



## EFFICACY OF 0.2% ROPIVACAINE ON POST THORACOTOMY IPSILATERAL SHOULDER PAIN EITHER VIA INTRAPLEURAL INSTILLATION OR PHRENIC NERVE INFILTRATION

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### ABSTRACT

**Background:** Post thoracotomy ipsilateral shoulder pain (PTISP) is the most common complication following thoracotomy and unfortunately PTISP has not given much attention. There are many hypothesis for it's etiology

**Objectives:** To study the effect of Ropivacaine on PTISP given via either Phrenic nerve infiltration or via Intrapleural Instillation with epidural analgesia as the standard mode of analgesia in both the groups.

**Study Design:** Prospective observational study.

**Methods:** 80 patients were divided into 2 groups, "Group A (Intrapleural instillation) received 40ml of 0.2% Ropivacaine with 1:100000 epinephrine into basal chest drain at the end of the surgery" and "Group B (Phrenic nerve infiltration) received 10ml of 0.2% Ropivacaine into phrenic nerve infiltration prior to chest closure". Postoperatively patients were assessed for PTISP using VAS score at 0, 1,3, 6, 12, 24,36 and 48 hours(h). The number of rescue analgesia required were recorded.

**Results:** PTISP was relieved significantly in Group B as compared to Group A. The number of rescue analgesic required was less in Group B than in Group A (P value<0.05). Postoperative hemodynamics were stable in Group B than in Group A.

**Conclusion:** Ropivacaine is effective in relieving PTISP via Phrenic Nerve Infiltration, it has significantly reduced the incidence and delayed the onset of PTISP as compared to Intrapleural Instillation and was not associated with any adverse effects.

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### INTRODUCTION

Post-thoracotomy ipsilateral shoulder pain(PTISP)is a very distressing problem following thoracotomy. The reported incidence of PTISP is about 85%. Post thoracotomy ipsilateral shoulder pain is the most common complication. It can be very severe and poses the most challenging aspect for treatment<sup>1</sup>. It is very unfortunate that PTISP has not given much attention even after knowing how much prevalent it is. The adverse effects of thoracotomy on pulmonary functions can be decreased by providing effective perioperative analgesia. Post operative pain leads to surgical stress response which causes release of cytokines(e.g. interleukin-1,interleukin-6,and tumor necrosis factor-alfa) and precipitates adverse neuroendocrine and sympathoadrenal responses, resulting in detrimental physiologic responses<sup>2</sup>, the consequences of which include poor wound healing, muscle wasting, fatigue and impaired immunocompetency. The Post-thoracotomy pain is transmitted

via C and A -fibres. There are many hypothesis for the etiology of ISP including transection of major bronchi, ligament distraction or strain as a result of surgical retraction, shoulder joint strain from intraoperative malpositioning, myofascial involvement, irritations of the pleura by chest drains, referred pain from irritation of pericardium, mediastinum, or diaphragmatic surface, by strain of ligaments and muscles of scapula, arcaution of patient in lateral decubitus position or rib retraction<sup>3</sup>.

There are several methods for alleviating post thoracotomy ipsilateral shoulder pain including superficial cervical plexus block, intrapleural local anesthetics, interscalene brachial plexus block<sup>4</sup>, suprascapular nerve block (SNB)<sup>5</sup>, phrenic nerve block (PNB)<sup>6</sup>, stellate ganglion block<sup>7</sup>, non-steroidal anti-inflammatory drugs (NSAIDS)<sup>8</sup> and acetaminophen<sup>9</sup>. Thoracic epidural analgesia is considered the safe and gold standard analgesia for PTISP. Acetaminophen has shown opioid-sparing effect and efficacy in reducing PTISP. PNB at the cardiophrenic angle has been shown to significantly reduce

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the incidence of PTISP without any adverse effects. Intrapleural local anesthetic instillation has also been shown to improve postoperative pulmonary functions and PTISP.

We conducted a prospective, observational study with an objective to evaluate and compare the efficacy of 0.2% ropivacaine on PTISP either via intrapleural instillation (IPI) or via phrenic nerve infiltration (PNI) in patients undergoing elective thoracotomy with thoracic epidural as the standard mode of analgesia in both the groups.

