

**A COMPARATIVE STUDY BETWEEN DEXMEDETOMIDINE AND FENTANYL
ADDED TO ROPIVACAINE AS ADJUVANT IN PARAVERTEBRAL BLOCK FOR
POST OPERATIVE ANALGESIA IN PATIENTS UNDERGOING
THORACOTOMY FOR VARIOUS SURGICAL PROCEDURES**

Dexmedetomidine vs fentanyl to ropivacaine for post operative analgesia

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ABSTRACT

Pain after thoracotomy is one of the most severe pains after surgery. Respiratory muscle splinting due to poor control of post-operative pain may lead to respiratory complications and delayed recovery. In studies addition of dexmedetomidine or fentanyl to local anaesthetics showed enhanced quality of anaesthesia, reduced post-operative analgesic requirement and improved quality and duration of sensory neural blockade. But there are very few studies comparing dexmedetomidine and fentanyl as an adjuvant to ropivacaine in paravertebral block for post thoracotomy analgesia. 80 patients scheduled to undergo elective thoracotomy were randomly divided into two groups. Group A patients received infusion of 0.2% ropivacaine + 2µg/ml(microgram/millilitre) fentanyl @ 0.1ml/kg/h(millilitre/kilogram/hour) and Group B patients received infusion of 0.2% ropivacaine + 1µg/ml dexmedetomidine @ 0.1ml/kg/h in continuous paravertebral block. The patients had visual analogue scale(VAS) at rest between 1-3 in fentanyl group and 1-2 in dexmedetomidine group.(p value >0.05) The mean VAS score for the severity of pain at coughing was between 2-3 in fentanyl group and 1-2.5 in dexmedetomidine group and the difference is statistically significant.(p value <0.05) 12 patients in fentanyl group received rescue analgesic compared to 4 patients in dexmedetomidine group.(p value <0.05) Total fentanyl consumption was more in fentanyl group compared to dexmedetomidine group.(p value >0.05) There was no difference in incidence of side effects in both groups.(p value >0.05) Dexmedetomidine as an adjuvant to ropivacaine provided better post-operative analgesia during coughing and significantly reduced the requirement of rescue analgesic in comparison to fentanyl group without any significant adverse effects.

Key words: Dexmedetomidine, fentanyl, paravertebral block, thoracic surgery, Visual analogue scale

INTRODUCTION

Pain after thoracotomy is considered to be one of the most severe pain after surgery [1]. There are multiple sources of pain after thoracic surgery like site of surgical incision, disruption of intercostal nerves, inflammation of pulmonary parenchyma or pleura or thoracostomy drainage tubes [1]. Respiratory muscle splinting due to poor control of post-operative pain may lead to ventilation perfusion mismatch, atelectasis, hypoxemia, inability to clear secretions by coughing, which can result in pneumonia, respiratory failure and delayed recovery [2,3].

Thoracic epidural analgesia is considered to be the gold standard for treatment of post thoracotomy pain but it can cause devastating complications like spinal hematoma, epidural abscess and resulting paraplegia [4].

Paravertebral nerve block is another modality for post thoracotomy pain relief which is as good as or even superior to epidural analgesia [5,6]. The quality of block is very high at dermatome site of injection. Bathing of the 'relatively naked' spinal nerve in intervertebral foramen is similar to the technique of transforaminal sleeve nerve root blockade which produce high quality pain relief for very long duration in chronic pain [7].

The addition of adjuvants to local anaesthetics decrease the dose of local anaesthetics and improve the quality and duration of sensory neural blockade [8].

Fentanyl is an opioid receptor agonist and its main effect is through opioid receptors in brain and spinal cord. However addition of opioids to local anaesthetics has disadvantage of pruritis and respiratory depression. Dexmedetomidine is a potent and highly selective α_2 adrenoceptor agonist with a selectivity ratio of 1600:1 ($\alpha_2 : \alpha_1$). Its pharmacological properties include sedation associated with easy arouse ability and orientation without causing respiratory depression, analgesia, anxiolysis, anti-shivering effects, hemodynamic stability and less incidence of post-operative nausea and vomiting [9].

