made:

- Pulse rate
- Non invasive blood pressure
- Electrocardiogram
- SpO2

Assessment of sedation

Sedation is assessed by the Ramsay sedation score preoperatively and every 15 minutes intraoperatively.

Table 1

Score	Responsiveness
1	Patient is anxious and agitated or restless or both
2	Patient is co-operative, oriented and tranquil
3	Patients responds to commands only
4	Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5	Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6	Patient exhibits no response

Adverse effects

1) Nausea
2) Vomiting
3) Bradycardia
4) Hypotension
5) Desaturation
6) Pruritis
7) Dry Mouth
8) Urinary Retention

Results

Throughout the study period, SBP was significantly higher in fentanyl group.

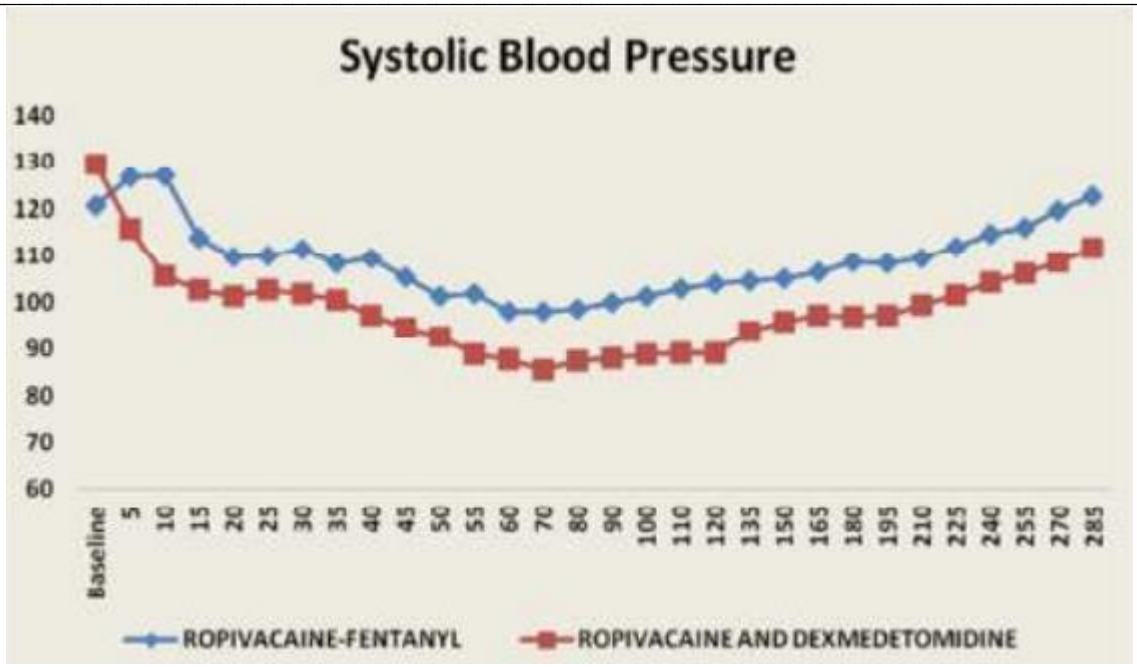

Figure 1: Systolic Blood Pressure

The diastolic blood pressure was higher in fentanyl group and lower in the dexmedetomidine group with lower levels during the fifth minute and from 135th minute till 285th minute

