A Comparative Study of 0.25% Ropivacaine And 0.25% Bupivacaine Along With Fentanyl for Postoperative Epidural Analgesia in Patients Undergone Lower Abdominal and Lower Limb Surgeries

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Abstract:

Background: To compare onset and duration of analgesia and hemodynamic changes between 0.25% Ropivacaine and 0.25% Bupivacaine along with 25ug fentanyl in 60 patients, who underwent elective lower abdominal and lower limb surgeries.

Aim: This study has been conducted to compare:

• The onset and duration of postoperative analgesia & the hemodynamic changes

Methods: Randomly divided into 2 groups, Group R and Group B, of 30 each.

Group r – Receiving 10ml of 0.25 % Ropivacaine with 25µg of inj. Fentanyl

Group b – *Receiving 10 ml of 0.25% Bupivacaine with 25µg of inj.Fentanyl.*

Results: The mean onset of sensory block was significantly lower (quicker) in Group B compared to group R (4.63 vs 6.03). Significantly higher in group B (301.3 min. vs. 187.2 min) compared to group R (P<0.001;S). The mean diastolic blood pressure was similar in group B and group R for all time periods up to 120 minutes. it was significantly lower in group B (78.4 ± 4.79) compared to group R (81.2 ± 3.46) at 180 minutes (P<0.001;S). The mean respiratory rate was similar in group B and group R for all time periods up to 120 minutes.it was significantly lower in group B (13.1) compared to group R (14.4) at 180 minutes (P<0.001;S). The mean VAS was similar at the start of procedure but was significantly lower in group B after 10 minutes (3.50) compared to group R (3.98). It remained similar at 20 min but fell significantly lower in group R compared to group B (1.63 vs 2.03) while it remained similar at 60 and 120 minutes. at 180 minutes, the score was very highly significantly lower in group B (0.60) compared to that in group R (4.80) (P<0.001;S). The mean sedation score (SS) was similar in group B and group R for all time periods up to 120 minutes. it was significantly lower in group B (3.00) compared to group R (3.96) at 180 minutes (P<0.001;S).

Conclusion: It was concluded that

- 1. Bupivacaine had a slightly faster(quicker) onset of action.
- 2. Duration of analyseia was longer and better in Group B patients who received bupivacaine with fentanyl.
- 3. Hemodynamic stability was more with Ropivacaine.
- **4.** Patients who received 0.25% Bupivacaine with fentanyl had some degree of motor blockade, whereas 0.25% Ropivacaine with fentanyl didn't cause any motor blockade in patients in Group R. so faster mobility and early rehabilitation was observed in patients who received 0.25% ropivacaine with fentanyl due to its decreased potency and shorter duration of action.

Keywords: 0.25% Bupivacaine with fentanyl 25 μg, 0.25% Ropivacaine with fentanyl 25 μg.

I. Introduction

Epidural analgesia is considered as gold standard analgesic technique for post-operative pain relief after major abdominal and lower limb surgeries. Epidural analgesia has the ability to maintain continuous analgesia after placement of an epidural catheter, thus making it suitable for continuous post-operative pain relief

Bupivacaine: It is an amide type of local anaesthetic marketed in concentration of 0.5% and 0.25% and pH of 4.9-5.5. and pka of 8.1

Fentanyl Citrate: It Is a Phenylpiperidine derivative soluble in water, slightly soluble in alcohol, chloroform and ether, soluble in methyl alcohol. The injection has a pH of 4.0-7.5 and pka value of 8.3It is available as ampoules of 2 ml and vial of 10 ml with 50µg/ml.

Ropivacaine: Ropivacaine, a local anesthetic agent, is indicated in local or regionalanesthesia or analgesia for various types of surgical, obstretic, diagnostic and therapeutic procedures.

Absorption: Bioavailability is 87%–98% following epidural administration.

Protein binding: 94%, mainly to alfa 1 -acid glycoprotein

Metabolism: metabolized in the liver. **Route of elimination**:. excreted in the urine.