Many studies have been conducted in the past using dexmedetomidine [10,11] or fentanyl [12-14] as an adjunct to local anaesthetics. They observed that addition of dexmedetomidine or fentanyl to local anaesthetics enhanced the quality of anaesthesia, reduced post-operative analgesic requirement and improve the quality and duration of sensory neural blockade as compared to local anaesthetics when used alone [8]. Due to very few studies comparing them, it was decided to evaluate dexmedetomidine and fentanyl as an adjuvant to ropivacaine in paravertebral block for post thoracotomy analgesia regarding efficacy of pain relief, hemodynamic stability and possible complications.

OBJECTIVES

Primary Objective

To compare the effectiveness of post-operative analgesia using VAS score.

Secondary Objectives

- Need for rescue analgesic and total dose of rescue analgesic required.

- Patient satisfaction score at the end of catheter removal.

METHODOLOGY

After approval from institutional scientific and ethical committees, a prospective, randomised and double blind study was conducted in 80 adult patients scheduled to undergo elective thoracotomy.

Inclusion criteria included patients of either sex between 18-60 years of age belonging to American Society of Anaesthesiology (ASA) Physical status II and III scheduled to undergo elective thoracotomy for different surgical procedures (minimally invasive mitral valve replacement, minimally invasive aortic valve replacement, lobectomy, pneumonectomy, decortications, etc).

Exclusion criteria included patients with ASA physical status IV, atrial fibrillation, congestive heart failure or EF<30%, severe pulmonary artery hypertension, coagulopathy, local sepsis, allergy to local anaesthetic or study drugs, spinal deformities, have undergone thoracotomy in past or pregnant and breast feeding patients.

Procedure

After preoperative assessment, informed and written consent was taken from the patients. All patients were explained about the procedure in detail, its benefits, complications and were also educated how to report pain on the 10 point visual analogue scale (VAS), where 0= no pain and 10= worst imaginable pain. 80 patients were randomly divided into two groups with 40 patients each by computer generated randomisation. Group A patients received infusion of 0.2% ropivacaine + 2 µg/ml(microgram/millilitre) fentanyl @ 0.1 ml/kg/h(millilitre/kilogram/hour). Group B received infusion of 0.2% ropivacaine + 1 µg/ml dexmedetomidine @ 0.1 ml/kg/h.

After patient's arrival into operation theatre an intravenous line was secured with 16 (G)Gauze cannula and radial artery was cannulated with 20 G radial cannula under local anaesthesia. All routine monitors like invasive blood pressure, electrocardiogram, pulse oximetry were connected. Patient was induced with inj.(injection) midazolam 1 mg, inj. thiopentone 3-5 mg/kg body weight, inj. fentanyl citrate 1-2 µg/kg and inj. rocuronium 0.8 mg/kg was used to facilitate tracheal intubation. Anaesthesia was maintained with oxygen, air and isoflurane. Boluses of inj. fentanyl and inj. rocuronium were used intravenously in titrated doses as required. Right internal jugular vein was cannulated with 8.5 Fr(French) 4 lumen catheter after tracheal intubation.

After induction of general anaesthesia paravertebral block was administered under ultrasound guidance by in plane approach with patients in lateral decubitus position. After skin disinfection, 6 to 13 MHz(megahertz) linear transducer of sonosite edge ultrasound machine kept in sterile sleeve, was placed in an axial (transverse) plane on the rib at the selected thoracic level just lateral to the spinous process. Machine was optimised for imaging capability by selecting the appropriate depth of field, focus range and gain. The transverse process and rib were visualised as a hyperechoic line with acoustic shadowing below it. Thoracic paravertebral space (TPVS) localisation was done by moving the transducer caudally into the intercostal space between adjacent ribs.

The transverse process was visualised on the medial side as a hyperechoic convex line with acoustic shadowing beneath. The TPVS and the adjoining intercostal space could be visualised as a wedge shaped hypoechoic layer demarcated by the hyperechoic lines of the pleura below and the internal intercostal membrane above.

