Original Research Article

Comparative study of epidural 0.2% ropivacine and fentanyl with 0.2% levobupivacine and fentanyl for postoperative pain relief for modified radical mastectomy

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Abstract

Background: Effective pain control is crucial for optimal care of surgical patients.Effective post operative analgesia results in decreased stress response and also reduces risk of recurrence and metastasis in cancer patients.Epidural anaesthesia offers most post operative pain relief compared with systemic drugs.Thoracic epidural analgesia is most effective in reducing pain after thoracic and upper abdominal surgeries.In this study,thoracic epidural technique is chosen for post operative management of patients undergoing modified radical mastectomy procedure.
Aims and objectives: To compare the analgesic efficacy and adverse effects after adding 0.2%Ropivacine and 0.2%Levobupivacine with Fentanyl when administered post operatively in thoracic epidural infusion for post operative pain relief. **Methodology:** This is a prospective randomised clinical study, approved by the institutional ethical committee.An individual consent was taken from all patients selected for the study. Total 100 adult female patients undergoing modified radical mastectomy were divided into 2 groups with 50 patients in each group.All patients belonging to ASA grade III.Patients with contraindication for epidural anaesthesia were excluded. **Discussion:** Thoracic Epidural analgesia offers effective postoperative pain relief for patients undergoing oncological breast surgeries.In this study we are comparing the local anaesthetics Levobupivacine and Ropivacineincombination with Fentanyl for epidural analgesia for modified radical mastectomy. **Conclusion:** Ropivacaine 0.2% and Levobupivacaine 0.2% concentration when combined with fentanyl were found out to be equally effective in providing postoperative pain relief with no rescue analgesic consumption, but with a significant higher incidence of hemodynamic side effects and motor blockade noted in Levobupivacaine group,which were easily manageable. There was no significant difference in sedation level and other adverse effects.

Key words: Epidural, Ropivacaine Levobupivacaine, Fentanyl.

Introduction

Pain is a predominant complaint of most of the patients following surgical interventions. Pain is defined as an unpleasant sensory and emotional experience mostly related with definite or potential tissue damage. Effectivepostoperativepain management has a humanitarian role and reduces morbidity, patient agony, length of hospital stay, promotes wound healing, fast recovery and discharge.The regional anaesthetic techniques considerably reduce post operative pain and analgesic requirements. In oncological surgeries, postoperative pain relief reduces the risk of cancer recurrence and metastasis.

Epidural anaesthesia is the most commonly used technique for providing postoperative analgesia in major surgeries.Thoracic epidural analgesia is particularly effective in reducing pain after thoracic and upper abdominal surgery. In my study, thoracic epidural technique is chosen for postoperative pain management for patients undergoing modified radical mastectomy procedure.Lower concentration of local anaesthetic agent either alone or in combination with opioids or alpha-2 agonists are used in epidural for postoperative analgesia. Bupivacaine, Lignocaine with adrenalinearemost commonly used local anaesthetic in epidural technique. As compared with Bupivacaine, Levobupivacaine and ropivacaine are associated with less risk of cardiac and central nervous system toxicity and are less likely to result in unwanted postoperative motor blockade. Addition of opioid like fentanyl helps in improving the analgesic efficacy. This study was done to compare the efficacy of 0.2% Ropivacaine with fentanyl and 0.2% Levobupivacaine with fentanyl in thoracic epidural infusion for postoperative analgesia in modified radical mastectomy surgery.

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Materials and methods

This prospective randomised controlled study was conducted between December 2020 - December 2021 at AlluriSitaramaRaju Academy of MedicalSciences, Eluru, in the Department of Anaesthesiology, after getting approved by the institutional ethical committee and with informed consent.

Inclusion criteria

Female patients aged 35 to 65 years with carcinoma breast posted for modified radical mastectomy and belonging to ASA III

Exclusion criteria

1. Patients refusal
2. Patients allergyto Local anaesthetics and opioids.
3. Patients refusal
4. BMI>35

Procedure

The study was conducted in 100 subjects selected from who were undergoing modified radical mastectomy.The study is carried out after obtaining permission from the concerned authorities and consent from the patients.

Patients were randomly assigned into two groups of 50 each.
GROUP RF:Patients received 0.1ml/kg/hr 0.2%ROPIVACINE WITH 1mcg/ml fentanyl in thoracic epidural infusion for 24hrs in postoperative period
GROUP LF:Patients received 0.1ml/kg/hr 0.2%Levobupivacine with 1mcg/ml fentanyl in thoracic epidural infusion for 24hrs postoperatively
Preoperative evaluation was done a day prior to elective surgery.
Patients were explained about the procedure to be undertaken and also made well conversant with visual analogue scale for post operative pain assessment.
After receiving patient in the theatre,baseline pulserate,BP,ECG,Spo2 are measured and intravenous crystalloids started.After informing the procedure,epidural catherterisation was performed.

