

A Study to Compare Intravenous Fentanyl With Epidural Bupivacaine-Fentanyl Combination For Post Operative Analgesia in Patients Undergoing Modified Radical Mastectomy



Medical Science

KEYWORDS : Thoracic epidural, MRM, fentanyl, pain

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ABSTRACT

Thoracic epidural analgesia is increasingly being used nowadays for post operative pain for better outcomes. The aim of this study was to compare the pain relief and complications when fentanyl is given through intravenous (IV) route versus epidural route in combination with bupivacaine in patients undergoing Modified Radical Mastectomy (MRM). The study was conducted on 60 females undergoing Modified Radical Mastectomy. 30 patients were given epidural fentanyl and bupivacaine and 30 patients received fentanyl through intravenous route. The post operative analgesia was evaluated and the data from the above study was systematically collected, compiled and statistically analyzed to draw relevant conclusions.

INTRODUCTION:

Breast cancer has remained the second leading cause of cancer death among women worldwide over the past three decades and contributes significantly to cancer surgical load.¹ The various treatment modalities of breast cancer are pharmacological, surgical, radiation therapy and chemotherapy. The various types of mastectomies are:

Simple: Also called a total mastectomy. It involves removal of the entire breast and nipple, but not the underarm lymph nodes or muscle underneath the breast.

Skin Sparring: It involves removal of the breast, taking the nipple and areola and only the skin that must be removed to prevent the spread of cancer.

Radical: It involves removal of the breast, axillary lymph nodes and the chest muscles under the breast.

Modified Radical: It involves removal of the breast and some axillary lymph nodes.

Post operative pain results in impaired ventilation of the patient due to painful restricted movement and ultimately leads to deterioration of the patient.² When the patients remain pain free after surgery and there is no discomfort, the time of hospital stay and their expenditure will decrease and they can be ambulated rapidly and there would be much less complications.^{3,4,5}

MATERIALS AND METHODS

The present study was conducted on 60 females of grade I and II of American Society of Anesthesiologists (ASA) undergoing Modified Radical Mastectomy (MRM), in the department of Anaesthesia at Sri Guru Ram Dass Institute of Medical Sciences and Research, Amritsar, after taking informed consent from the patients and attaining approval from hospital ethics committee.

The presence of any of the following conditions excluded the patients from this study:

1. Patients having bleeding diathesis
2. Patients on any anticoagulant therapy
3. Patients with known hypersensitivity to local anaesthetics or study drugs.
4. Patients having history of drug abuse
5. Patients who are mentally retarded
6. Patient suffering from asthma, cardiac, respiratory, renal,

hepatic and CNS disorders.

7. Patients with local sepsis or spinal deformity.

Allocation of Groups:

After taking informed consent, the patients were randomly allocated into two groups of 30 each:

Group A (n=30) Received 6ml of 0.125% bupivacaine+ 2 microgram/ml fentanyl through epidural route.

Group B (n=30) Received 2 microgram/kg of fentanyl through intravenous (IV) route.

A day before surgery, all the patients were examined and investigated. Details pertaining to the patients clinical history, general physical and systemic examinations and basic routine investigations like Hb, BT, CT, urine for albumin and sugar were noted. The patient was kept fasting overnight. All patients were given tablet anxit 0.5 mg orally at night before surgery and 6 A.M. on the morning of surgery and were re-assessed in the pre-anaesthetic room. Patients were explained in their own vernacular language linear visual analogue scale using a 10 centimeter line, where 0 denoted "no pain" while 10 "worst pain imaginable"

In the operation theatre intravenous line with ringer lactate was started and all patients in both the groups were preloaded at rate of 10 ml/kg over 15-20 minutes. Reading of heart rate, blood pressure, electrocardiogram and peripheral arterial oxygen saturation measured were taken as baseline parameters. Premedication consisted of injection midazolam 0.03 mg/kg body weight. In group I, an epidural catheter was inserted at T4-5 level or T5-6 level with full aseptic precautions with head supported and flexed. The Tuohy's needle (18 gauze) was inserted in the midline after local infiltration with 2% lignocaine hydrochloride. Loss of resistance technique to air and saline was used to identify the epidural space. A test dose of 3ml 2% lignocaine containing epinephrine was given to exclude intravascular or intrathecal injection. Then, 6ml of 0.125% bupivacaine + 2 microgram/ml fentanyl was given through epidural route in patients of group I, 10 minutes before the surgery.

In patients of group II, 2 microgram/kg of fentanyl was given through intravenous route 10 minutes before the surgery.

In both the groups, general anesthesia was induced using injection propofol 2mg/kg and injection vecuronium 0.08 mg/kg was given to facilitate intubation. Maintenance was done by oxygen/

nitrous oxide/ halothane.

Intraoperatively IV Paracetamol 10mg/kg was given 2 hours after induction or before that if heart rate or BP had risen by >20% of baseline values. At the end of the surgery, reversal was done with glycopyrrolate (0.4 mg) and neostigmine (2.5 mg) and the patients were extubated and shifted to the recovery room. On arrival in the recovery room, the patients were evaluated for vitals, pain, sedation, side effects and were counted as zero hours. The patients were observed 2 hourly thereafter for:

- A) Pain: It was measured using Visual Analogue Scale (VAS) at arrival in the recovery room, then every 2 hourly upto 24 hours.
- B) Sedation score of the patients: It was assessed at arrival in the recovery room, then every 2 hourly upto 24 hours.
- C) Side effects (pruritus, nausea, vomiting, hypotension, bradycardia, respiratory depression)
- D) Post operative analgesia: The patients in group A received top up with epidural bupivacaine-fentanyl while the patients in group B received IV fentanyl on the request of the patient if VAS>3 with a lock-out period of 4 hours in both groups during which the top up was not repeated. If pain was still not controlled, rescue analgesia was given by 75 mg diclofenac IM.

