ORIGINAL ARTICLE

Thoracic epidural for post-thoracotomy and thoracomyoplasty pain: a comparative study of three concentrations of fentanyl with plain ropivacaine

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ABSTRACT

Aim: Optimum pain relief after thoracotomy is essential to reduce atelectasis and postoperative pneumonias. The aim of this prospective, double blind, randomised controlled trial was to compare the analgesic and adverse effects of three concentrations of fentanyl with 0.2% ropivacaine in thoracic epidural in patients undergoing thoracotomy andthoracomyolpasty.

Methodology: After getting approval from Ethical Committee, this study was performed in 60 patients of either sex, aged 18-60 years, American Society of Anaesthesiology (ASA) grade I to III. Informed consent was taken from all of the patients, who were recruited and divided into three groups of 20 patients in each group. Patients scheduled for elective thoracotomy surgery were enrolled in the study. Patients with preexisting motor and sensory deficit, addicted to hypnosedative drugs, on chronic opioid or analgesic therapy, sensitive to local anaesthetic or study medication, or having contraindications to regional anesthesia were excluded from this study. In patients, with whom communication difficulties prevented reliable assessment, were also excluded.

Patients received either 2.5μg/ml (Group I), 5.0μg/ml (Group II) or 7.5μg/ml of fentanyl (Group III) respectively, with ropivacaine 0.2% via thoracic epidural. Postoperatively, pain at rest, on coughing and with ambulation was assessed using a visual analogue scale (VAS) and observer verbal ranking score (OVRS) at 2, 6, 12 and 24 hours. Sedation scores were also noted. Adverse effects were simultaneously assessed.

Results: There was no significant difference in the baseline characteristics between the three groups. The number of patients with episodes of unsatisfactory pain relief, i.e. a VAS scores >40 and OVRS >2, at each of the four assessments postoperatively, was higher in Group I than with Group II or Group III ($p < 0.05$). In Group III, four (20%) patients had a sedation score >3 compared with one (5%) in Group II. No patient in Group I had a sedation score >3 ($p < 0.05$). In addition, all patients experienced pruritus in Group I compared with 10% and 5% in Group II and Group I respectively. 30% of the patients had emetic symptoms in Group III, compared to 20% and 5% in Group II and Group I respectively ($p < 05$).

Conclusion: We conclude that a thoracic epidural bolus of 10 ml ropivacaine 0.2% with fentanyl 5.0 μg/ml provides the optimal balance between pain relief and sedation.

Keywords: Thoracic epidural; Pain; Fentanyl; Ropivacaine; Thoracotomy; Thoracomyolpasty; Pain relief; Visual analogue scale; VAS; Observer verbal ranking score; OVRS

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INTRODUCTION

After thoracotomy, the sources of perceived pain are numerous, which are surgical incision, disruption of ribs and intercostal nerves, inflammation of chest wall structures adjacent to the incision, incision or crushing of pulmonary parenchyma or pleura, stretching of shoulder joint and placement of thoracostomy drainage tubes.[1] Optimum pain relief is essential if the incidence of atelectasis and postoperative pneumonias are to be reduced.[2,3] Patients must not only be pain free at rest but must also be able to breathe deeply, cough effectively and comply with postoperative physiotherapy. Additional challenges faced by clinicians in these

patients include old age, malnourishment, and frequent co-existing cardio-respiratory diseases. A number of analgesic techniques have been used to achieve pain relief.[3,4]

Ropivacaine is an amino-amide local anaesthetic and a less toxic homolog of bupivacaine. It can produce excellent analgesia and result in less intense motor block than bupivacaine when given by epidural infusion.[5] However, the incidence of hypotension with 0.5% ropivacaine is high and lower concentrations when used alone are likely to be less effective.[6,7]

Fentanyl is a short-acting lipophilic opioid analgesic developed fentanyl by assaying analogues of the structurally related drug pethidine for opioid activity. Epidural opioids have also been used after thoracotomy. There has been much interest in attempts to improve the quality of epidural opioid analgesia by the addition of a low concentration of local anesthetic to reduce the incidence of side-effects.[7, 8] The important clinical question is what concentration of fentanyl in ropivacaine 0.2% will provide effective analgesia with minimal adverse effects after invasive thoracic surgery. Therefore, this prospective, randomized, double blind study was designed to compare the analgesic and adverse effects of three different concentrations of thoracic epidural fentanyl with 0.2% ropivacaine in patients undergoing thoracotomy and thoracomyolpasty.