Epidural techniques
Strict aseptic precaution
Patient in sitting position
Skin infiltration with 2ml of 2%Lignocaine at T5-6 or T6-7 space. Epidural space is identified by loss of resistance technique using 18G Touhy's needle.
Epidural catheter introduced through 18G Tuohy needle and advanced cephalad for a length of 5cm and fixed.
Test dose of 3ml of 1.5% Lignocaine with adrenaline (1 in 2,00,000 dilution)given.
Intradural/Intravascular placement of the catheter is ruled out.
surgery proceeded with general anaesthesia

Drugs used
Ropivacaine 0.2%
Levobupivacaine 0.2%
Fentanyl

Postoperative period
Visual analogue scale to assess pain sensation, motor block, sedation, hemodynamicsand adverse events were evaluated during 24hours infusion.

Pain score
Assessed by Visual analogue scale.
Pain score is assessed every 15 minutes for first hour,every 30 minutes for next six hours,and every one hour thereafter for 24 hours postoperatively.
If pain score reaches more than or equal 2,the rate of infusion was increased by 2ml/hour maximum upto 14 ml/hour till VAS score becomes less than 2.

Assessment of hemodynamic parameters
Hemodynamic parameters was measured every 15 minutes for first hour,every 30 minutes for next six hours,and every one hour thereafter for 24 hours postoperatively. The following variables are measured:
Pulse rate
Non invasive blood pressure
Electrocardiogram
SpO2

Assessment of motor blockade
Assessment of motor block is done by modifiedBromagescale, assessed every 15 minutes for first hour,every 30 minutes for next six hours,and every one hour thereafter for 24 hours postoperatively.
1-No block(Able to raise extended arm to 90 degree for a full 2s)
2- Partial block(Able to flex the elbow and move fingers but unable to raise the extended arm)
3- Almost complete block(Unable to flex the elbow but able to move finger)
4-Complete block(Unable to move arm,elbow,fingers)
If the patient's bromage score reaches 1,then the infusion rate was tapered by 0.02 to 0.04ml/kg/hour and extent of motor blockade was reassessed every 15mins, till it reaches 0.

Assessment of sedation
Sedation is assessed by the Sedation score,every 15 minutes for first hour, every 30 minutes for next six hours,and every one hour thereafter for 24 postoperatively.
1- Oriented conversation
2- Confused conversation
3- Inappropriate conversation
4- Severe sedation/No conversation.

Adverse effects
1) Nausea
2) Vomiting
3) Bradycardia
4) Hypotension
5) Desaturation
If the patient develops severe nausea and vomiting,antiemetic ondansetron 8mg iv given.

Results
In our study visual analogue scale was used to assess pain intensity and analgesic efficacy between both groups.Decreased pain scores for both groups with time are normal.The patient in both groups did not need any rescue systemic analgesics. statistical analysis shows both drugs are equally effective in providing postoperative pain relief at a concentration of 0.2%,as P-values are not statistically significant $P<0.05$.

