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A Comparative Study of Postoperative Pulmonary Complications Using Fast Track Regimen and Conservative Analgesic Treatment: A Randomized Clinical Trial

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ABSTRACT

Background: Postoperative pulmonary complications and pain are important causes of postoperative morbidity following thoracotomy. This study aimed to compare the effects of fast track and conservative treatment regimens on patients undergoing thoracotomy.

Materials and Methods: In this randomized controlled clinical trial, we recruited 60 patients admitted to the thoracic ICU of Imam Reza Hospital in two matched groups of 30 patients each. Group 1 patients received fast track regimen randomly; whereas, group 2 cases randomly received conservative analgesic regimen after thoracotomy and pulmonary resection. The outcome was determined based on the incidence of pulmonary complications and reduction of post-thoracotomy pain in all patients with forced expiratory volume in one second (FEV1) <75% predicted value which was measured while the patients were in ICU. The length of ICU stay, thoracotomy pain, morbidity, pulmonary complications and mortality were compared in two groups.

Results: A total of 60 patients, 45 (75%) males and 15(25%) females with ASA class I-III were recruited in this study. Postoperative pulmonary complications were observed in 5 (16.7%) patients in group 1 versus 17 (56.7%) patients in group 2. There were statistically significant differences in development of postoperative pulmonary complications such as atelectasis and prolonged air leak between both groups ($P < 0.001$ and $P = 0.003$). There was also a statistically significant difference in the rate of preoperative FEV1 ($p = 0.001$) and ASA scoring ($p = 0.01$) and value of FEV1 <75% predicted in the two groups. The difference in length of ICU stay in two groups was statistically significant ($P = 0.003$ and $P = 0.017$ in FEV1 <75% group). Four patients in group 1 and 9 patients in group 2 had FEV1 reduced to less than 75% of predicted value ($p = 0.03$).

Conclusion: Using fast track regimen reduced postoperative pain and incidence of some pulmonary complications significantly when compared to the conservative regimen following thoracotomy and various lung surgeries. (Tanaffos 2011; 10(3): 12-19)

Key words: Fast track regimen, Pulmonary complications, Thoracotomy, Pain

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INTRODUCTION

Most pulmonary complications after thoracic surgery are related to pain, and inadequate analgesia. Following thoracotomy, postoperative pulmonary complications are an important cause of morbidity and mortality. When postoperative pain is minimized by using opioids, rate of postoperative pulmonary complications and also the duration of ICU and hospital stay decrease significantly(1). The incidence of postoperative pulmonary complications such as pneumonia, atelectasis and pleural effusion is as high as 25% and mortality rate is about 7.5% as reported in the literature (2). The incidence of morbidity after lung surgery reaches up to 39.6% (3). Because of the inadequate analgesic effect of single dose opioids, attention is being directed towards multimodal therapies that reduce surgical stress and post thoracotomy pain because postoperative analgesia reduces pulmonary complications after thoracic surgeries (1).

This randomized clinical trial aimed to compare the effects of fast track regimen with conservative analgesic treatment on post thoracotomy pain, complications, and length of ICU and hospital stay.

MATERIALS AND METHODS

This was a double blind randomized controlled clinical trial and 60 patients with ASA (American Society of Anesthesiologists) class I-III admitted to the ICU of Imam Reza Hospital affiliated to Tabriz University of Medical Sciences, who had undergone standard thoracotomy for pulmonary resections, from July 2010 to August 2010 were randomly divided into two groups. The study was approved by the Ethics Committee of Tabriz University of Medical Sciences and registered with IRCT number: 138902093831N1.

Inclusion criteria:

- Patients with resectable pulmonary mass or lesions.
- Patients with no coagulopathy.

- Patients with no preexisting underlying pulmonary conditions such as asthma, bronchitis or emphysema.