Half-life: 4.2 hours.

Toxicity: Excessive doses of ropivacaine result in central nervous system (CNS) and cardiovascular effects.

AIM: This study has been conducted to compare:

- The onset and duration of postoperative analgesia.
- The hemodynamic changes

Materials And Methods

This is a comparative study conducted in GGH, Guntur in various OT's "a comparative study of 0.25% Ropivacaine and 0.25% Bupivacaine along with Fentanyl for postoperative analgesia in patients undergone lower abdominal and lower limb surgeries"

Inclusion Criteria:

- Patient belonging to ASA grade 1 &2
- Patient of either gender, Age between 20-65yrs

Exclusion Criteria:

- Patient refusal
- Patients belongs to ASA 3 & 4
- Age (< 20 and >65 years)
- Patient with history of bleeding diathesis.
- Patient on anticoagulant therapy, History of drug abuse.
- Patients having history of hypersensitivity to anesthetic agents, neuromuscular diseases or spine surgeries,
 Patients with spinal deformities.

Patients divided into two groups of 30 each.

- Group R received 10ml of 0.25% Ropivacaine with fentanyl 2 5μg
- Group B received 10ml 0.25% Bupivacaine along with Fentanyl 25µg.

Parameters studied are: heart rate, blood pressure, respiratory rate, sedation score and visual analogue score were recorded.

Preparation of the patient: All routine investigations were done. After obtaining informed consent, initial preoperative counseling and reassurance was given to all the patients, also taught to assess the intensity of pain using the VAS. Patients were instructed to point the intensity of pain on the scale.

For the purpose of assessing the pain

- 0 2.5 cm taken as no pain, 2.5 5 cm taken as mild pain
- 5 7.5 cm taken as moderate pain, 7.5 10 cm taken as severe pain.

The patients were kept in fasting overnight and instructed to take Tab. Ranitidine 150 mg and Tab. Alprazolam 0.25 mg orally night before the surgery. Patients were shifted to the operation theatre. Base line parameters were recorded. Patients were planned for surgery under combined spinal epidural in sitting/ lateral position. epidural procedure was done. The catheter was properly fixed to administer the intermittent bolus doses. In the post-operative period:

a. Vital parameters such as the heart rate, blood pressure, respiratory rate, sedation score and visual analogue score were recorded .b. Onset of analgesia c. Duration of analgesia: d. Side effects: also observed. Epidural catheter was removed after 24 hours of postoperative period.

Statistical Methods

(Unpaired) 't' test, Chi-square test.

II. Results
Onset of sensory block and duration of analgesia compared between two treatment Groups:

S.No.	Parameter	Group B	Group R	P value
1	Onset of sensory block	4.63 ± 0.71	6.03 ± 0.80	<0.001; S
2	Duration of analgesia (min)	301.3 ± 5.11	187.2 ± 4.33	<0.001; S

The mean onset of sensory block was found to be significantly lower (quicker) in Group B compared to group R (4.63 vs 6.03). The mean duration of analgesia was also found to be very highly significantly higher in group B (301.3 min. vs. 187.2 min) compared to group R (P<0.001; S).

Heart rate changes compared between two treatment Groups:

S.No.	Parameter	Group B	Group R	P value
1	Basal level	73.7 ± 3.92	72.6 ± 3.44	0.25; NS
2	After 5 minutes	71.7 ± 3.20	71.0 ± 3.85	0.44; NS
3	After 10 minutes	69.6 ± 3.18	68.8 ± 3.38	0.39; NS
4	After 20 minutes	69.3 ± 3.25	67.9 ± 3.30	0.11; NS
5	After 30 minutes	67.8 ± 3.40	67.7 ± 3.54	0.91; NS
6	After 60 minutes	67.4 ± 3.04	66.9 ± 2.99	0.49; NS
7	After 120 minutes	66.1 ± 2.60	67.3 ± 2.36	0.06; NS
8	After 180 minutes	66.0 ± 2.47	71.2 ± 2.73	<0.001; S

Similar in group B and group R for all time periods up to 120 minutes. it was significantly lower in group B (66.0) compared to group R (71.2) at 180 minutes (P<0.001; S).