## METHODOLOGY

After approval from the Institutional Ethical Committee, 80 patients of either gender aged 20 years with the American Society of Anesthesiology physical status (ASA) of 1, 2 and 3, admitted for elective unilateral thoracotomy were included in the study.

Patients were excluded as per the following exclusion criteria: Patients who will need elective ventilation, Haemodynamically unstable patients, Patients undergoing surgery more than a single side thoracotomy and total pleurectomy, Conduction disturbances like CHB, AV Blocks, Hepatic and renal impairment, Pregnancy, Patients with known allergy to the drug to be used in the study, Dementia or similar cerebral conditions, Patients on anti-convulsants, anti-depressants, or chronic analgesic use, alcohol and/or drug abuse.

Patients were informed about the purpose of study and informed written consent obtained from them. All the patients enrolled were reliable, cooperative and mentally capable of adhering to the protocol. At the preoperative visit, patients were instructed in the evaluation of pain using visual analogue scale (VAS) of 0 – 10 cm. (0 cm = no pain, and 10 cm = the worst pain). All patients were clinically evaluated, assessed and investigated a day before surgery. The patients were kept fasting overnight. The patients were randomized into two groups with 40 subjects in each group by computer generated numbers. Both the groups received thoracic epidural analgesia with 8ml of 0.2% Ropivacaine with 25mcg fentanyl as a standard for acute post thoracotomy pain relief.

On arrival to the operating room, an IV line was established and standard monitoring established. Heart rate, non invasive blood pressure and pulse oximetry (SpO<sub>2</sub>) were recorded. The patients were kept in sitting position. Under all aseptic precautions, an epidural catheter was placed via midline or paramedian thoracic approach according to desired level for analgesia. The epidural space was identified by the loss of resistance to saline technique. Epidural catheter was inserted and fixed at 4-5 cm inside the space. A test dose of 3 mL of 2% xylocaine was given to rule out intravascular or intrathecal placement of the catheter. Catheter was covered with a sterile transparent dressing.

General anaesthesia was administered using propofol after turning the patient to supine position. Analgesia for the surgery was provided using 2-3mcg/kg of fentanyl intravenously. Injection atracurium 0.8mg/kg was used for providing muscle relaxation for laryngoscopy and intubation. Anaesthesia was maintained with oxygen (50%), nitrous oxide (50%) and isoflurane (upto 1.5 MAC). Muscle relaxant  $\frac{1}{4}$ th dose of atracurium used at induction was administered when required. Patients were given ondansetron hydrochloride 0.1mg/kg 15 minutes before the completion of surgery. Heart rate,

respiratory rate, blood pressure and SpO<sub>2</sub> were recorded continuously till the end of the surgery.

Towards the end of surgery the participating patients were randomized into two groups:

*Group-A (Intrapleural Group)* received 40 ml of ropivacaine 0.2% with adrenaline 1:100,000 intrapleurally. Using antiseptic technique, the solution injected into the drain tube via 23G needle proximal to the clamped chest drain, the needle was then withdrawn but the drain was kept clamped for 20min. *Group-B (Phrenic Nerve Infiltration)* received infiltration of ipsilateral phrenic nerve with 10ml of 0.2% ropivacaine just before lung expansion and chest closure. The phrenic nerve infiltration was performed using 22G spinal needle inserted into the fat pad which includes the phrenic nerve at the level of diaphragm.

After the procedure and extubation, patients were interrogated for pain by VAS scoring system at 0 h (at extubation), thereafter at 30min, 1hr, 3hr, 6hr, 12hr, 24hr, 36hr and 48hr, from extubation. In addition to VAS scoring at these intervals the other parameters noted were, heart rate (HR); blood pressure-systolic (SBP), diastolic (DBP) and mean arterial (MAP); pulse oximetry (SpO<sub>2</sub>); respiratory rate (RR); incidence of post-operative nausea and vomiting (PONV) or any other side effects.