Exclusion criteria:

- Operation time more than 3 hours.
- Patients who lost blood more than 25% of their circulating blood volume intraoperatively.
- Patients with cardiac compromise.
- Patients with ASA class IV

Patients were randomly divided into two groups: group I was given fast track analgesic regimen through a preoperatively inserted epidural catheter which was placed in intervertebral spaces T5-T6 using loss of resistance technique. At the end of surgery, 0.25% epidural marcaine and 2µg/ml fentanyl were infused. Marcaine (2-2.5 µg/hour) was transfused at the rate of 5ml/hour postoperatively via patient controlled epidural analgesia (PCEA) in the ICU. Diclofenac suppository (100 mg) was also administered when needed. Feeding and ambulation started the night after and one day after surgery, respectively. Group II was given conservative treatment. In this regimen at the end of thoracotomy, intercostals blockade was performed in four intercostals spaces using single shot injection of marcaine 0.25%. Morphine (1mg/hour) was infused postoperatively via intravenous patient controlled analgesia (IVPCA) in the ICU and if needed suppository diclofenac (100mg) was used every 12 hours. This regimen was repeated every 24 hours. Both feeding and ambulation started the day after surgery. The results obtained from the study were evaluated as the percentage of patients with analgesia failure and postoperative complications (pulmonary and non pulmonary) during ICU or hospital stay.

No analgesic medication was used during the surgery in both groups.

Complications related to the analgesic methods used such as abscess formation at the site of intravenous catheter insertion, displacement of epidural catheter, CSF (Cerebrospinal fluid) leakage, meningitis or postoperative headache did not occur in

any of our patients. Sporadic intravenous phlebitis was seen in some patients which was treated successfully.

Chest physiotherapy and pulmonary rehabilitation which included training patients how to make an effective cough, postural drainage positions, manual cough technique, exercises to mobilize the chest, pursed-lip breathing and diaphragmatic breathing were routinely performed for all patients in both groups.

Technique of anesthesia:

In both groups anesthesia induction was performed using fentanyl 2µg/kg, propofol 2-2.5 mg/kg and atracurium 0.4-0.6 mg/kg. Anesthesia was maintained using TIVA (Total Intravenous Anesthesia) in both groups using propofol 50-150 µg/kg/h and remifentanyl 1 µg/kg/min. Intraoperative pain was controlled using remifentanyl infusion 1 µg/kg/min and N₂O administration 3 Lit/min in both groups. IPPV mode was utilized in all patients with a tidal volume of 100mg/kg while end-tidal CO₂ remained in the range of 34-40 torr. Double Lumen Endotracheal Tube was used in all patients and correct tube position was confirmed by fiberoptic bronchoscopy. After completion of the surgery all patients who had undergone extensive thoracotomy and pulmonary resections were extubated in the operating room, transferred to Post Anesthesia Care Unit (PACU) and after two hours to the ICU.

Stable vital signs, absence of arrhythmias or respiratory failure, normal ABG and acceptable reduction of postoperative pain were discharge criteria for transferring patients from the ICU to the thoracic ward.

Statistical analysis

The primary and secondary endpoints of the present study were to compare the reduction of post thoracotomy pulmonary complication rates and pain between the two groups, respectively. Data were presented as mean± SD and N (%). Variables were analyzed with the independent samples t test for

continuous variables and Chi-square or Fisher's exact test for nominal or ordinal variables. P-value less than 0.05 was considered statistically significant. SPSS version 16 software was used for statistical analysis.

RESULTS

There were 26 (86.7%) males and 4 (13.3%) females in group I while in group II, 19 (63, 3%) were males and 11 (36.7%) were females. The mean age of all patients was 45.1± 2 years (range 18-75 yrs). The mean age of patients was 49.7± 1.4 years (range 21 – 75 years) in group I and 40.5± 1.6 years (range 18-74 years) in group II. There were no statistically significant differences between the two groups in terms of age, gender, preoperative FEV1, ASA scoring, type of surgery and intraoperative bleeding time (Table 1).