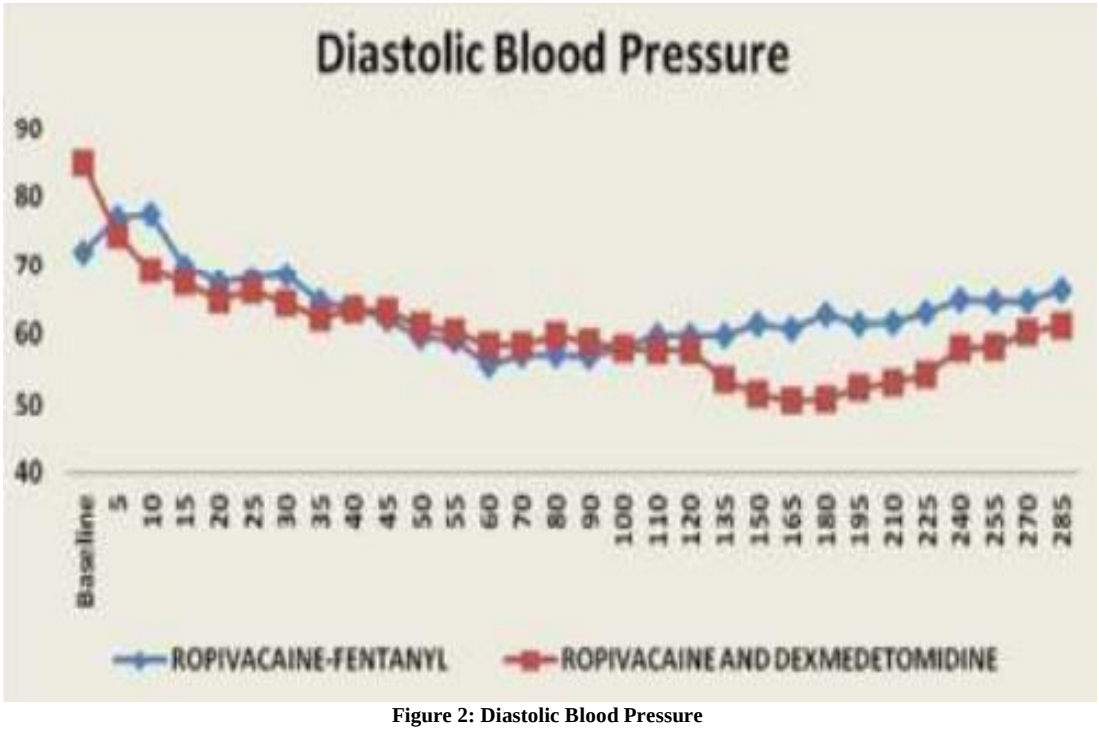

Figure 2: Diastolic Blood Pressure

The mean arterial pressure was lower in the dexmedetomidine group with a statistically significant lower level during 5 - 15 minutes, 30th minute, 40th minute and from 100th to 285th minute.

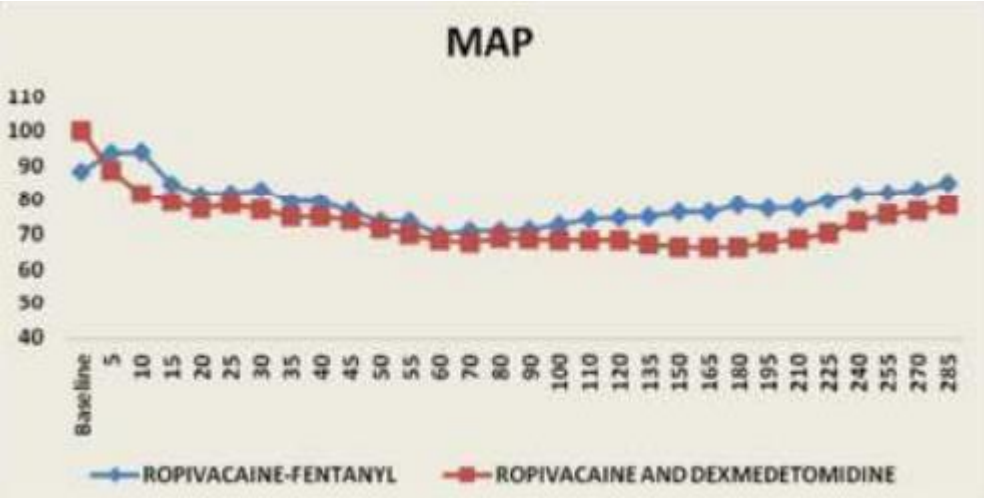

Figure 3: MAP

The mean pulse rate was lower in the dexmedetomidine for most of the period with statistically significant level during 10, 55,135 and 255th minute.

The sedation level is better with dexmedetomidine with statistically significant level seen from the 30th minute.

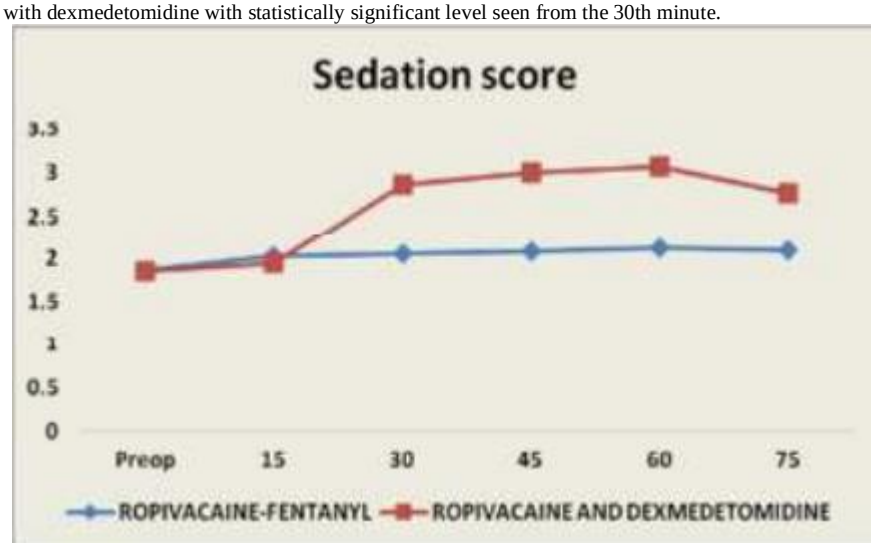

Figure 4: Sedation Score

The mean time for onset of the sensory block to T10 level in dexmedetomidine group is 10.72 ± 2.681minutes and fentanyl group is 12.47±1.961 minutes, Mean time to achieve the maximum level of sensory block with dexmedetomidine group is 15.88± 3.494 minutes and fentanyl group is 18.12± 3.043 minutes, Mean time for two segment regression in dexmedetomidine group is 152.23 ±20.062 minutes and fentanyl group is 135.02±13.226 minutes, Mean time for regression to L1 with the dexmedetomidine group is 396.00±25.475 minutes and with fentanyl group is 316.42±25.229 minutes, Pain onset in the dexmedetomidine group is 396.00±25.475 minutes and fentanyl group is 316.42±25.229 minutes, The time for requirement of the rescue analgesics in dexmedetomidine group was 409.58±20.363 minutes and in fentanyl group was 325.50±22.898 minutes