The time to first rescue analgesic was recorded for both the groups and total consumption of rescue analgesics for the first 24 hours was calculated to keep VAS  $\leq 3$ . In case of breakthrough pain (VAS  $\geq 4$ ) a top-up of rescue epidural injection of ropivacaine 0.2% 4ml was administered. In case of persistent pain fentanyl 0.5 $\mu$ g/kg IV was offered and recorded. In case of persistent breakthrough pain i.e. VAS  $>4$  then 1gm of paracetamol IV was given and noted. The total number of rescue analgesics in 24 hours post extubation were recorded for both groups. The target pain scoring as per VAS was  $\leq 3$ .

### Statistical Analysis

All the continuous variables of the study were represented by descriptive statistics (frequency, percentage, mean and SD). All the categorical variables were analyzed by applying Chi square & Fisher's Exact test after confirming the normal distribution of data. In addition to all this all the vitals comparison were done by student's-t-test for statistical analysis. The results were discussed at 5% level of significance i.e. p value less than 0.05 was considered statistically significant also appropriate statistical charts were used to represent the analysed data. All the data was analysed with the help of Statistical Software Package:-SPSS-v-23.0.

## RESULTS

Mean age in Group A and Group B was 39.35 $\pm$ 12.67 and 44.30 $\pm$ 16.02 years, respectively (P=0.129). There were no significant differences between the study groups regarding age, gender, surgical approach, ASA, P value  $>0.05$  [Table 1].

The incidence of ISP is shown in Table 2, in group A 10% patients experienced ISP after 1 hr of surgery and in group B 3.75% had ISP at 1 hr of surgery (p = 0.014). The reduction of PTISP was significant in group B in comparison to group A at one hr, three hrs, six hrs and 12 hrs post thoracotomy. The overall incidence of ISP among the two groups was statistically significant 85% in group A and 62.5% in group B.

The comparison of pain score among the two groups postoperatively shows statistically significant result; the pain score (VAS) at different intervals was lower in group B than group A [Table-2].

The number of rescue analgesia requirement was more in group A than group B, there was a statistically significant difference between the two groups (p value=0.001) Table-3. The maximum number of rescue analgesic doses required in group A were 4 and in group B were 3.

There was statistically significant difference in mean and SD Heart rate at three hrs of postoperative interval with p value < 0.019 Table 4.

There was no statistical significant difference in mean and SD systolic and diastolic BP postoperatively at studied intervals, p value>0.05[table 4].

There was no statistical significant difference in mean oxygen saturation between the two groups at the studied intervals postoperatively p value > 0.05[Table 4].

There was no statistically significant difference in mean RR and SD between the two groups at studied intervals postoperatively p value > 0.05[Table 4]and there was no incidence of hypoventilation( RR <10) in either groups.

**Table 1** Age, Gender distribution and ASA physical status

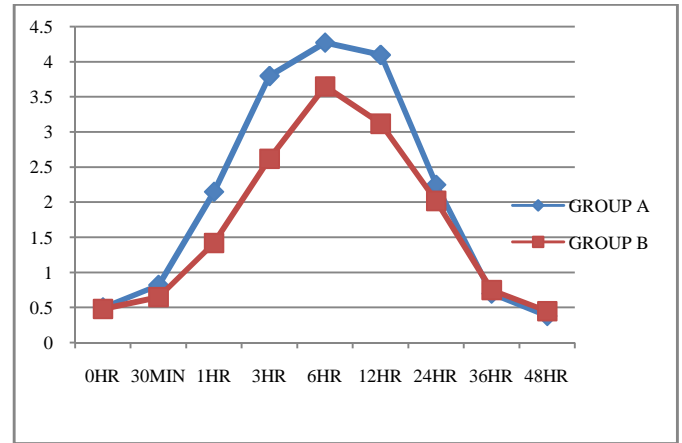
	Group A	Group B	P
Age(years)	20	20	
Mean±SD	39.35±12.67	44.30±16.02	0.129
Gender n,(%)			
Male	26(65.0)	21(52.5)	0.256
Female	14(35.0)	19(47.5)	
ASA, n(%)			
ASA 1	21(60.0)	24(60.0)	0.205
ASA 2	15(40.0)	13(32.5)	
ASA 3	0(0.0)	3(7.5)	

P value significant if 0.05,n: Number of patients, ASA: American Society of Anesthesiology physical status, SD: Standard deviation. Statistics done by Student t test, descriptive analysis, chi square test.