Postoperative pulmonary complications occurred in 5/30 (16.7%) patients in fast track regimen versus 17 /30 (56.7%) in the conservative treatment group. Some patients in both groups had more than one pulmonary complication. Types and details of pulmonary and other types of complications are presented in Table 2. The two groups had statistically significant differences in terms of rate of pulmonary complications such as atelectasis, and prolonged air leak >7days (P< 0.001 and P= 0.003, respectively). Incidence of other complications (Table 2) was not significantly different between the 2 groups. Diagnosis of atelectasis was made based on clinical signs and fever as well as decreased pulmonary sounds and confirmed by chest imaging. In the ICU, flexible bronchoscopy was required in 1 patient in group 1 and 9 patients in group 2 for treatment of atelectasis. Pleural effusion diagnosed with chest x-ray alone with no need for intervention was seen in one patient in group 2. Arrhythmias were seen in two patients in group 2 and one patient in group 1. One patient in group 2 died due to pulmonary edema. Regarding the rate of some pulmonary

complications, a significant reduction was observed in fast track patients.

Table 3 demonstrates the detailed characteristic of subgroups of patients with reduced pulmonary capacity of FEV1 < 75% of predicted value ($p=0.001$) and ASA scoring of the patients ($p=0.01$).

The two groups had a statistically significant

difference in terms of the length of ICU stay and hospitalization period ($P=0.003$, and $p=0.03$) and also in the subgroup of FEV1 < 75% ($P=0.017$ and $p=0.018$).

The incidence of mortality was 0 in group 1 versus 1 patient in group 2.

Table 1. Patients' characteristics in two groups

	Group I N (%)	Group II N (%)	P-value
Pulmonary function			
FEV1 (pre op)	2.7 ± 0.8 (1.1 – 4.4)	2.3 ± 0.8 (0.8– 4.4)	0.12
ASA score			0.13
ASA I	4(13.3)	2(6.7)	
ASA II	8(60)	25(83.3)	
ASA III	18(26.7)	3(10)	
Surgical procedures			0.81
Wedge resection	9(30)	12(40)	
Lobectomy	14(46.7)	13(43.3)	
Bilobectomy	2(6.7)	2(6.7)	
Pneumonectomy	4(13.3)	3(10)	
Sleeve resection	1(3.3)	-	
Length of ICU stay (days)	2 (1-4)	3 (1-5)	0.003
Day of discharge	7 (2-23)	10 (4-22)	0.03
Surgical time (hours)	2.4 ± 0.5 (1.15-3)	2.1 ± 0.5 (1.30-3)	0.13
Bleeding volume (ml)	640 ± 240 (250-1000)	550 ± 230 (200-1250)	0.15
Postoperative fever	5 (16.7)	10 (33.3)	0.11

Table 2. Postoperative complications and death in both groups

	Group I N(%)	Group II N (%)	P value
Pulmonary complications			
Atelectasis	1 (3.3)	13 (43.3)	< 0.001
Pleural effusion	-	1 (3.3)	1
Empyema	1 (3.3)	1 (3.3)	1
Pulmonary edema	-	1 (3.3)	1
Prolonged air leak > 7 days	5 (16.7)	16 (53.3)	0.003
Others			
Arrhythmias	2 (6.7)	1 (3.3)	1
Mortality	-	1 (3.3)	1

Table 3. Detailed characteristics of patients in the subgroup of FEV1, below 75% predicted value in both groups.

	Group I n(%)	Group II n(%)	P value
Pulmonary function			0.001
FEV1 (% of predicted value)	59.8± 2.1 (38-73)	58.3 ± 2.8 (28-71)	
ASA score			0.01
ASA I	-----	1 (5)	
ASA II	11 (61.1)	16(80)	
ASA III	7 (38.9)	3 (15)	
Surgical procedures			0.06
Wedge resection	5 (27.8)	10 (50)	
Lobectomy	8 (44.4)	5 (25)	
Bilobectomy	1 (5.6)	2 (10)	
Pneumonectomy	4 (22.2)	3 (15)	
Sleeve resection	-----	-----	
Length of ICU stay (days)	2± 0.2 (1- 4)	3± 0.6 (1- 5)	0.017
Hospitalization period	8± 1.3(2- 23)	14± 1.2 (2- 22)	0.018

DISCUSSION

This randomized clinical trial study showed that fast track multimodal analgesia regimen with fentanyl and marcaine (PCEA) following thoracic surgery had better analgesic results and significantly reduced the incidence of some pulmonary complications when compared to conservative multimodal analgesia using morphine (IVPCA).