After ultrasound guided identification of paravertebral space, 15 ml of 0.75% ropivacaine was injected using 18G Tuohy's epidural needle, which was attached to 10 cm (centimetre) extension line for convenience of administration of medication. Local anaesthetic deposition translated as an anterior displacement of the parietal pleura on the ultrasound image. Vascular puncture was ruled out by aspiration before administration of the drug. Subsequently, a 20G epidural catheter was threaded into the TPVS, 5 cm beyond the needle tip, with the bevel facing cranially.

The study drug was started 2 hours after the initial block regardless of the duration of surgery. Paravertebral infusion was continued for 48 hours post operatively. Patient was shifted to ICU (intensive care unit) and extubated when extubation criteria were met.

The primary outcome measured was pain score at rest and on coughing measured on ten point VAS score where 0 signifies no pain and 10 signifies worst imaginable pain recorded at 1h, 2h, 4h, 8h, 12h and 24h post extubation. Rescue analgesic in ICU consists of intravenous fentanyl 25µg bolus if pain score was ≥ 4 .

Other outcomes measured were hemodynamic parameters, need for rescue analgesic and total intravenous fentanyl consumption post operatively as rescue analgesic, patient's satisfaction on a ten point VAS scale, nausea, vomiting, urinary retention and pruritus if present. Inj. ondansetron 4mg i.v. (intravenously) was given if patient had nausea or vomiting. Inj. paracetamol 1g 8 hourly was given intravenously to each patient as routine protocol. We also used observers assessment of alertness and sedation score to assess level of alertness where 5=patient respond readily to name spoken in normal voice, 4=patient sleepy but arousable to normal tone voice, 3=patient sleepy but arousable to loud or repeated verbal stimulation, 2=patient sleepy but arousable by mild prodding or shaking, 1=comatose patient.

Sample size

The minimum sample size required at 5% level of significance and 80% power is obtained as at least 37 patients in each group taking into consideration previous similar studies.^{10,12}

Statistical tests

The quantitative variables in both groups were expressed as mean \pm SD and compared using unpaired t-test between groups and paired t-test within each group at various follow-ups. The qualitative variables were expressed as frequencies/percentages and were compared using Chi-square test. A p-value < 0.05 was considered statistically

significant. Statistical Package for Social sciences (SPSS) version 16.0 was used for statistical analysis.