Systolic blood pressure changes compared between two treatment Groups:

S.No.	Parameter	Group B	Group R	P value
1	Basal level	126.2 ± 7.02	123.7 ± 5.81	0.13; NS
2	After 5 minutes	124.1 ± 5.92	122.3 ± 6.29	0.25; NS
3	After 10 minutes	122.6 ± 5.35	121.1 ± 6.57	0.34; NS
4	After 20 minutes	121.2 ± 6.42	120.6 ± 6.54	0.72; NS
5	After 30 minutes	120.2 ± 7.00	119.8 ± 6.32	0.86; NS
6	After 60 minutes	119.9 ± 6.62	118.7 ± 6.15	0.47; NS
7	After 120 minutes	118.3 ± 6.88	118.2 ± 5.56	0.93; NS
8	After 180 minutes	118.6 ± 7.33	124.6 ± 5.01	<0.001; S

Similar in group B and group R for all time periods up to 120 minutes. it was significantly lower in group B (118.6 mm Hg) compared to group R (124.6 mm Hg) at 180 minutes (P<0.001; S).

Diastolic blood pressure changes compared between two treatment Groups:

Basal level	83.0 ± 4.67	92 (. 2 50	
		82.6 ± 3.50	0.73; NS
After 5 minutes	82.3 ± 5.03	82.3 ± 3.25	0.95; NS
After 10 minutes	81.3 ± 4.90	82.0 ± 3.17	0.51; NS
After 20 minutes	80.1 ± 4.72	80.5 ± 3.23	0.68; NS
After 30 minutes	79.3 ± 4.52	79.8 ± 3.05	0.59; NS
After 60 minutes	79.4 ± 4.55	80.3 ± 3.36	0.37; NS
After 120 minutes	78.2 ± 4.67	78.9 ± 2.91	0.47; NS
After 180 minutes	78.4 ± 4.79	81.2 ± 3.46	0.01; S
	After 10 minutes After 20 minutes After 30 minutes After 60 minutes After 120 minutes	After 10 minutes 81.3 ± 4.90 After 20 minutes 80.1 ± 4.72 After 30 minutes 79.3 ± 4.52 After 60 minutes 79.4 ± 4.55 After 120 minutes 78.2 ± 4.67	After 10 minutes 81.3 ± 4.90 82.0 ± 3.17 After 20 minutes 80.1 ± 4.72 80.5 ± 3.23 After 30 minutes 79.3 ± 4.52 79.8 ± 3.05 After 60 minutes 79.4 ± 4.55 80.3 ± 3.36 After 120 minutes 78.2 ± 4.67 78.9 ± 2.91

Similar in group B and group R for all time periods up to 120 minutes. it was significantly lower in group B (78.4 ± 4.79) compared to group R (81.2 ± 3.46) at 180 minutes (P<0.001; S).

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S.No.	Parameter	Group B	Group R	P value
1	Basal level	15.2 ± 1.00	14.9 ± 0.99	0.30; NS
2	After 5 minutes	14.7 ± 0.70	14.8 ± 0.84	0.62; NS
3	After 10 minutes	14.2 ± 0.79	14.2 ± 0.96	0.88; NS
4	After 20 minutes	13.7 ± 0.69	13.8 ± 0.83	0.61; NS
5	After 30 minutes	13.4 ± 0.62	13.3 ± 0.71	0.70; NS
6	After 60 minutes	13.3 ± 0.82	13.2 ± 0.76	0.74; NS
7	After 120 minutes	13.2 ± 0.85	13.4 ± 0.92	0.56; NS
8	After 180 minutes	13.1 ± 0.66	14.4 ± 0.93	<0.001; S

Similar in group B and group R for all time periods up to 120 minutes. it was significantly lower in group B (13.1) compared to group R (14.4) at 180 minutes (P<0.001; S).