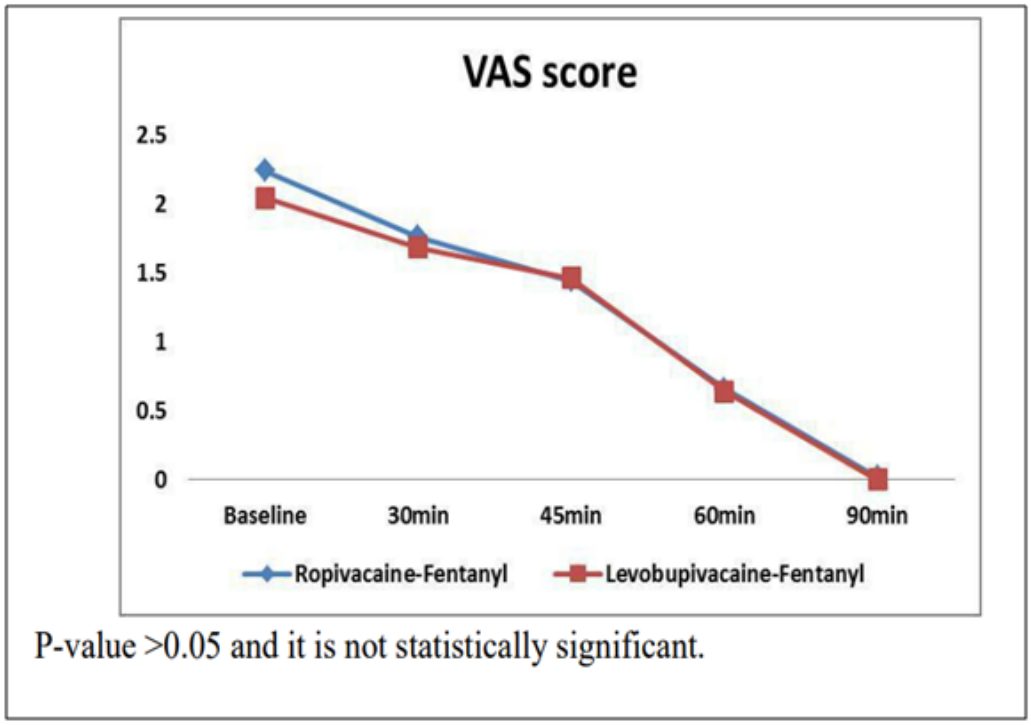

Figure 1: Visual Analogue Score (VAS SCORE)

Patients in Levobupivacaine with fentanyl group developed motor blockade with a modified bromage scale score of 1 at 45 minutes and 60 minutes after onset of continuous epidural infusion with P- value<0.05.

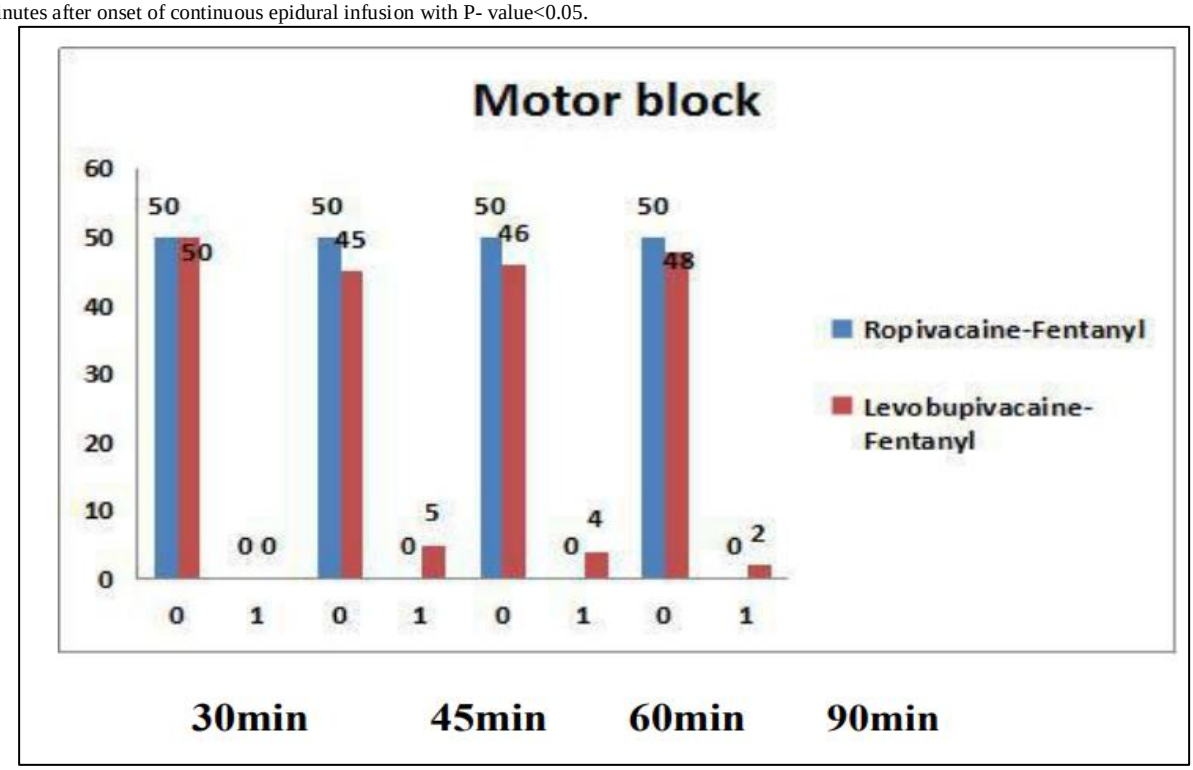

Figure 2: Motor Block

Pulse rate was significantly lower in Levobupivacaine with fentanyl group at 30,45, 60 and 90 minutes interval after onset of thoracic epidural infusion with p- value <0.05.