METHODOLOGY

After obtaining institutional ethical committee approval and written informed consent, 60 patients undergoing thoracotomies, aged 18–60 years, of either sex admitted in the Surgical Department, King George's Medical University, Lucknow, between August 2011 to July 2012, belonging to American Society of Anesthesiologists (ASA) physical status I-III were recruited in the study and divided into three groups of 20 patients in each group. Exclusion criteria were patient refusal, any contraindication for epidural anesthesia, preexisting motor and sensory deficit, sensitive to local anaesthetic, patients with previous thoracic surgeries or known drug allergy.

Patients were randomized to receive one of three epidural solutions using a computer-generated table of random numbers.

Group I: Patients received 10 ml solution of 0.2% ropivacaine with 2.5μg/ml fentanyl.

Group II: Patients received 10 ml solution of 0.2% ropivacaine with 5μg/ml fentanyl.

Group III: Patients received 10 ml solution of 0.2% ropivacaine with 7.5μg/ml fentanyl.

The study solution was provided in 50 ml syringes labelled with the patient's name and trial code. Thus, patients as well as staff in theatre and in the ward were blinded to the study solution. On arrival of the patient in the operating room, a peripheral venous line was secured and IV infusion was established. Oxygen supplementation was given to all the patients using Venturi mask. FEV1, FVC and PEFR were measured pre-operatively and post-operatively at 2, 6, 12 and 24 hours. All patients received a standardized anesthetic with midazolam 0.05 mg/kg and fentanyl 1 μg/kg IV. After pre-oxygenation for 5 min, general anesthesia was induced with propofol 2–3 mg/kg IV. Neuromuscular block was achieved with atracurium 0.5mg/kg IV and trachea was intubated using an appropriate sized cuffed double-lumen endobronchial tube. Correct tube position was confirmed with help of stethoscope and $EtCO_2$ and anesthesia was maintained with with halothane 0.5–1% in N_2O and oxygen 50% each. Thoracic epidural catheter was inserted under the general anesthesia at T4/5 or T5/6 inter-space at this time and the study solution was administered at 0.1 ml/kg/h after a loading dose of 0.1 ml/kg using syringe pump, prior to surgery.

Surgical incision was allowed after 10 min of epidural bolus. At any time during surgery, if the mean arterial pressure and heart rate increased to $\geq$25% of baseline, supplemental analgesic in the form of fentanyl 1μg/kg IV was given. Any episode of hypotension (systolic arterial pressure $<$90 mmHg) excluding surgical blood loss was treated with incremental doses of ephedrine, and bradycardia (heart rate $<$ 50/min) was treated with atropine. On completion of surgery the patients were reversed with neostigmine 2.5 mg and glycopyrrolate 500 mcg. Patients were then managed in a post-anesthesia care unit (PACU) for 24 hours. Analgesia was assessed at 2, 6, 12 and 24 hours using a visual analogue scale (VAS) (0 = no pain; 100 = worst pain imaginable) both at rest, and with cough and ambulation, after extubation. At the same time, pain was assessed using a four-point observer verbal ranking scale (OVRS) for pain[9] (Table 1).

Table 1: Observer verbal ranking scale for pain[8]

Pain score	Pain experience
0	No pain; pain not restricting any activity e.g. cough, turning on the side
1	Mild pain, able to take maximal deep breath but movement and coughing slightly restricted by pain; physiotherapy effective
2	Moderate pain, needs help to move onto side; cough and deep breathing restricted by pain; physiotherapy effective
3	Severe pain; pain making turning onto side impossible and/or patient refuses to try

Sedation scores were also judged by the observer (0= awake; 1 = mild sedation; 2 = moderate sedation, easily arousable; 3 = heavily sedated difficult to rouse; 4 = over sedated, unrousable).[9]

At a VAS score of >40 and OVRS >2 supplemental analgesic was given in the form of epidural bolus of 0.1 ml/kg solution. Any episodes of nausea and/or vomiting, pruritus, urinary retention, sedation and respiratory depression were recorded at the same time as pain scores and treated accordingly.

