



Anaesthesiology

A PROSPECTIVE RANDOMIZED STUDY TO COMPARE THE EFFECT OF 0.125% BUPIVACAINE WITH FENTANYL OR WITHOUT FENTANYL VIA EXTRAPLEURAL PARAVERTEBRAL CATHETER FOR CONTINUOUS POSTOPERATIVE ANALGESIA IN THORACIC SURGERIES.

Kaushal Kabir

Associate Professor, Department of anaesthesiology, M Y Hospital and M G M Medical College , Indore, M. P. India

Madhuri Bharang

Assistant Professor, Department of anaesthesiology, M Y Hospital and M G M Medical College , Indore, M. P. India

Brejendra Singh Gill

P G Resident, Department of anaesthesiology, M Y Hospital and M G M Medical College , Indore, M. P. India

K K Arora

Professor and Head, Department of anaesthesiology, M Y Hospital and M G M Medical College , Indore, M. P. India

KEYWORDS :**INTRODUCTION**

The most common problem of any surgical intervention is postoperative pain, which requires appropriate analgesia. The differential responses to the tissue injury during incision are often influenced by many variables including global (i.e. age, personality, gender, surgical approach, genetic, preexisting pain syndrome) and specific (i.e. anxiety, anger, fear, depression, psychological factors).^[1]

Pain is a complex process for the patient and the Anaesthesiologist who are tasked with managing it. Four processes cause pain perception: transduction, transmission, modulation, and perception. Postoperative pain is related to many factors, including the amount of soft tissue injury, resulting inflammation, and rib injury as in the case of a thoracic surgical procedure.

Post-thoracotomy pain is one of the severe sorts of postoperative pain. The insufficient treatment of post-thoracotomy pain results in reduced pulmonary compliance, inability to breathe deeply or cough forcefully and retention of secretions, atelectasis and pneumonia.^[2] Several techniques are available for management of pain in thoracic surgery, including paravertebral, intercostals, interpleural and epidural blocks with local anaesthetics and opioids.^[3]

Thoracotomy pain arises due to intercostal nerve damage. Due to this pain, respiratory functions compromise leading to post-op pulmonary complications and patient stay for a long time in hospital thus increases the burden. There are many drugs and techniques for relief of postoperative pain, Regional technique or systemic analgesics are common. Systemic opioids carry the risk of respiratory depression and NSAIDs are poor analgesics for thoracotomy incision. Extrapleural paravertebral catheter is an alternative technique to decrease the pain in thoracotomy.^[4] Numerous studies have evaluated the efficacy of combined narcotic/local anesthetic epidurals and found them to provide excellent pain relief.^[5,6,7,8] An alternative method of providing post-thoracotomy analgesia is the use of continuous infusion of local anaesthetics via extrapleural catheter. This form of analgesia shows excellent results with minimal complications.^[6,8,9,10] For the placement of extrapleural catheters an 18-gauge Tuohy needle is placed through the chest wall at a convenient site two interspaces below the thoracotomy incision and few centimeters away from the chest tube site. The needle's stylet is removed, and an epidural catheter is passed through the needle and is placed inside the extrapleural space.

We carried out this study to prospectively compare the effect of 0.125% Bupivacaine with Fentanyl or without Fentanyl via extrapleural paravertebral catheter insertion for continuous postoperative analgesia in patients undergoing thoracic surgeries.

MATERIALS AND METHODS

This prospective, randomized, comparative study was conducted for a period of one year in the Department of Anaesthesiology, M.Y. Hospital & M.G.M medical college, Indore.

Sample Size

The study was comprised of 40 patients divided in to two groups of 20 each scheduled for elective thoracic surgery under general anaesthesia. The sample size was calculated using G* power, software version 3.1.9.2 and 95% confidence level and 80 % power for two groups using 't' test (mean difference between two independence groups) for large effect size 'd' (0.8).

Inclusion Criteria

- Patients posted for thoracic surgery (decortications, pleurectomy).
- Age group 18-65 year of age
- ASA grade I, II.

Exclusion Criteria

- Patient refusal.
- ASA grade III, IV.
- Hypersensitivity to local anaesthetics.
- Coagulation profile deranged.
- Platelet count <50000.
- Non intact pleura at paravertebral space.
- Adhesion, infection, tumor, scarring in paravertebral space.

Ethical Clearance

The study was approved by the institutional ethics and scientific review committee of M.G.M. Medical college and M.Y. hospital indore prior to commencement.

Randomization

Patients were randomly allocated by chit method just before surgery to group 1 (B) or group 2 (B+F) comprising 20 patients each.