Visual Analogue Score (VAS) changes compared between two treatment Groups:

Similar at the start of procedure but was significantly lower in group B after 10 minutes (3.50) compared to group R (3.98). It remained similar at 20 min but fell significantly lower in group R compared to group B(1.63 vs 2.03) while it remained similar at 60 and 120 minutes. However at 180 minutes, the score was very highly significantly lower in group B (0.60) compared to that in group R (4.80) (P<0.001; S).

Sedation Score (SS) changes between two treatment Groups:

Similar in group B and group R for all time periods up to 120 minutes. It was significantly lower in group B (3.00) compared to group R (3.96) at 180 minutes (P<0.001; S).

Side effects compared between two treatment Groups:

Similar in the two treatment groups without any statistically significant difference.

III. Discussion

Epidural anaesthesia is a central neuraxial block technique with many applications in surgery, obstetrics and pain clinic. In this study comparison done in 60 patients, who underwent lower abdominal and lower limb surgeries randomly, divided into 2 groups of 30 each, with 10 ml of 0.25% of ropivacaine and 0.25% of Bupivacaine along with 25 mcg of inj. fentanyl for post operative analgesia in group R and in group B . Age: 20 to 65 years of age either sex belonging to ASA grade I or grade II.

Following points were studied:Onset time and duration of postoperative analgesia, Effects on hemodynamics.

Onset of analgesia: Group-R - 6 min, Group-B - 4.6 min, faster (quicker) in group B compared to group R.

Brockway MS et al^{5:} conducted a randomized double blind study to compare Ropivacaine and Bupivacaine.

Visual Analogue scale: The mean VAS was found to be similar at the start of procedure but was significantly lower in group B after 10 minutes (3.50) compared to group R (3.98). It remained similar at 20 min but fell significantly lower in group R compared to group B(1.63 vs 2.03) while it remained similar at 60 and 120 minutes. At 180 minutes, the score was very highly significantly lower in group B (0.60) compared to that in group R (4.80) (P<0.001; S). This has significance as patients in Group R needed requirement of topup dose of ropivacaine with fentanyl much earlier than that of Group B.

Duration of Analgesia: In this comparative study, Patients in Group B received 4 additional topup doses of 10 ml of bupivacaine along with fentanyl as compared to 7 additional top up doses of ropivacaine along with fentanyl in group R over the postoperative period of first 24 hours. Total amount of bupivacaine patients in group B required 125 mg as that of total amount of ropivacaine 200 mg in group R over the first 24 hr. The total amount of opioid i.e fentanyl administered also proportionately less in group B. This correlated with study conducted by Pouzeratte et al¹, where it was stated that Bupivacaine when used in combination with sufentanyl was more effective than Ropivacaine. In a study by Tuttle A.A et al⁶ concluded that the sensory block caused by Ropivacaine was significantly of shorter duration likewise in our study also we observed that the duration of analgesia in group R was of shorter duration compared to group B. In this comparative study, patients in group B had some degree of motor block grade (1-2 on modified bromage scale), whereas 0.25% Ropivacaine with fentanyl in patients in Group R didn't cause any motor blockade. so faster mobility and early rehabilitation was

observed in patients who received 0.25% ropivacaine with fentanyl due to its less potency and shorter duration of action. This was concluded in study conducted by Brown DL et al³ and Brockway MS et al⁵.

The concentration of ropivacaine used in this study didn't cause motor blockade. As stated by Liu SS et al⁴ lesser concentration will provide comparable analgesia with less motor blockade.

On Cardiovascular system; No significance in Group B and Group R in the study of K.Knudsen et al⁷.

Respiratory rate: in this comparative study there is no significant respiratory depression in both groups.