All statistical analyses were performed using SPSS for windows vs. 15.0. Continuous variables were tested for normal distribution by the Kolmogorov–Smirnov test. Parametric data was compared using analysis of variance (ANOVA) within group comparisons at different time intervals assessed by using paired *t*-test. All the categorical data was compared by using chi square test. A sample size of 20 patients in each group was needed to detect an intergroup difference of at least 20% (α = 0.01, two-sided, power = 95%) with two sample *t*-test.[10] Data were collected by a blinded observer and are presented as mean ± SD or N (%). A p-value of < 0.05 was taken to be significant.

RESULTS

The three groups were comparable in age, weight, height, sex, ASA classification, lung function, duration of surgery and other variables recorded before operation (p > 0.05) (Table 2). In the 2.5μg/ml fentanyl and 5μg/ml fentanyl groups 80% and 30% patients, respectively, required supplementary fentanyl in the intraoperative period while none of the patients in the 7.5μg/ml fentanyl group required such (p < 0.05). The total dose of fentanyl required was also significantly higher in the group I than in the group II or III (p < 0.05) (Table 3). Intraoperatively, 80%, 30% and 25% of patients of Group I, Group II and III respectively, showed VAS score for pain ≥40 (Figure 1).

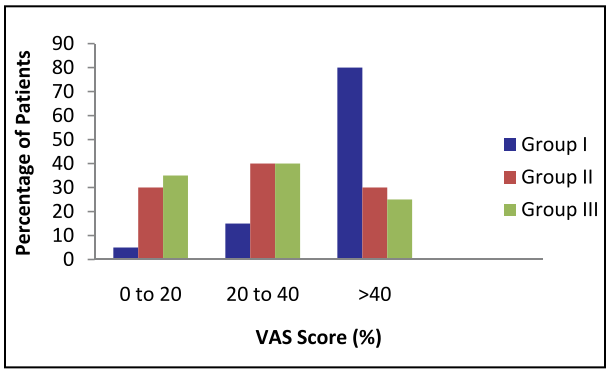

Figure 1: Total VAS score (%)

Table 2: Demographic characteristics and pre-operative variables of the three study groups

Parameter	Group 1	Group 2	Group 3
Age (year)	45 ± 8	42 ± 18	43 ± 16
Sex (M:F)	11:9	9:11	10:10
Height (cm)	165 ± 15	170 ±15	168 ±18
Weight (kg)	68 ± 12	65 ± 14	70 ± 16
Duration of surgery (min)	145 ± 35	150 ± 30	148 ± 36
ASA (I:II:III)	4:10:6	3:10:7	5:9:6
RR (per min)	22 ± 4	23 ± 4	22 ± 3
HR (per min)	82 ± 12	86 ± 14	80 ± 12
SAP (mmHg)	150 ± 28	142 ± 32	146 ± 30
FEV1 (forced expiratory volume in one second)(lit)	1.9 ± 0.3	2.0 ± 0.4	1.9 ± 0.2
FVC (forced vital capacity)(lit)	2.4 ± 0.6	2.5 ± 0.3	2.4 ± 0.4
REFR (peak expiratory flow rate)(lit/min)	390 ± 110	380 ± 120	395 ± 115

Table 3: Intra-operative supplementary fentanyl requirement

	Group I (n = 20)	Group II (n = 20)	Group III (n = 20)
Number of patients requiring supplementary fentanyl	16 (80%)	6 (30%)*	0*+
Total dose of fentanyl (Mean ± SD) (in μg)	76 ± 22	42 ± 18*	0*

* p < 0.05 (I vs II and I vs III)

+ p < 0.05 (II vs III)

None of the patients in the Group I had sedation (score ≥3) while in the Group II and III, 20% and 50% patients, respectively, had sedation (p < 0.05). Pruritus did not differ statistically among the groups though significantly higher incidence (30%)was observed in Group III (p < 0.05). None of the patients in any of the groups complained of numbness or limb weakness. Incidence of hypotension and nausea in each group was statistically comparable (p > 0.05). One patient in each group had bradycardia that required treatment (Table 4).

