

Comparison of Thoracic Analgesia with Epidural Fentanyl and Transdermal Fentanyl Patch: A Comparative Prospective Randomized Study

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Abstract

Background: Thoracic epidural analgesia (TEA) is used for analgesia following lower abdomen or orthopaedic surgeries. The aim of study was To compare the effects of 0.125% Bupivacaine with 2mcg/ml of Fentanyl infusion (group A) and 0.125% Bupivacaine with fentanyl patch (group B).

Methods: Patients undergoing elective surgery were randomized in a non-blinded fashion to receive postoperative analgesia at a single teaching hospital. A nested qualitative study (reported elsewhere) explored the dual primary outcome of patient experience and acceptability. Secondary outcome measures included rest and movement pain scores over 72 h, functional analgesia, analgesia satisfaction, opiate consumption, functional recovery, morbidity, safety, and cost-effectiveness.

Results: A total of 40 patients were randomized. The median (interquartile range; i.q.r.) dynamic pain score at 24 h was significantly lower after TEA than RSCA (33 (11–60) *versus* 50.5 (24.50–77.25); $P=0.018$). Resting pain score at 72 h was significantly lower (4.5 (0.25–13.75) *versus* 12.5 (2–13); $P=0.019$). Opiate consumption on postoperative day 3 (median (i.q.r.) morphine equivalent 17 (10–30) mg *versus* 40 (13.25–88.50) mg; $P=0.038$), hypotension, or vasopressor dependency (29.7 *versus* 49.2 per cent; $P=0.023$) and weight gain to day 3 (median (i.q.r.) 0 (–1–2) kg *versus* 1 (0–3) kg; $P=0.046$) were all significantly greater after TEA.

Conclusions: TEA provided superior initial postoperative analgesia but only for the first 24 h. By 72 hours and provides superior analgesia, is associated with a lower incidence of unwanted effects, and may be more cost-effective.

Keywords: fentanyl, analgesia, pain, chest wall

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Introduction

Thoracic surgery pain is most common severe types of postoperative pain commonly occurring in more than 70.0% of patients. Its after effects might last for several months or even years, significantly degrading quality of life¹. Not only is postoperative analgesia required ethically, but it is also necessary because it helps control the stress response and maintain respiratory function. Loss of pulmonary parenchyma and postoperative discomfort have a negative impact on the mechanisms of the chest wall, making it difficult for patients who are at high risk for respiratory and cardiac issues to receive the necessary postoperative physiotherapy². Reduced lung function is correlated with preoperative respiratory capacity, lung resection extent, and level of pain. Cough, depth of breathing, and expectoration are improved by successful analgesia. This also reduces the occurrence and severity of hypoxia, atelectasis, pneumonia, retention of secretions and respiratory failure. These improvements affect the rate of sequelae³.

Multiple nociceptive and descending modulatory inputs are involved in the pathophysiology of thoracotomy pain, therefore it is impossible to predict an appropriate postoperative analgesia from knowledge of the relevant components. Surgery-related traumatising events include making surgical incisions, stretching ligaments, and inserting rib retractors in intercostal gaps to facilitate pleural manipulation. A bigger inflammatory process is started when peripheral nociceptors are activated by the inflammatory response. This larger inflammatory process amplifies pain transmission and changes pain perception through central sensitization. Through the afferent branches of the vagus and phrenic nerve, which appear to be the cause of shoulder pain, manipulation of the pleura/pericardium and bronchi stimulates visceral discomfort⁴.

Material and Methods

After approval from institutional ethical committee this prospective randomized study was conducted on 40 patients, of either sex, aged 18 years and older, ASA physical status I- III scheduled for thoracic surgeries through posterolateral thoracotomy.