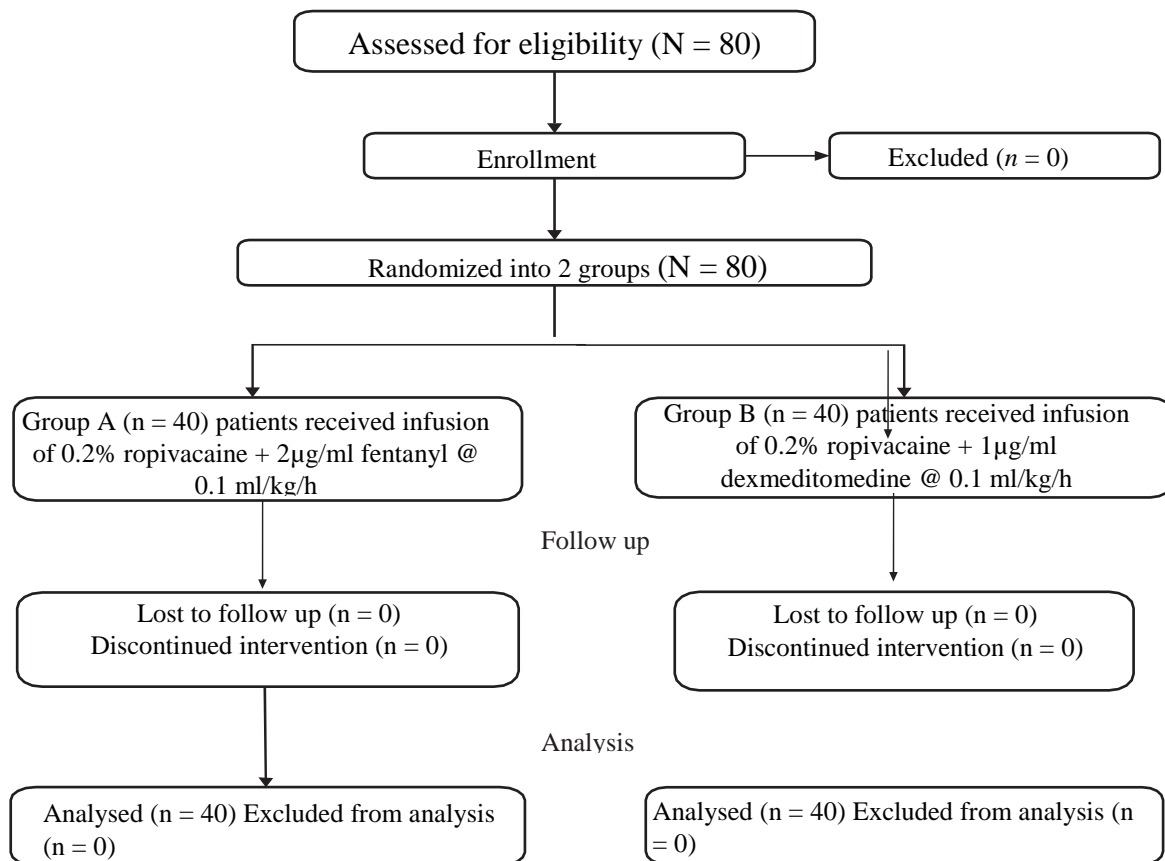


Figure 1: Consort flow chart describing the study design

OBSERVATION AND RESULTS

Total 80 patients were included in the study, of which 40 patients (Group A) received infusion of 0.2% ropivacaine + 2 µg/ml fentanyl @ 0.1 ml/kg/hr and another 40 patients (Group B) received infusion of 0.2% ropivacaine + 1 µg/ml dexmedetomidine @ 0.1 ml/kg/hr.

Table 1: Demographic variables

		Group A (fentanyl)	Group B (dexmedetomidine)	P value
Age(years)		41.30±10.42	42.00±9.23	0.751
Sex	Male	21(52.5%)	23(57.5%)	0.653
	Female	19(47.5%)	17(42.5%)	
Type of surgery	MICS AVR	14(35%)	16(40%)	
	MICS MVR	11(27.5%)	10(25.0%)	
	Lobectomy	8(20.0%)	9(22.5%)	
	Decortication	7(17.5%)	5(12.5%)	

Table 2: Comparison of VAS score at rest (Mean± SD) in both groups

Observation Time	Group A (Fentanyl)	Group B (Dexmedetomidine)	P value
1 st hour	1.85±0.66	1.62±0.58	0.101
2 nd hour	1.90±0.59	1.72±0.55	0.162
4 th hour	2.2±0.85	2.0±0.78	0.276
8 th hour	2.1±0.90	1.9±0.84	0.307
12 th hour	2.0±0.80	1.75±0.77	0.158
24 th hour	1.85±0.76	1.55±0.64	0.064

† All observations were made post extubation at time intervals as per study protocol.
(Unpaired t-test)

The severity of pain at rest was assessed using VAS (visual analogue scale) scale in both groups at different time intervals over the 24 hours period. p value were calculated and it shows a statistically insignificant difference in two groups. The chart and table clearly shows that most of the patients had VAS score between 1-3 in group A and between 1-2 in group B.

Table 3: Comparison of VAS score at cough (Mean± SD) in both groups

Observation Time	Group A (Fentanyl)	Group B (Dexmedetomidine)	p value
1 st hour	2.42±0.67	1.77±0.61	0.0001
2 nd hour	2.52±0.71	1.90±0.63	0.0001
4 th hour	3.0±1.06	2.40±1.12	0.0161
8 th hour	2.82±0.98	2.27±1.06	0.0183
12 th hour	2.65±0.80	2.0±0.84	0.0007
24 th hour	2.50±0.67	1.8±0.85	0.0001

† All observations were made post extubation at time intervals as per study protocol.
(Unpaired t-test)

The severity of pain on cough was also assessed using VAS (visual analogue scale) scale in both groups at different time intervals over the 24 hours period. The chart and table clearly shows that the patients had mean VAS score between 2-3 in group A and mean VAS score between 1-2.5 in group B on cough. Group B had less VAS score in comparison to Group A at all the time intervals. p value calculated at different intervals shows a statistically significant difference in these two groups regarding severity of pain at cough (p value <0.05).