FEV1, FVC and PEFR were all reduced to 40–50% of their preoperative values throughout the study period in all three groups. Nausea and $PaCO_2$ did not differ between the three groups.

DISCUSSION

Pain in thoracotomy arises as a result of severe chest wall trauma which includes fractured ribs and

Table 4: Comparison of adverse effects in three groups. Data expressed as N(%)

Adverse effects	Group I (n-20)	Group II (n-20)	Group III (n-20)
Sedation (≥ 3) score	0(0)	1(5)	4(20)
Pruritus	1(5)	2(10)	6(30)
Emetic symptoms	1(5)	4(20)	6(30)
Numbness	0(0)	0(0)	0(0)
Limb weakness	0(0)	0(0)	0(0)
Hypotention	1(5)	1(5)	2(10)
bradycardia	1(5)	1(5)	1(5)
Shoulder pain	0(0)	0(0)	0(0)

damaged peripheral nerves and central nervous system hypersensitivity. Thoracic pain cannot be controlled by chest wall immobilized; if secretions are to be cleaned, it must remain in constant motion, indeed vigorous motion. Incidence of pneumonia and atelectasis is to be reduced with pain relief after thoracotomy, thereby patients can take deep breath, cough effectively.

Our results show that significantly ($P < 0.01$) more patients receiving epidural fentanyl 2.5 μg/ml with ropivacaine 0.2% had VAS ≥ 40 compared with those who received fentanyl 5 or 7.5 μg/ml. In addition, there was a tendency for a higher incidence of sedation scores > 3 and of pruritus, in Group III compared with Groups II and I. No significant difference in hypotension and bradycardia between the three groups was noted.

Our results concur with those of a randomized controlled trial of thoracic epidural fentanyl 2.5, 5, 10 and 20 μg/ml with no local anaesthetic.[11] It was shown that there was a concentration-dependent reduction in pain intensity in patients undergoing thoracotomy for lung resection. With fentanyl 2.5 μg/ml, there was a significant decrease in proportion of patients with $> 50\%$ reduction in pain scores, compared with higher concentrations (fentanyl 5, 10 and 20 μg/ml). In another study comparing thoracic epidural fentanyl in doses of 1, 2 and 4 μg/ml in ropivacaine 0.2% for patients undergoing major abdominal surgery, it was shown that pain intensity was significantly greater in patients receiving fentanyl 1 to 2 μg/ml than those having fentanyl 4 μg/ml.[12]

Epidural local anesthetic agents have an established role in analgesia during thoracic surgery. Opioids administered via the epidural route have been found to be superior in terms of analgesia, side-effects, length of stay and postoperative complications after thoracotomy.[13] Hypotension was the most common side-effect with the use of the above and ropivacaine 0.5% in thoracic epidural, occurring in 80% of cases of patients in whom satisfactory analgesia was achieved.[7] The high incidence of hypotension with ropivacaine can be attributed to sympathetic block.[14] Although epidural administration of opioids does not result in sympathetic block[15] hypotension has been observed with an epidural fentanyl,[16] which could be related to systemic uptake from epidural space. In view of these findings and to avoid hypotension associated with either a high concentration of ropivacaine or a high dose of fentanyl, we used a continuous infusion (2.5 μg/ml, 5 μg/ml and 7.5μg/ml) rather than bolus high doses of fentanyl in a lower concentration of ropivacaine (0.2%).

On demand patient-controlled epidural analgesia after thoracotomy and upper abdominal surgery using fentanyl 1 μg/ml with ropivacaine 0.125% assessed in a previous study[6] did not significantly reduce the amount of supplementary fentanyl required, the pain scores or the side effects. Taking this into consideration we chose to use three different concentrations of fentanyl in 0.2% ropivacaine in our study. It has been demonstrated that epidural fentanyl contributes significantly to the analgesia component of balanced anesthetic during lung surgery[15]. Our result showed that epidural fentanyl with ropivacaine produces analgesia and is concentration dependent. The duration and intensity of pain relief were increased when a higher concentration of the drug was given, up to a maximum concentration of 7.5μg/ml. More patients receiving epidural fentanyl 2.5μg/ml in ropivacaine 0.2% had pain (VAS ≥ 40) compared with those who received fentanyl 5.0μg/ml or 7.5μg/ml in ropivacaine 0.2% (Figure 1). Preoperative and postoperative thoracic epidural analgesia techniques have been assessed on post-thoracotomy pain: preoperative epidural analgesia was found to be an appropriate method and was more effective in preventing acute post-thoracotomy pain[17]. Taking this into consideration; we administered perioperative thoracic epidural analgesia in our study.