**Table 2** Pain scoring trend of PTISP

Time Interval	Group A(mean±SD)	Group B(mean±SD)	P
0hr	0.50±0.555	0.48±0.554	0.841
30min	0.82±0.781	0.65±0.736	0.305
1hr	2.15±1.252	1.42±1.318	0.014
3hr	3.80±1.400	2.62±1.390	0.000
6hr	4.275±1.109	3.65±1.210	0.018
12hr	4.10±1.081	3.12±1.381	0.001
24hr	2.25±1.080	2.02±1.330	0.409
36hr	0.70±0.687	0.75±0.899	0.781
48hr	0.38±0.490	0.45±0.552	0.523

P value significant if 0.05, SD: Standard deviation, hr: hour, min:minute. Statistical analysis done by Student t test.



**Figure 1** line diagram showing visual analog scale scoring.

**Table 3** Number of rescue analgesia required

Number of rescue analgesic	Group A	Group B	Total
0	0	4	4
1	4	13	17
2	11	13	24
3	15	10	25
4	10	0	17

P value 0.001: P value significant if 0.05. Analysis done by chi square test.

**Table 4** Comparison of postoperative Heart rate,blood pressure,Spo2 and respiratory rate

	1hr	3hr	6hr	12hr	24hr	48hr
HR(beats/min), mean±SD						
Group A	89.05±12.66	94.25±12.83	95.05±11.41	92.72±12.56	84.72±9.30	81.65±7.36
Group B	87.15±11.29	87.70±11.59	92.02±12.02	88.58±10.72	83.58±8.97	80.02±7.326
SBP(mmHg), mean±SD						
Group A	125.20±10.9	127.72±12.5	128.42±12.4	126.92±10.2	123.48±8.7	120.80±9.0
Group B	125.20±8.6	126.22±9.5	129.22±11.7	127.40±11.0	123.55±9.6	123.40±8.7
DBP(mmHg), mean±SD						
Group A	76.02±7.0	79.05±8.0	79.18±7.6	77.65±7.4	75.55±5.6	74.55±5.4
Group B	75.82±5.0	78.52±7.5	79.45±8.0	77.85±7.3	74.95±12.4	75.15±5.4
Spo2%, mean±SD						
Group A	96.10±1.9	96.32±1.9	96.10±1.7	95.82±1.4	96.18±1.3	96.18±1.5
Group B	96.08±1.7	96.18±1.5	95.90±1.5	95.78±1.5	96.08±1.4	96.18±1.7
RR(beats/min), mean±SD						
Group A	15.6±2.4	16.2±2.9	17.0±3.6	16.8±3.1	16.2±1.2	16.3±1.1
Group B	14.7±1.9	15.8±2.2	15.9±2.4	15.8±1.9	15.9±1.4	15.9±1.2

P value significant if 0.05. SD: Standard deviation, HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure,Spo2%:oxygen saturation, RR: Respiratory rate. Statistical analysis done by Student t test.

## DISCUSSION

Ipsilateral shoulder pain is often difficult to treat as it is resistant to intravenous opioids and require increased epidural infusion rates. The shoulder pain is referred from diaphragm to the shoulder by phrenic nerve which can be managed by infiltrating the phrenic nerve with local anaesthetic, also the chest drains in the pleural, space cause diaphragmatic irritation which leads to shoulder pain can be reduced by instilling the pleural space around the drain site with local anaesthetic.<sup>10</sup>

Ropivacaine is used in this study as it has safer adverse effect profile, it's a long acting amide with less lipophilic characteristics, for which it has a higher threshold for toxicity levels with long lasting analgesic effects.<sup>11</sup>

Patients in this study experienced ISP in both the groups within 12 hrs of surgery, with longer time gap to experience pain was in group B (6hrs) as compared to group A( 3hrs).