Table 4: Comparison of Sedation score (Mean± SD) in both groups

Observation Time	Group A (Fentanyl)	Group B (Dexmedetomidine)	p value
1 st hour	4.92±0.26	4.87±0.33	0.453
2 nd hour	4.92±0.26	4.87±0.33	0.453
4 th hour	4.97±0.15	4.92±0.26	0.295

8th hour	4.95±0.22	4.95±0.22	1.000
12th hour	4.97±0.15	4.87±0.33	0.085
24th hour	5.0±00.00	4.97±0.15	0.209

† All observations were made post extubation at time intervals as per study protocol.

(Unpaired t-test)

Patient alertness was also assessed during 24 hours at different time intervals using observer's assessment of alertness and sedation score. The patients had mean score between 4-5 in both the groups. p value calculated at different time intervals and it showed a statistically insignificant difference in the two groups at all the time intervals (p value >0.05).

Table 5: Need of Rescue Analgesic in both groups in 24 hours period

	Group A (Fentanyl) N*(%)	Group B (Dexmedetomidine) N*(%)	p value
Number of patients who needed rescue analgesic	12(24)	4(10)	0.025
24 hour fentanyl consumption (mean±SD)	17±1.62	8.75±2.47	0.190

(Chi-square test)

*Total no. of the patients are taken

Total number of patients who received rescue analgesic were 12(24%) in group A and 4(10%) in group B. Rescue analgesic used was fentanyl bolus 25 µg intravenously single dose when VAS score was ≥4 in these patients. The difference was found to be statistically significant (p value <0.05).

Total fentanyl consumption was also calculated over 24 hours in both the groups and is represented as mean±SD in the above table. Group B has less fentanyl consumption in comparison to group A but found to be statistically insignificant on calculating the p value between the two groups (p value >0.05).

Total number of patients who had adverse effects were 4(10%) in group A (3 patients has nausea and 1 patient had vomiting) and 2(5%) patients in group B had nausea, difference was statistically insignificant (p value =0.395).

Patients satisfaction accessed using 10 point VAS score was found to be 8.82±1.23 in group A and 9.02±1.04 in group B and the difference was statistically insignificant in both groups (p value 0.434).

DISCUSSION

Postoperative pain relief has become an integral part of the anaesthesia practice. Inadequate treatment of postoperative pain has its own detrimental effects on the outcome of the patient. The acute effects are due to the increase in the catabolic hormones and catecholamine secretion. This also has its sequelae in the long term wellbeing of the patient. Pain after thoracotomy is one among the most severe pain in the postoperative period. Such pain can result in splinting of the respiratory muscles

causing decrease in pulmonary function. In the long term it can result in development of post thoracotomy pain syndrome [1].

Thoracic paravertebral block, has recently gained popularity, which provides unilateral analgesia along thorax and abdomen with minimal hemodynamic instability [15]. In this block local anaesthetic act on spinal nerves, dorsal ramus and sympathetic chain. The main complication of thoracic paravertebral is the pleural puncture and development of pneumothorax which is offset by the presence of intercostal drainage tube in thoracotomy [5-7].