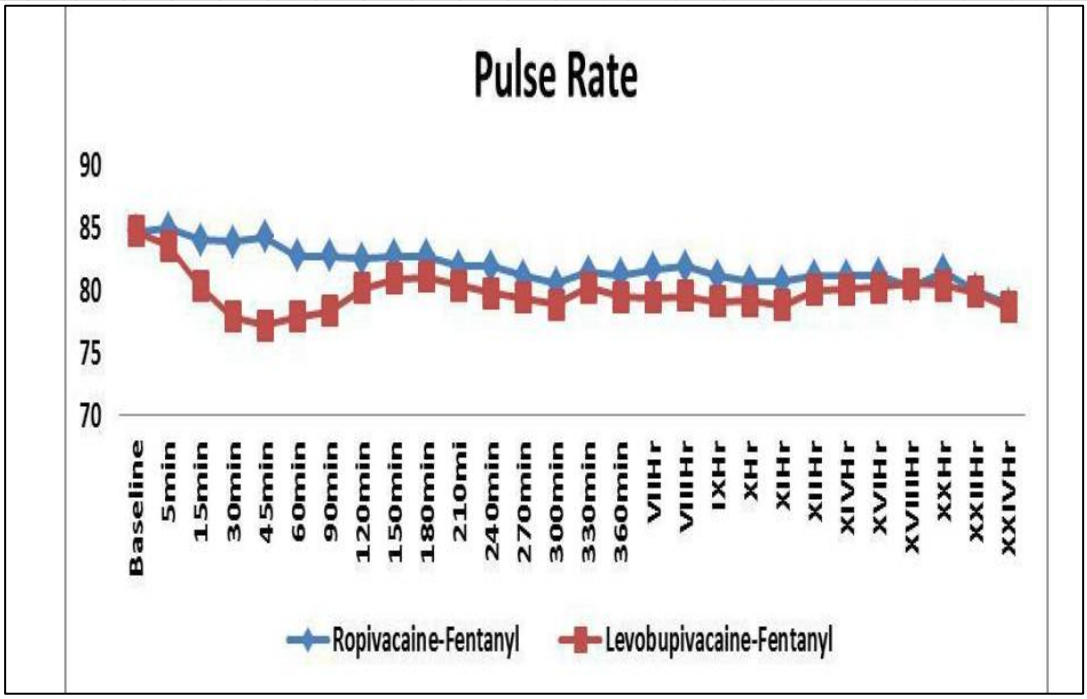

Figure 3: Pulse Rate

The systolic blood pressure, diastolic blood pressure and mean arterial pressure was significantly lower in Levobupivacaine with fentanyl group at 30,45 and 60 minutes interval after onset of thoracic epidural infusion with p- value <0.05.