Exclusion Criteria Included

- History of relevant drug allergy
- Opioid dependence
- Contraindication for thoracic epidural
- Morbid obesity (BMI>40)
- Bleeding disorders (Coagulopathy)
- Psychiatric Illness
- Infection at injection site
- Liver or renal impairment

Inclusion Criteria Included

- Patients of either sex
- Age group of 20-60 years
- ASA Staus I-III

Pre-operative assessment was done a day prior to surgery. This includes a detailed history regarding physical health, other co-morbidity, current medication, drug allergy and previous anesthetic and surgical experience. The clinical examination was done along with laboratory investigations which includes complete hemogram, serum electrolytes, blood urea, serum creatinine, pulmonary function test, electrocardiogram and chest roentgenogram. Study protocol was explained to the patients and written informed consent was obtained from all the participants during pre-anesthetic evaluation. Visual analogue scale (VAS) 64 was explained to the patients. It consisted of a 10-cm unmarked linear scale where 0=no pain and 10=worst imaginable pain. All the patients was kept fasting after 12 midnight for solid food. By using a computer generated randomization table all the subjects were divided into two groups (A and B) consisting of 20 patients in each group.

Following premedication was advised:

- Tab Alprazolam 0.25 mg orally at 10 pm night before surgery and 0.25 mg at 6am on day of surgery.
- Tab Rantidine 150 mg orally at 10 pm night before surgery and 150 mg at 6 amon day of surgery.

Group-A: In Group A patients, epidural analgesia was activated using 5-10 ml bolus of 0.25% of bupivacaine which were administered over a period of 10 min toward the start of the surgery, before

chest incision and infusion of 0.125% bupivacaine with 2 mcg/ml of fentanyl will be started at a rate of 5–8 ml/h through syringe pump. Placebo patch was applied 12 hours before surgery on the back of patient away from surgical field.

Group-B: In Group B patients, epidural analgesia was activated using 5–10 ml bolus of 0.25% of bupivacaine which were administered over a period of 10 min toward the start of the surgery, before chest incision and infusion of 0.125% bupivacaine was started at a rate of 5–8 ml/h through syringe pump. Fentanyl patch was applied 12 hours before surgery on the back of patient away from surgical field. All the participants and investigator providing postoperative care were blinded to the group assignment.

Intraoperative monitoring consisted of:

- 5-lead electrocardiogram (ECG)
- Invasive blood pressure (IBP)
- finger pulse oxymetry
- end tidal carbon-di-oxide (EtCO₂)
- nasopharyngeal temperature
- Central venous pressure.

Results

In our study, 40 patients were studied and were randomly divided into 2 groups of 20 patients each -

Table 1: Distribution of patients on the basis of group

Groups	Administration drug	Number of patients (%)
Group A	Bupivacaine with fentanyl + placebo patch	20 (50.0%)
Group B	Bupivacaine + Fentanyl patch	20 (50.0%)

Group A-consisting of 20 patients on the basis of drug administered consisting 0.125% Bupivacaine with 2mcg/ml of fentanyl at 6ml/hr rate + placebo patch applied 12 hours before surgery and Group B consisting 0.125% Bupivacaine to be started at 6ml/hr rate + Fentanyl patch applied 12 hours before start of surgery.

Distribution of patients on the basis of sex

Majority of patients were male. In Group A 60.0% were male and 40.0% were female whereas Group B consisted of 75.0% male and 25.0% female. Sex showed statistically non-significant association in both the groups ($p>0.05$).

Comparison of demographic details of patients of both groups:

In group A mean age of studied patients was recorded 34.80 ± 10.75 years while in group B it was recorded 38.90 ± 14.31 years.

In group A mean height of studied patients was recorded 154.75 ± 5.34 cms while in group B it was recorded 156.45 ± 4.71 cms.

In group A mean weight was recorded 56.50 ± 10.13 kg, while in group B it was recorded 61.05 ± 10.50 kg.

In group A mean BMI of the studied patients was recorded 23.52 ± 3.73 kg/m² while in group B mean BMI of studied patient was 24.88 ± 3.68 kg/m².

In group B mean age, mean height, mean weight and mean BMI of the studied patients was Demographic variables showed statistically nonsignificant association with both the groups ($p>0.05$).

Distribution of patients on the basis of ASA grading

Majority of patients, 65 % belong to ASA Grade II in both groups and rest patients belonged to ASA Grade III. ASA Grade showed statistically non-significant association between both the groups ($p>0.05$).