The data from the above study was systematically collected, compiled and statistically analyzed to draw relevant conclusions

OBSERVATIONS AND DISCUSSION:

Both the groups were comparable in terms of mean age of patients, hemodynamics and mean duration of surgery.

PAIN:

It was assessed using the VAS score. Patients were explained in their own vernacular language 10 point scoring system where 1 denoted “no pain” and 10 denoted “worst pain ever”. It was measured using Visual Analogue Scale (VAS) at arrival in the recovery room, then every 2 hourly upto 24 hours.

In our study, the patients in group II (receiving intravenous fentanyl) had statistically significant higher mean VAS scores than the patients in group I at 10 hours post-operatively. The mean number of top ups also had comparatively been more in patients of group II although it was statistically non-significant.

Correspondingly, more number of patients in group II (receiving intravenous fentanyl) required second dose of top-up which was statistically greater than the number of patients in group I requiring second dose of top-up thus pointing to prolonged duration of analgesia by epidurally administered bupivacaine-fentanyl combination. Also, the time to first top-up requirement post-operatively was statistically less in patients of group II again pointing to prolonged duration of analgesia by epidural bupivacaine-fentanyl.

Thus it can be concluded that patients receiving epidural bupivacaine-fentanyl combination had a comparatively better pain relief than patients receiving intravenous fentanyl. Also, according to Lynch et al in 1995, the use of thoracic epidural for breast surgery could improve patients’ recovery and reduce the cost of these procedures. Our results were also in agreement with the studies conducted by Yeh CC⁶ et al (1999). Further, similar results were also found in a study conducted by Doss et al⁷ in 2001, which further goes on to report prolonged post-surgical pain relief in patients of thoracic epidural in agreement with our study. Sundarathithi et al⁸ in 2005 also concluded better postoperative pain relief, faster anesthetic recovery and greater patient satisfaction by using thoracic epidural anaesthesia in combination with ipsilateral brachial plexus block. A study conducted by

Eva Oktavia⁹ in 2015 also concluded that thoracic epidural anesthesia gives a shorter hospital stay due to reduced pain post-operatively.

SEDATION SCORE:

First 4 hours post-operatively sedation score was comparatively more in patients of group II although it was statistically non-significant.

RESPIRATORY RATE:

The difference of respiratory rate between both the groups was statistically non-significant intraoperatively as well as post-operatively. This was in agreement to the studies conducted by Sundarathithi et al (2005) and Hansdottir V et al (2006)¹⁰

COMPLICATIONS:

Intra-operatively, 2 patients in group I (epidural bupivacaine-fentanyl) experienced hypotension which was statistically non-significant.

Post operatively, one patient in both group I (epidural bupivacaine-fentanyl) and group II (intravenous fentanyl) experienced hypotension which was statistically non-significant. Three patients in group II experienced nausea and vomiting as compared to one patient in group I (epidural bupivacaine-fentanyl) which was statistically non-significant. Rest all other complications like respiratory depression, pruritus were not seen.

Figure 1: Comparison of VAS Between Both the Groups Post-operatively

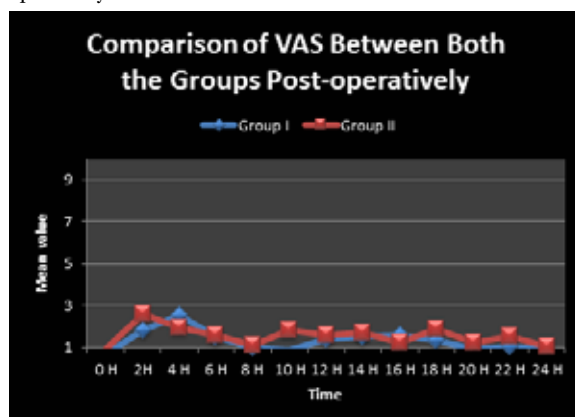


Figure 2: Time for first top-up

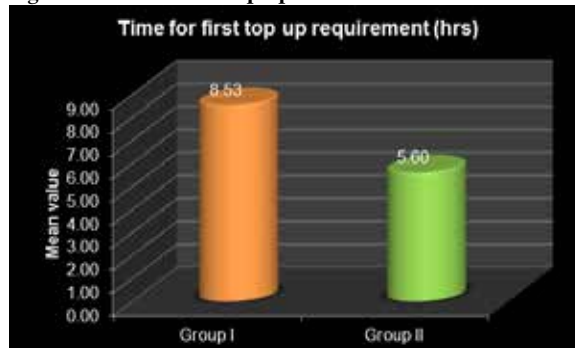


Table 3: No. of patients requiring 2nd top-up

Second top up	Group I	Group II
Required	13	22
Not required	17	8
Total	30	30

Group I-Epidural bupivacaine-fentanyl, Group II –Intravenous

fentanyl

$\chi^2 = 5.554$; $df = 1$; $p = 0.018$; Significant

As shown by table 3, the number of patients requiring second dose of top-up was more in patients of group II compared to group I which was statistically significant ($p=0.018$).

CONCLUSION:

Overall, the patients receiving bupivacaine-fentanyl combination through the thoracic epidural route experienced lesser pain, better VAS scores, with prolonged duration of analgesia and hence can be regarded as a better method than intravenous fentanyl for pain relief.

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