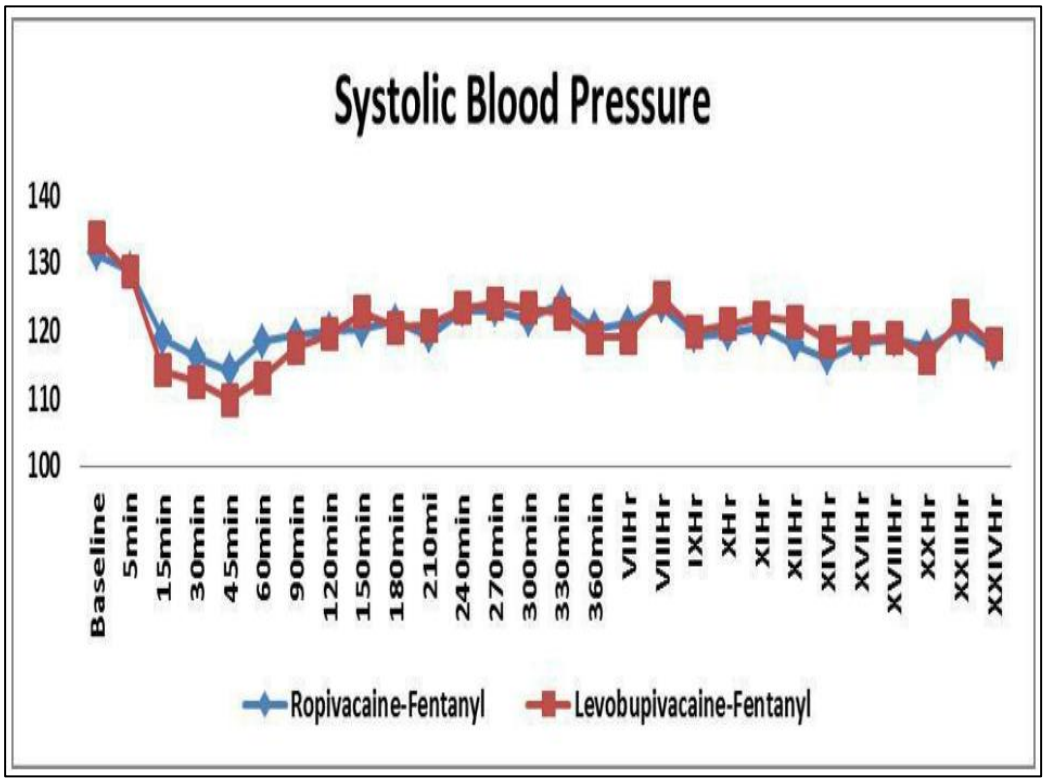

Figure 4: Systolic Blood Pressure

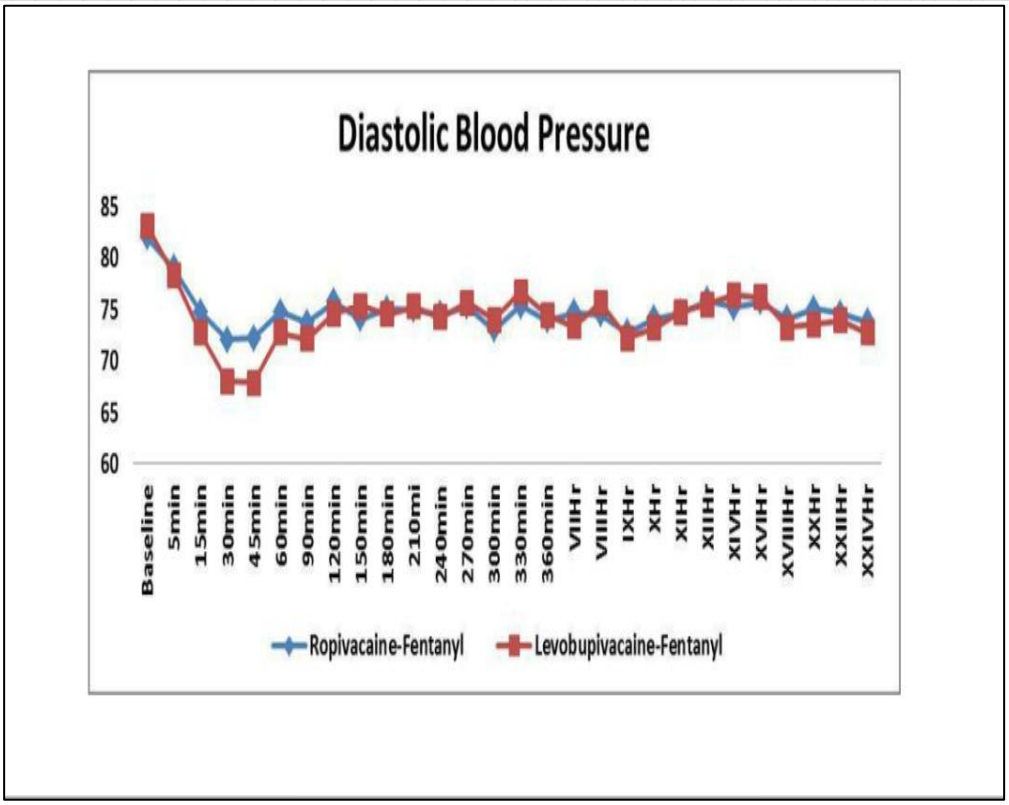

Figure 5: Diastolic Blood Pressure

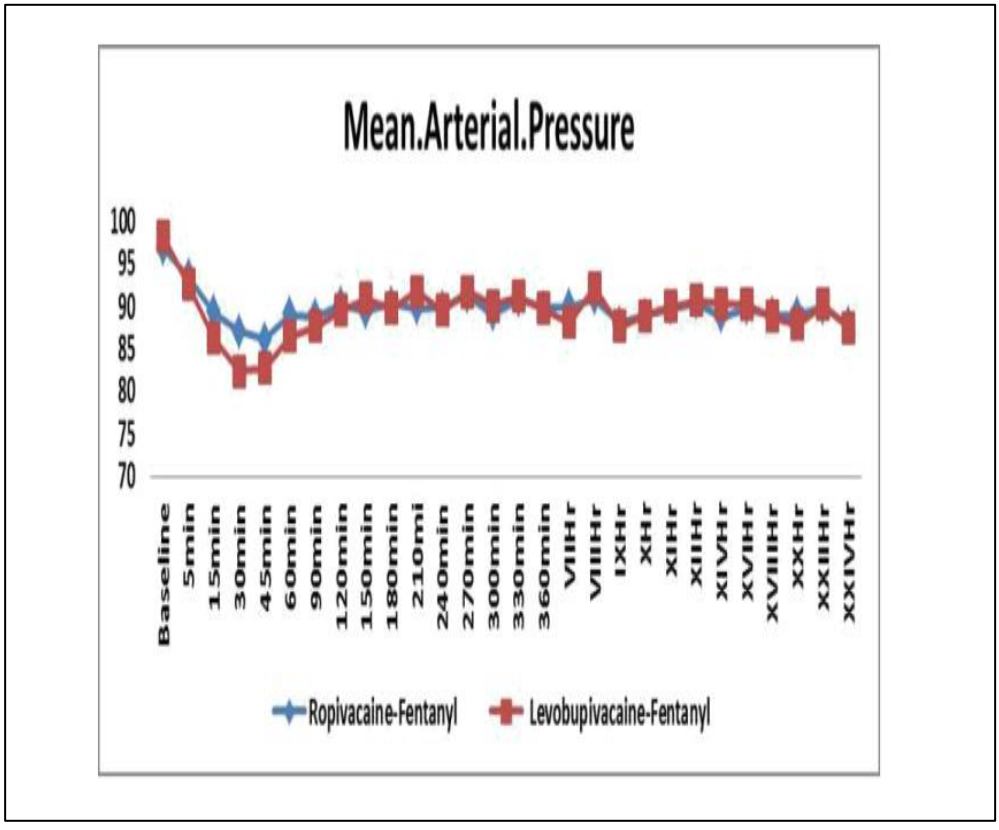

Figure 6: Mean Arterial Pressure

In our study, bradycardia was noted in 9 patients in Levobupivacaine with fentanyl group(HR<60/min). Hypotension (MAP< 70mmHg) was seen in 15 patients in Levobupivacaine with fentanyl group and 9 patients in Ropivacaine with fentanyl group, which was treatable. Nausea and vomiting were higher in Levobupivacaine with fentanyl group compared to Ropivacaine