Comparison of Duration of surgery of patients of both groups

Mean duration of surgery in Group A was 5.95 ± 0.83 hour and mean duration of surgery in Group B was 6.05 ± 0.51 hour. It showed statistically non-significant association with both groups ($p>0.05$).

Comparison of HR of patients of both groups

Mean Heart rate was lower in Group A than group B and showed significant correlation in both groups ($p<0.05$).

Comparison of SBP of patients of both groups

Mean Systolic Blood Pressure (SBP) was recorded to be lower in Group A than it was recorded in Group B and showed significant correlation in both the groups ($p < 0.05$).

Comparison of DBP of patients of both groups

Mean Diastolic Blood Pressure (DBP) was recorded to be lower in Group A than it was recorded in Group B and showed significant correlation in both the groups ($p < 0.05$).

Comparison of RR of patients of both groups

Mean Respiratory Rate (RR) was recorded lower in Group A than it was recorded in Group B and showed significant correlation in both groups ($p < 0.05$).

Comparison of VAS (at rest) of patients of both groups

At rest (VAS) was recorded lower in A Group than in B Group and showed significant correlation in both from 1 Hrs to 24 Hrs ($p < 0.05$).

Comparison of VAS (at movement) of patients of both groups

Visual Analog Scale (VAS) At movement was recorded lower in A Group than in B Group and showed significant correlation in both at 24 Hrs ($p < 0.05$).

Comparison of VAS (at cough) of patients of both groups

Visual Analog Scale (VAS) At cough was lower in A Group than in B Group and showed significant correlation from 1 Hrs to 24 Hrs ($p < 0.05$).

Comparison of Sedation of patients of both group

Sedation was recorded lower in B Group than in A Group and showed significant correlation in both groups from baseline to 24 Hrs ($p < 0.05$).

Comparison of Rescue Analgesia of patients of both groups :

Mean duration in hours for patients in Group A to demand rescue analgesia was 10.10 ± 1.47 hrs post operatively while in group B mean duration in hours to demand rescue analgesia was 18.10 ± 3.95 hours.

This correlation was statistically significant and signified Group B has less amount of pain and lesser dosage of drug required for analgesia Similarly mean dose of tramadol required by patient in group A for rescue analgesia in first 24 hours was 58.75 ± 12.23 mg.

On other hand mean dose of tramadol required in Group B was lower as compared to group A and was 15.50 ± 9.72 .

Mean total dose in 24 hrs in Group A (58.75 ± 12.23) was higher than Group B (15.50 ± 9.72) and was found to be statistically significant between both groups ($p < 0.05$).

Comparison of complication of patients of both A, B groups

Nausea was reported in 3 (15.0%) patients of - Group A , 5 (25.0%) patients in B group and showed statistically non-significant association between both groups ($p > 0.05$).

Discussion

Important component of anesthesia-based acute pain services is Thoracic Epidural Analgesia (TEA), and is used for treatment of the acute pain after the thoracic surgery, abdominal surgery, and rib fractures 5. When planning a moderate-to-large thoracic or upper abdominal incision it is warranted. By maximising, the pain management, reducing the surgical stress response, and enabling the early mobilization, TEA is an advantageous adjunct in fast-track surgery. The need to provide one lung ventilation in order to facilitate an acceptable operative field for surgeons as well as the potential for significant bleeding and hemodynamic changes because of surgeons operating close to the heart and its associated major vascular structures are among the clinical challenges and concerns for anesthesiologists that are associated with thoracic surgery. Thoracotomies are associated with severe postoperative pain, resulting in respiratory problems including hypoventilation, hypoxemia, atelectasis, lung infections, and respiratory failure. As a result of inadequate postoperative pain management, many patients may develop postoperative thoracotomy pain syndrome which can last for months or years⁷.

Conclusion

Bupivacaine with 2mcg/ml of Fentanyl was found to be more effective than Bupivacaine with fentanyl patch in postoperative pain in thoracic surgeries.

Declaration of Ethical clearance: Taken from ethical committee of institute(SSRI/2020 198)

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Conflict of Interest: Nil

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