The results of this study revealed that addition of fentanyl and dexmedetomidine to ropivacaine in continuous paravertebral block in 24 hour post operative period had VAS score at rest between 1-3 in fentanyl group and 1-2 in dexmedetomidine group. The difference was statistically insignificant.(p value >0.05) (Table:2) The mean VAS score for the severity of pain at coughing was between 2-3 in fentanyl group and 1-2.5 in dexmedetomidine group. Dexmedetomidine had less VAS score at cough in comparison to fentanyl group at all the time intervals and the difference is statistically significant. (p value <0.05) (Table:3) There was no statistical difference between both groups as regard to heart rate, systolic and diastolic blood pressure. 12 patients in fentanyl group received rescue analgesic in comparison to 4 patients in dexmedetomidine group. Clearly fentanyl group had more patients getting rescue analgesic in comparison to dexmedetomidine and on statistical analysis it was found to be statistically significant.(p value <0.05) (Table:5) Total fentanyl consumption was more in fentanyl group compared to dexmedetomidine group but the difference was not statistically significant.(Table:5) Patient alertness assessed by observers assessment of alertness and sedation score found that the patients had mean score between 4-5 in both fentanyl and dexmedetomidine groups with p value >0.05.(Table:4) Nausea was the most common adverse effect in both the groups. 3 patient in group A and 2 patients in group B had nausea while 1 patient in group A had vomiting. The difference in incidence of side effects was found to be statistically insignificant.(p value >0.05) (Table:6) Patients satisfaction score calculated at the end of the study period after catheter removal found mean score of 8.82 ± 1.23 in fentanyl group and 9.02 ± 1.04 in dexmedetomidine group.(p value > 0.05) (Table:7)

Sabry M.H.I.A et al conducted a randomized study to compare dexmedetomidine or fentanyl added to bupivacaine in ultrasound guided paravertebral block in unilateral renal surgery. They stated that there was no significant difference in the mean and the diastolic blood pressure between both groups. There was statistically significant decrease in the systolic blood pressure and heart rate in Gp D than in Gp F in post operative period(P<0.05). There was statistical significant decrease in VAS postoperatively in Gp D (2.67 ± 0.71) than in Gp F (2.97 ± 0.76) (P<0.05). Sedation score postoperatively was statistically significantly increased in Group D (2.4 ± 0.93) than in Gp F (1.8 ± 0.41) (P<0.05). Total dose of Mepridine requested by patients was significant statistically less in Group D (69.81 ± 24.28) than in Group F (83.75 ± 21.46) (P <0.05) [16].

Marzouq A.A.A et al compared fentanyl and dexmedetomidine added to bupivacaine in paravertebral nerve block for analgesia in laparoscopic cholecystectomy. Visual analogue scale (VAS) during rest was lower in dexmedetomidine group at 1 hour, 2 hours, 6 hours, 12 hours and 24 hours postoperatively as compared with other groups and the difference was statistically significant. There were statistically significant differences found between the three groups regarding total dose of morphine required as rescue analgesic. In the dexmedetomidine group the total dose was statistically significantly lower as compared with the other groups [17].

Elsharkawy R.A et al compared dexmedetomidine vs fentanyl added to bupivacaine in paravertebral block for renal surgeries. They found post-operative visual analogue score was significantly lower in dexmedetomidine group and post-operative sedation score was significantly more in dexmedetomidine group. There was no statistical difference between both groups as regard to heart rate, mean blood pressure and oxygen saturation. No postoperative adverse effects were recorded. Moreover, the addition of dexmedetomidine reduces the postoperative pain score and decreases the needs for postoperative analgesia with lengthening the duration of postoperative analgesia [18].

Ahmed S.A et al compared the effect of fentanyl or dexmedetomidine on the ultrasound-guided paravertebral block for patients undergoing renal surgeries. They stated that addition of fentanyl or dexmedetomidine to plain bupivacaine in continuous paravertebral block significantly decreased the dose of postoperative morphine consumption from $(11.33 \pm 5.05 \text{ mg})$ to $(7.33 \pm 4.59 \text{ mg})$ $(7.80 \pm 4.15 \text{ mg})$, significantly prolonged the time for first request of rescue analgesia from $(6.87 \pm 3.81 \text{ h})$ to $(9.80 \pm 4.50 \text{ h})$ $(10.80 \pm 5.22 \text{ h})$, and significantly decrease VAS score 2 hour and 6 hour postoperatively with insignificant difference between fentanyl and dexmedetomidine [15].(P>0.05)

CONCLUSION

Dexmedetomidine as an adjuvant to ropivacaine provided better post-operative analgesia during coughing and significantly reduced the requirement of rescue analgesic in comparison to fentanyl with ropivacaine in patients undergoing thoracotomy for various surgical procedures without any significant adverse effects.

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