with Fentanyl group.Incidence of pruritus and shivering were equal in both the groups.

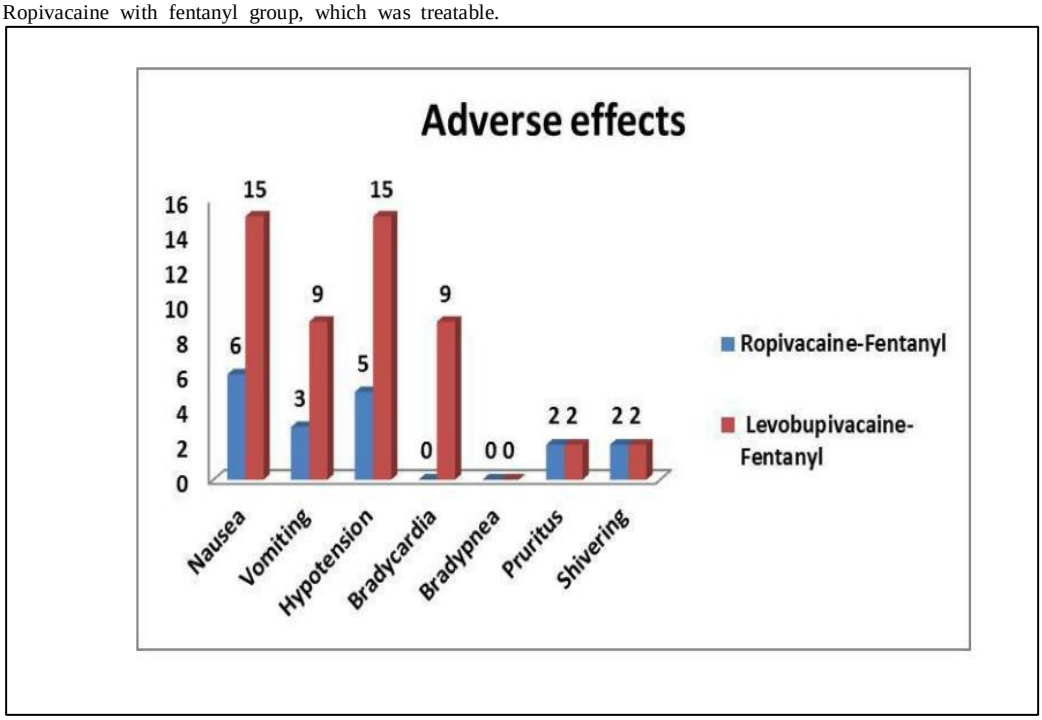

Figure 7: Adverse Effects

Discussion

Thoracic Epidural analgesia offers effective postoperative pain relief for patients undergoing oncological breast surgeries.Other beneficial effects of thoracic epidural analgesia in perioperative period includes:

Decreased need of opioids

Reduced incidence of postoperative pulmonary complications

Reduced postoperative nausea and vomiting

Reduction in cancer progression

Decreased duration of hospital stay.