Procedure

After obtaining written informed consent and recording vitals and nil by mouth status as per institutional protocol, all patients were started intravenous fluids. Routine monitors were attached (pulse oximeter for SpO₂, heart rate (HR), non-invasive blood pressure and ECG). General anaesthesia was given as standard institutional protocol. Intubated with appropriate size double lumen endotracheal tube after giving muscle relaxant. Thoracotomy was done. An extrapleural catheter was inserted by the surgeon under direct vision external to the parietal pleura just before thoracotomy closure. Then an infusion of 0.125 % Bupivacaine @ 0.15 ml/kg/hr in Group 1 (B) and 0.125% Bupivacaine with fentanyl 2mcg/ml @ 0.15 ml/kg/hr in Group 2 (B+F) was started. Then dose or rate of infusion was decreased after 2 days or chest drain removal, as pain subsided.

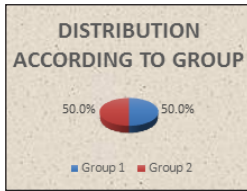
Assessment Of Postoperative Pain And Management

The pain score using visual analogue scale was assessed at 1, 6, 12, 18, 24, 48 and 72 hours after the surgery. Patients who complained of pain with a VAS score of more than or equal to 4 were given Inj. Tramadol 1mg/kg (rescue analgesia). The peak expiratory flow rate assessed at 12, 24, 48, 72 hrs. The hemodynamic changes and adverse events including sedation, hypotension, nausea, vomiting, pruritus, etc. were

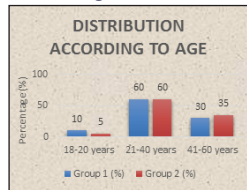
assessed in all the patients at 1, 6, 12, 18, 24, 48 and 72 hrs.

Statistical Analysis

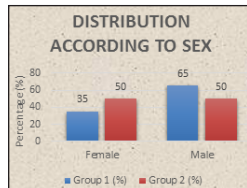
Data was initially collected in the customized proforma designed for the purpose of the study. Then this data transferred to Microsoft Excel for analysis and online statistical software graph pad and Epi info was used for calculating p value. comparison of means between the two group was done using unpaired 't' test. A p value of < 0.05 was considered as statistically significant. The final data was presented in the form of tables and graphs.



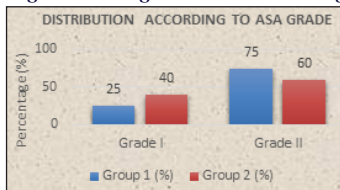
Graph 1: Pie Diagram Showing Distribution According To Group



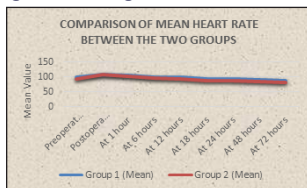
Graph 2 : Bar Diagram Showing Distribution According To Age



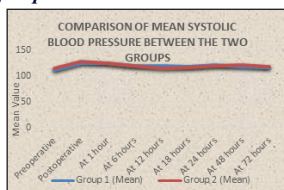
Graph 3 : Bar diagram showing distribution according to sex



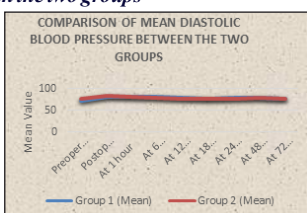
Graph 4 : Bar diagram showing distribution according to ASA grade



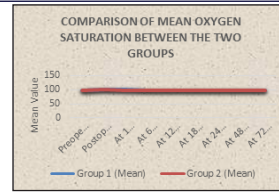
Graph 5: Line diagram showing comparison of mean heart rate between the two groups



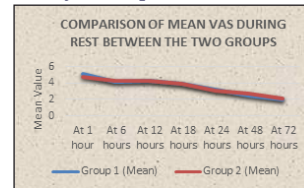
Graph 6: Line diagram showing comparison of mean systolic blood pressure between the two groups



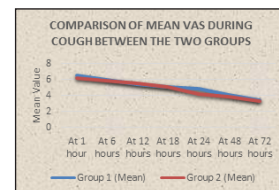
Graph 7: comparison of mean diastolic blood pressure between the two groups



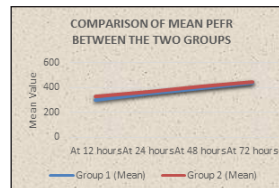
Graph 8: comparison of mean SpO2 between the two groups



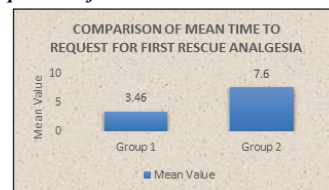
Graph 9: comparison of mean VAS during rest between the two groups



Graph 10: comparison of mean VAS during cough between the two groups



Graph 11: comparison of mean PEFR between the two groups



Graph 12: Bar diagram showing comparison of mean time to request for first rescue analgesia

DISCUSSION

Thoracic surgeries are associated with severe postoperative pain. Pain is mainly associated with the incision that is made. Control of pain following a thoracic surgery is very important concern as uncontrolled pain may lead to respiratory complications like atelectasis, diaphragmatic dysfunction, respiratory failure, splinting, and ineffective cough resulting in pneumonia. Local anesthetics was given through extrapleural catheter to reduce postoperative pain in thoracic surgery patients.