Different epidural analgesics and their effects on pulmonary function have been compared in the past[9]. Throughout the postoperative period, reductions of up to 70% of the preoperative values (FEV1, FVC and PEFR) were noticed in all the study groups that mean with the different concentrations of fentanyl used in our study, no difference was found among the groups with regard to pulmonary functions.

Epidural opioids are associated with dose-dependent adverse effects of sedation, pruritus, nausea and

respiratory depression.[18] In this regard, in our study a concentration of 5μg/ml fentanyl was found to be optimum. On the other hand, lower concentrations of epidural fentanyl (2.5μg/ml) do not provide high quality analgesia following thoracic surgery. In patients who receive insufficient analgesia, an alternative method of increasing the concentration of epidural opioids is to consider an additional drug, i.e. clonidine [19].

In our study there appeared to be an increased incidence of pruritus (30%) in patients receiving epidural fentanyl 7.5 μg/ml. Our findings are in accordance with those of the previous report.[20]

This trend is consistent with a RCT in which the incidence of pruritus increased from 17% at fentanyl 10 μg/ml, to 36% at fentanyl 20 μg/ml[11]. In other studies of lower fentanyl concentrations, this concentration dependent effect was also demonstrable. For instance, the incidence of pruritus was 23%, 8%, 4% and 4% in obstetric patients receiving epidural fentanyl of concentrations 4, 3, 2 and 1 μg/ml, respectively.[21] Furthermore, in a RCT of 244 patients undergoing major abdominal surgery, thoracic epidural fentanyl 4 μg/ml was associated with a significantly ($P < 0.02$) higher incidence of pruritus than fentanyl1 μg/ml to 2 μg/ml.[12]

Our study in which there was a tendency to increased sedation in 20% of patients in the 7.5 μg/ml fentanyl group had a sedation score ≥3, concurs with a study by Welchew and colleagues.[11] He showed that increased sedation occurred at fentanyl 10, 20 μg/ml but not at fentanyl 2.5 μg/ml. In two other RCTs of patients receiving thoracic epidural fentanyl 1, 2 and 4 μg/ml in ropivacaine 0.2%, sedation scores were low and no significant difference in sedation was detected [12, 21].

In our study a significant difference in nausea and vomiting was found between the three treatment groups. The patients in the Group III, 30% experienced nausea and vomiting, while in Group I 5% and Group II 20%. This result differs from results obtained in an earlier study.[22] This difference may be because our patients received general anesthesia with epidural analgesia, while in the other studies mentioned the patients received only epidural anesthesia.

In our study, assessments were made in the first 24 h postoperatively, and so our results are applicable to this period. After thoracotomy for lung resection, patients may have an epidural in situ for 5 days. Analgesic requirements are expected to be much reduced on day 3 compared with the immediate postoperative period. Thus if this study was extended beyond the first 24 h, then it is likely that we would have recorded a progressive reduction in opioid consumption in all treatment groups. By day 3, opioid consumption would be low; any possible differences in pain scores and opioid related adverse effects would not be detectable between groups.

CONCLUSION

In conclusion, our study has shown that thoracic epidural fentanyl 5 μg/ml or 7.5 μg/ml are associated with superior analgesia after thoracotomy compared with fentanyl 2.5 μg/ml, when used in conjunction with ropivacaine 0.2% in the immediate postoperative period. However, the use of fentanyl 7.5 μg/ml is associated with excessive sedation and pruritus. Therefore, epidural fentanyl 5 μg/ml in ropivacaine 0.2% would appear to provide the optimal balance between pain relief and adverse effects following thoracic surgery.

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