Local anaesthetics such as Lignocaine,Bupivacaine are commonly used drugs in epidural anaesthesia.Newer drugs such as Ropivacaine and Levobupivacaine are long acting amide type of local anaesthetic with comparatively lower CNS and Cardiac toxicity than Bupivacaine. Based on the previous studies it was found that using local anaesthetic with opioids provides better analgesia when compared with using local anaesthetic alone in epidural analgesia.

Visual analogue scale

In our study visual analogue scale was used to assess pain intensity and compare analgesic efficacy between both groups.Decreased pain scores for both groups with time are normal.The patient in both groups did not need any rescue systemic analgesics.The statistical analysis shows both drugs are equally effective in providing postoperative pain relief at a concentration of 0.2%, as P-values are not statistically significant.

Motor blockade

Nine patients in levobupivacaine with fentanyl group experienced partial block with Bromagescore of 1, whereas patients in ropivacaine with fentanyl group had nil motor blockade. The statistical analysis further concluded that motor blockade was significant with P- value <0.05. Levobupivacaine with Fentanyl group (0.2% concentration) at 45 minutes and 60 minutes after onset of continuous epidural infusion.

Sedation score

From our statistical analysis, it is concluded that sedation level was equal among both groups and is not statistically significant.

Hemodynamic parameters

Significant fall in systolic blood pressure, diastolic blood pressure,mean arterial pressure and bradycardia was noted in Levobupivacaine with fentanyl group .The statistical analysis shows blood pressure and heart rate was significantly lower in Levobupivacaine with fentanyl group at 30,45 and 60 minutes interval after onset of thoracic epidural infusion with p- value <0.05%.

Hemodynamic side effects depends upon the route through which local anaesthetic is administered.There were studies which compared 0.2% Ropivacaine versus 0.2% Levobupivacaine in regional nerve blocks which provides equally effective analgesia with safer hemodynamic profile in both groups.But there were no studies in the literature review comparing 0.2% Ropivacaine versus 0.2% Levobupivacaine in thoracic epidural infusion.

However, there were studies comparing 0.2% Ropivacaine with lower concentration of Levobupivacaine 0.125% in epidural route which concluded both are comparable in its potency and nil hemodynamic side effects were noted.

Respiratory parameters

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

Adverse effects

Adverse effects like hypotension and bradycardia was more in Levobupivacaine with fentanyl group.Nausea was seen in 15 patients in LF group and 6 patients in RF group,Vomiting was observed in 9 patients in LF group and 3 patients in RF group .The statistical analysis of our study shows Levobupivacaine - fentanyl group has higher incidence of nausea and vomiting compared with Ropivacaine-fentanyl group with significant P-value <0.05%.

Summary

In this study we compared the efficacy of 0.2% Ropivacaine with fentanyl versus 0.2% Levobupivacaine with fentanyl in thoracic epidural infusion after modified radical mastectomy surgery for postoperative analgesia.The following conclusions were made from our study: Analgesic efficacy were found to be similar in both groups.The patient in both groups did not need any systemic analgesics.Decreased pain scores for both groups with time are normal.Both drugs found to reduce the adrenocortical stress response associated with pain and patient was found comfortable ,with less VAS scores throughout 24 hours infusion period. Motor blockade was significant among Levobupivacaine-fentanyl group with a modified bromage score of 1 at 0.2%concentraion.The level of sedation was less than 2 in both groups for the entire study period.

Significant fall in systolic blood pressure, diastolic blood pressure and mean arterial pressure was noted in Levobupivacaine-fentanylgroup. Bradycardia was significant in Levobupivacaine-fentanyl group than with Ropivacaine-fentanyl group. Adverse effects like hypotension, bradycardia ,nausea, vomiting was higher in Levobupivacaine-fentanyl group than with Ropivacaine-fentanyl group

Conclusion

Ropivacaine 0.2% and Levobupivacaine 0.2% concentration when combined with Fentanyl in thoracic epidural infusion for oncological breast surgeries were found out to be equally effective in providing postoperative pain relief .No usage of rescue analgesic consumption. Higher incidence of hemodynamic side effects and motor blockade noted in Levobupivacaine group, which were easily manageable. There was no significant difference in sedation level and other adverse effects.