Sedation: The mean sedation score (SS) was found to be similar in group B and group R for all time periods up to 120 minutes. However, it was found to be significantly lower in group B (3.00) compared to group R (3.96) at 180 minutes (P<0.001; S). Casati.A et al² in their study concluded that in prolonging the block for the first 12 hours after surgery with a patient-controlled epidural infusion, 0.125% levobupivacaine provides adequate pain relief after major orthopedic surgery when compared to that of bupivacaine. Liu SS et al⁴ in their study concluded that concentration and dose of local anesthetic solution is a primary determinant of motor block with patient-controlled epidural analgesia after lower abdominal surgeries. Peter S. Hodgson et al⁸, in their study concluded PCEA decreased the consumption of local anesthetics, bupivacaine is more potent than ropivacaine and lesser concentrations of LA cause less motor blockade.

IV. Conclusion

When 10 ml of 0.25% Ropivacaine with 25 mcg of Inj.Fentanyl was compared with 10 ml of 0.25% Bupivacaine along with 25 mcg of inj.Fentanyl for Epidural analgesia, the following observations were made and it was concluded that:

- **1.** Bupivacaine had a slightly faster(quicker) onset of action.
- 2. Duration of analgesia was longer and better in Group B patients who received bupivacaine with fentanyl.
- **3.** Hemodynamic stability was more with Ropivacaine as the fall in blood pressure and heart rate was gradual though statistically not significant.
- **4.** Patients who received 0.25% Bupivacaine with fentanyl had some degree of motor blockade, whereas 0.25% Ropivacaine with fentanyl didn't cause any motor blockade in patients in Group R. so faster mobility and early rehabilitation was observed in patients who received 0.25% ropivacaine with fentanyl due to its decreased potency and shorter duration of action.

References

- [1]. Pouzeratte Y, Brunat G, Boccara G, Vergne C, Jaber S, Fabre J.M Patient controlled epidural analgesia after abdominal surgery: ropivacaine versus bupivacaine Analgesia 2001;93: 1587 -92.
- [2]. Casati A et al: Intraoperative epidural anesthesia and postoperative analgesia with levobupivacaine for major orthopedic surgery: a double-blind, randomized comparison of racemic bupivacaine and ropivacaine. J Clin Anesth. 2003 Mar;15(2):126-31.
- [3]. Brown DL, Carpenter RL, Thompson GE: Comparison of 0.5% ropivacaine and 0.5% bupivacaine for epidural anesthesia in patients undergoing lowerextremity surgery. Anesthesiology. 1990 Apr;72(4):633-6.
- [4]. Liu SS, Moore JM, Luo AM, Trautman WJ, Carpenter RL: Comparison of three solutions of ropivacaine/ fentanyl for postoperative patient-controlled epidural analgesia. Anesthesiology. 1999 Mar;90 (3):727-33.
- [5]. Brockway M.S, Bannister J, McClure JH, McKeown D, Wildsmith JA: Comparison of extradural ropivacaine and bupivacaine. Br J Anaesth.1991 January; 66 (1) 31-7.
- [6]. Tuttle AA et al: A double-blind comparison of the abdominal wall relaxation produced by epidural 0.75% ropivacaine and 0.75% bupivacaine in gynecologic surgery. Reg Anesth. 1995 Nov-Dec;20(6):515-20.
- [7]. K.Knudsen, M.Beckman suurkula, S Bloomberg, J Sjovall & N.Edwardsson: Central nervous system and cardiovascular effects of I.V.Infusion of ropivacaine, bupivacaine and placebo in volunteers. Br J Anaesth. 1997
- [8]. May;78(5):507-14
- [9]. Peter S.Hodgson, MD and Spencer S, Liu, MD: Comparison of ropivacaine with fentanyl to bupivacaine with fentanyl for post-operative patient controlled epidural analgesia. A&A April 2001 Vol. 92 NO.4 1024-1028.