Time to attain complete motor block is earlier in dexmedetomidine group (23.92 ± 4.792) than fentanyl group (29.17±6.255), The duration of the motor blockade is also prolonged in the dexmedetomidine (202.23±20.016) group than with the fentanyl group (185.02±13.226)

Bradycardia was noted in 23 patients in the dexmedetomidine group and 17 patients in fentanyl group, Hypotension in this study is noted in 7 patients in dexmedetomidine group and 3 patients in fentanyl group. Both hypotension and bradycardia was easily manageable in both the study groups. Nausea and vomiting was higher in fentanyl group with 8 patients compared to only 2 patients in the dexmedetomidine group. None of the patients in the dexmedetomidine group had shivering as the adverse effect compared to 10 patients in the fentanyl group. Incidence of dry mouth was higher in the dexmedetomidine group with seven patients compared to two in the fentanyl group. Only one patient in the fentanyl group complained of headache whereas none of the patient in the dexmedetomidine group had headache as an adverse effect.

Discussion

Neuraxial blockade is the anaesthesia of choice for below the umbilical region surgeries as it provides better pain control and less need of the intravenous narcotics both intraoperatively and postoperatively, earlier recovery of bowel function, ,and thus less respiratory issues, early ambulation and above all it spares endotracheal intubation and its side effects. Epidural anaesthesia has better hemostability and can be prolonged in postop period for pain control. Several local anaesthetics are available for epidural neuraxial blockade, the most common ones are bupivacaine, lignocaine and

ropivacaine. Compared to lignocaine, bupivacaine and ropivacaine are longer acting amide local anaesthetics. Although both the agent are longer acting, ropivacaine has the advantage over bupivacaine by providing better cardiovascular and neurological stability.

Adjuvants are the drugs which are added to the local anaesthetics for reducing the dose of the local anaesthetics but at the same time maintaining or prolonging the duration of the desired effects of sensory and motor block. Adding adjuvants epidurally also prevents adverse affects of the adjuvants ehn given alone, Fentanyl is the synthetic lipophilic, opioid that is been used for a long time as an adjuvant. Recently , dexmedetomidine is a emerging α2 agonist as an adjuvant for epidural anaesthesia.

In this study we are comparing the adjuvants fentanyl and dexmedetomidine when administered with ropivacaine for epidural anaesthesia for infra umbilical surgeries. The variables compared includes sensory and motor blockade, systolic, diastolic and mean arterial pressure, pulse rate, sedative effect, respiratory rate, oxygen saturation and the adverse effects.

This study was conducted in 120 patients, randomly allocated into two groups with Group I: Patients receiving 0.75% Ropivacaine 18ml with fentanyl 25µg (0.25 ml) and Group II: Patients receiving 0.75% Ropivacaine 18ml with Dexmedetomidine 50 µg (0.5 ml).

Both the groups are demographically comparable with respect to the age, gender and the ASA physical status as the p values were not statistically significant.

Sensory block

In our study, the statistical analysis of the data showed that the time of onset of the sensory block to T10 and the time taken to achieve the maximum sensory block was significantly faster when dexmedetomidine was added as an adjuvant to ropivacaine than when fentanyl was used. Time for two segmental regression and the time for sensory regression to L1 was prolonged in ropivacaine with dexmedetomidine group. Time of onset of the pain and the time of demand for the first rescue analgesics was delayed in ropivacaine with dexmedetomidine group than with fentanyl group.

Motor block

The time taken to achieve the maximum motor block was significantly faster with dexmedetomidine ropivacaine group than with ropivacaine fentanyl group. The duration of motor block is also high in dexmedetomidine group compared to fentanyl group.

Hemodynamic variables

Incidence of hypotension and mean arterial pressure on lower side is more with dexmedetomidine group. Fall in pulse rate was more in dexmedetomidine group. Sedation level was better with dexmedetomidine ropivacaine

Respiratory parameters

No statistically significant difference was noted in both the group with regard to the oxygen saturation or respiratory rate.

Adverse effects

Adverse effects like hypotension and bradycardia was more in dexmedetomidine ropivacaine group.Shivering and pruritis was more in the fentanyl group than with dexmedetomidine group. Nausea and vomiting was more in fentanyl ropivacaine group Dry mouth was higher in dexmedetomidine ropivacaine group . There were no adverse effects like respiratory depression in both the groups. Headache was reported by only one patient in ropivacaine fentanyl group.

Conclusion

The addition of dexmedetomidine as an adjuvant to ropivacaine is better than fentanyl in providing sensory block, motor block and the analgesic effect with side effects that are easily manageable.

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