References

1. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian J Anaesthesia2011;55:104- 10
2. Meena Shyam ,DularaSuresh,JoshiAdhokshaj: A Review Study on “Levo-Bupivacaine”.IOSR Journal Of Pharmacy Volume 4, Issue 11 (November 2014), PP. 15-18
3. Bajwa SS, Kaur J. Clinical profile of levobupivacaine in regional anesthesia: A systematic review. J Anaesthesiology Clinical Pharmacology 2013;29:530-9
4. E. Sitsen, M.D, F. van Poorten, M.D et al;A comparison of the efficacy of levobupivacaine 0,125%, ropivacaine 0,125% and ropivacaine 0,2%, all combined with sufentanil 0.5 µg/mL, in patient-controlled epidural analgesia after hysterectomy under combined epidural and general anesthesia.Department of Anesthesiology, Leiden University Medical Center.ActaAnaesth. Belg., 2012, 63, 169-175
5. Casati, Andrea, MD, Vinciguerra, Federico, MD, Cappelleri, Gianluca,MD et al Anesthesia&Analgesia:September 2004 - Volume 99 - Issue 3 -p 919-923 Regional anaesthesia: Research Report.
6. Afaf AA1, Liu CY, Joanna OS et al:Levobupivacaine for postoperative epidural analgesia in orthopaedic surgery.Clin Ter. 2013;164(2):91-5.
7. Chuttani P, Singh U, Grewal A, Katyal S, Kaura A. A comparative study of low concentration of levobupivacaine versus ropivacaine with fentanyl for patient-controlled epidural labour analgesia. J ObstetAnaesth Crit Care 2018;8:35-42.
8. Takashi Egashira,MD, Makoto Fukusaki, MD,et al Comparative Efficacy of Levobupivacaine and Ropivacaine for Epidural Block in Outpatients with Degenerative Spinal Disease.Department of Anesthesia Nagasaki Rosai Hopital, 2-12-5, Setogoshi, Sasebo, Nagasaki, 857-0134,Japan.
9. Saroa R, Palta S, Puri S, Kaur R, Bhalla V, Goel A. Comparative evaluation of ropivacaine and levobupivacaine for postoperative analgesia after ultrasound-guided paravertebral block in patients undergoing 97 percutaneous nephrolithotomy. J Anaesthesiol Clin Pharmacol2018;34:347-51.
10. Shen-Chih Wang et al, Comparison of Three Different Concentrations of Ropivacaine for Postoperative Patient-controlled Thoracic Epidural Analgesia After Upper Abdominal Surgery Acta Anaesthesiol Taiwan 2008;46(3):100−105 .
11. De Cosmo G,Mascia A et al,Use of levobupivacaine for the treatment of postoperative pain after thoracotomies.MinervaAnestesiologica 2005 June;71(6):347-51
12. Patil SS, Kudalkar AG, Tendolkar BA. Comparison of continuous epidural infusion of 0.125% ropivacaine with 1µg/ml fentanyl versus 0.125% bupivacaine with 1µg/ml fentanyl for postoperative analgesia in major abdominal surgery. J Anaesthesiol Clin Pharmacol2018;34:29-34.
13. Khan A, Nanda HS, Chandra R. Levobupivacaine versus Ropivacaine: A Comparative Study of the Analgesic and Hemodynamic Spectrum. Int J Sci Stud 2016;4(1):190-195.
14. Clinical Anesthesia,Paul G. Barash, MD, Bruce F. Cullen, MD Seventh edition,pg no:1615-1617;
15. Leone S, Di Cianni S, Casati A, Fanelli G. Pharmacology, toxicology, and clinical use of new long acting local anesthetics, ropivacaine and levobupivacaine. Acta Biomed. 2008;79(2):92-105.
16. Boregowda S M, Linganna B P, Raju S K, A clinical comparative study of 0.2% levobupivacaine with 25 mcg fentanyl versus 0.2% ropivacaine with 25 mcg fentanyl for post-operative epidural analgesia in patients undergoing lower limb orthopaedic surgeries. *Indian J Clin Anaesth* 2018;5(2):237-243
17. Lee HL, Lo LM, Chou CC, Chuah EC. Comparison between 0.08% ropivacaine and 0.06% levobupivacaine for epidural analgesia during nulliparous labour. Chang Gung Med J 2011;34:286-91.
18. Li Y, Hu C, Fan Y, Wang H, Xu H. Epidural analgesia with amide local anesthetics, bupivacaine, and ropivacaine in combination with fentanyl for labor pain relief: a metaanalysis. Med Sci Mon Int Med J Exp Clin Res 2015 Jan;21: 921e8.
19. Malinovsky JM, Charles F, Kick O, Lepage JY, Malinge M, Cozian A, et al. Intrathecal anesthesia: ropivacaine versus bupivacaine. AnesthAnalg. 2000;91(6):1457-60.
20. Kallio H, Snäll EV, Kero MP, Rosenberg PH. A comparison of intrathecal plain solutions containing ropivacaine 20 or 15 mg versus bupivacaine 10 mg. AnesthAnalg. 2004;99(3):713-7.
21. Gautier E, De Kock M, Van Steenberge A. comparison between intrathecal bupivacaine and ropivacaine for knee arthroscopy. Anaesthesiology. 1999;91(5):1239-45.