In our study the patients were comparable with respect to age, gender and demography wise distribution.

The mean preoperative heart rate was 100.2 ± 12.76 per minute In Group 1(B), and 94.4 ± 6.95 per minute in Group 2(B+F). The mean heart rate was comparable between the two groups at preoperative, postoperative, at 1 hour and at 6 hours postoperatively (P>0.05), while the mean heart rate was significantly lower in Group 2(B+F) at 12 hours, 18 hours, 24 hours and at 72 hours postoperatively (P<0.05) in comparison to Group 1(B).

The mean systolic blood pressure, mean diastolic blood pressure, mean oxygen saturation and mean pain score (VAS) – both during rest and during cough were comparable between the two groups at all the time intervals (P>0.05).

The mean VAS during rest at 1 hour postoperatively was 5.1 ± 0.91 In Group 1(B), and 4.7 ± 1.3 In Group 2(B+F), The mean pain score

(VAS) was comparable in both the groups in all time intervals. However the pain is controlled in both the groups effectively.

In Group 1(B), the mean VAS during cough at 1 hour postoperatively was 6.5 ± 0.83 , and In Group 2(B+F), the mean VAS during cough at 1 hour postoperatively was 6.2 ± 1.01 , The mean VAS during cough was comparable between the two groups at all time intervals ($P > 0.05$).

The mean PEFR was also comparable between the two groups at 12 hours ($P=0.114$), at 24 hours ($P=0.432$), at 48 hours ($P=0.495$) and at 72 hours ($P=0.832$). In both the groups, we have noticed, improvement in PEFR from 12 hours to 72 hours that is in group 1(B) 300.00 ± 79.07 L/min at 12 hours and 440.50 ± 63.12 L/min at 72 hours while in group 2(B+F) 332.50 ± 42.41 L/min at 12 hours and 444.00 ± 36.91 L/min at 72 hours. From above values, we observed improvement in lung functions.

These findings correlate with Eng et al^[11] and Barron D et al^[12] in which they found that extra-pleural infusion of local anaesthetics is a simple and easy technique, with low risk of complications and provides effective pain relief as well as an improvement in post-operative pulmonary function.

The mean time taken for request to first analgesia in Group 1(B) was 3.46 ± 4.22 hours and in Group 2(B+F) was 7.60 ± 6.95 hours and this mean time was found to be statistically comparable between the two groups ($P=0.091$). The reason for non-significant could be due to less number of patients requesting for rescue analgesia in both the groups.

There were no infusion related complications and toxicity in our both groups even after 72 hours of bupivacaine infusion. Safety profile was documented in Berrisford et al^[13], who also not found any toxicity even after 120 hours of bupivacaine infusion. Safety profile was also documented in Carabine et al^[14], in this study they found no associated adverse effects of use of extrapleural bupivacaine infusion.

Rationale Of Study

Adjuvant increases the efficacy & potency of local anesthetics drugs thus improves the analgesia and prolongs the duration of analgesia. Opioids are usually used as additive, Lipophilic drugs like Fentanyl has less side effects and improves analgesia. By this study we want to compare the quality and duration of analgesia. As pain decreases, the respiratory function subsequently improves and patient gets discharge earlier from hospital and the hospital burden also decreases in terms of stay and cost.

CONCLUSION

It can be concluded that continuous extrapleural paravertebral catheter infusion of local anaesthetics is effective in the management of postoperative pain in patients undergoing thoracic surgeries. Group 2 (B+F) has longer duration of analgesia and later requirement of first rescue analgesia, better PEFR compared to group 1(B), though it is not statistically significant.

Limitation Of Study

Although this study has tried to meet its aims and objectives in all aspects, there are few limitations to it. We conducted a single-centre study, we did not compare the efficacy of extrapleural catheter with thoracic epidural and inter pleural analgesia in our study, total sample size 40 (20 in each group), if sample size are large then results will be more precise.

To overcome these limitations, a multicentric study with larger sample size is needed to obtain more conclusive results.

Conflict Of Interest

None

Source Of Funding

None

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