Both the groups had functioning epidural and provided with rescue analgesia for ISP after assessing with Visual Analog Scale score and VAS score was less in group B with statistically significant difference between the studied intervals. The incidence of PTISP in group A was 85% and in group B was 62.5%. These results are consistent with the study done by Burgess *et al*<sup>12</sup> and Scawn *et al*<sup>13</sup> with reported incidence of PTISP that vary from 75% to 85%. However in PNB group the incidence was lowered and the VAS was significantly reduced.

In our study we demonstrated that phrenic nerve infiltration with 0.2% ropivacaine 10ml is more efficacious in preventing PTISP than intrapleural instillation of 0.2% ropivacaine 40ml with lesser incidence of any complications, no major adverse events seen such as phrenic nerve palsy, respiratory insufficiency, local anaesthetic toxicity.

Among all the evaluated demographic parameters, age in years, gender and ASA physical status, have not shown any statistical significant difference and were comparable in the two groups. These parameters were correlated with the study done by Carlos MB *et al*<sup>14</sup>. 45% patients underwent left posterolateral thoracotomy, 55% patients underwent right posterolateral thoracotomy. There was no statistically significant difference on basis of type of surgery, which were consistent with study by S H Pennefather *et al*<sup>10</sup>.

On assessing the VAS score between the two groups at various intervals statistically significant difference was found between Group A versus Group B, lower in group B.

The time gap between study drug intervention and the first rescue analgesia was longest in group B than group A. The difference among the two groups was statistically significant. Our study correlated with the study done by M Sobia *et al*<sup>15</sup> which has showed that the time for first rescue analgesia requirement was longer in phrenic nerve infiltration group as compared to paracetamol infusion group.

Group A required more number of rescue analgesia than group B. There was statistically significant difference in epidural top up requirement between the two groups. This was correlated with study by G. Danelli *et al*<sup>6</sup> who found that phrenic nerve infiltration reduced the incidence and delayed the onset of ipsilateral shoulder pain after thoracotomy. In Group A 72.5% incidence of complications seen like dizziness, somnolence, nausea, hypotension, tachycardia as compared to group B which had 42.5%. There was no statistical significant difference found between the two groups. However on observation scale incidence of complications are seen less in group B. These parameters correlate with the study done by M.R Blichfeldt-Eckhardt *et al*<sup>16</sup> with no major complications like respiratory compromise or nerve injury were observed.

Study done by S.H. Pennefather, M.E. Akrofi *et al*<sup>10</sup>, where patients were randomly allocated in two groups with one group received 40ml of intrapleural bupivacaine 0.25% with epinephrine 1:200,000 and other group received 40ml of intrapleural saline and concluded that intrapleural administration of bupivacaine does not provide effective pain relief for ipsilateral post thoracotomy shoulder pain, which correlates with our study as intrapleural infiltration didn't provide effective analgesia for relieving PTISP.

Blichfeldt *et al*<sup>16</sup> conducted a study in patients scheduled for lobectomy or pneumonectomy were subjected to either

ultrasound guided supraclavicular phrenic nerve block with 10ml ropivacaine or 10 ml saline (placebo). They found that lesser number of patients in ropivacaine group experienced shoulder pain than control group, which is in favour of our study.

Carlos *et al*<sup>14</sup> conducted a study comparing intraoperative periphrenic fat pad infiltration with lidocaine and post operative suprascapular nerve block with bupivacaine. They found that PNI technique is superior to SNB in providing effective analgesia for post thoracotomy ISP. This again has the similar results as that of our study.

Study done by Cremades *et al*<sup>17</sup> correlates with our study, in this study patients were divided into two groups, one received phrenic nerve infiltration with 0.2% ropivacaine and other one remained non infiltrated and concluded that phrenic nerve infiltration with ropivacaine relieves ISP without any respiratory compromise.

Our study contradicts the study done by Yoshihiro Ishikawa *et al*<sup>18</sup> which included two groups one received 0.375% ropivacaine into intrapleural space two times and the other group received continuous epidural analgesia with 0.375% ropivacaine and found that intrapleural group required less number of additional analgesia postoperatively.

## CONCLUSION

PTISP is very frequent problem associated with thoracotomy and is transmitted through phrenic nerve. Therefore blocking phrenic nerve with 0.2% ropivacaine significantly reduced the incidence and severity of PTISP with no major adverse effects.

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