Fast track analgesic regimen included infusion of marcaine, fentanyl via epidural catheter using patient controlled epidural anesthesia (PCEA) postoperatively+ diclofenac suppositories + chest physiotherapy and pulmonary rehabilitation + early ambulation. Conservative analgesic treatment comprised of intercostals block with marcaine at the end of surgery + infusion of morphine using intravenous patient controlled analgesia (IVPCA) continued during the ICU stay + diclofenac suppositories + chest physiotherapy and pulmonary rehabilitation + ambulation.

Pulmonary complications and pain were severe and serious during 3-5 days following major thoracic

surgeries and can result in morbidity and even mortality. Well-planned pain management has always played an important role in decreasing morbidity after thoracic surgery (4). Pain Relief, evacuation of secretions and early mobilization of the patient can lead to early recovery; decreased pulmonary complications and shortened hospital stay (5). Inadequate postoperative pain management may lead to the development of complications. Single intravenous analgesics seem to be inadequate; therefore, multimodal analgesic protocols are needed to decrease postoperative complications and morbidity. In this study, the efficacy of fast track regimen treatment was evaluated and compared with conservative treatment protocol. Our study evaluated pain management in all types of pulmonary diseases requiring surgery. Preoperative FEV1, ASA scoring and surgical approaches were compared in two groups. Early calorie intake, heat loss and early ambulation are the main factors in achieving early recovery in patients (6-8). Minimally invasive video-assisted thoracoscopic surgery, intravenous opioids

and cryoanalgesia can conservatively decrease post thoracotomy complications (9, 10).

Recently, two reliable multimodal analgesic treatments are being used following thoracotomy including intravenous patient controlled analgesia (IVPCA= conservative) and patient controlled epidural analgesic (PCEA). These two protocols have been reported to be preferable for preventing or decreasing postoperative pain and pulmonary complications (10).

Opioids administered through epidural segmental analgesia can improve the quality and duration of sensory block produced by local anesthetics (11, 12). Our results also show the superiority of fast track analgesic regimen after thoracotomy especially in decreasing the incidence of some pulmonary complications such as atelectasis, prolonged air leak more than 7 days, and ICU and hospital stay duration. Although PCEA or fast track regimen protocol has been reported to be superior compared to other protocols, there is a lack of information about these protocols and it seems that more studies are needed to confirm the superiority of PCEA or fast track regimen protocol in reducing postoperative pain and complications. This challenge still exists for the anesthesia and surgical community (13, 14). In this regard, Koehler and colleagues suggest that administration of opioids via intravenous patient-controlled anesthesia (IVPCA) should be concomitantly offered to thoracic surgery patients in addition to PCEA (15).

Benzo et al. carried out a Meta-analysis study on 30 patients and revealed a significant reduction in vital capacities after thoracic surgery which accelerated morbidity and pulmonary complications (16). Bauer, Weber and Concha also demonstrated the superiority of PCEA protocol in preventing pulmonary complications and relieving postoperative pain in their studies (13, 14, 17). Concha and colleagues studied two separate groups of patients: in group I

(n=16) patients received a 5 segment intercostals block plus IVPCA using morphine and in group II (n=15) patients received bupivacaine and fentanyl PCA infusion via thoracic epidural catheters and showed that intercostals block with bupivacaine combined with morphine PAC have good results in managing post thoracotomy pain (13). Weber et al.'s study was carried out on 20 adolescents and children with pectus excavatum who were treated with minimally invasive techniques and it was confirmed that thoracic epidural analgesia was superior to intravenous patient controlled analgesia, resulting in lower postoperative pain scores (7). Wu and colleagues performed a Meta-analysis study on 353 patients who underwent major thoracic surgeries and obtained better pain control results in patients with PCEA compared with intravenous patient controlled analgesia (10). A Meta analysis carried out by Ballantyne on seven types of analgesics showed that epidural opioids and local anesthetics improved pulmonary condition and decreased the incidence of pulmonary morbidity, but failed to demonstrate the benefit of the pain management on pulmonary functions (18).

In a systematic review by Hudcova and colleagues, intravenous opioids PCA provided better analgesia and patient comfort compared to parenteral methods of opioids administration (19).

The rate of complications after thoracic surgery is reported to be 25% to 40% in the literature (3). In our small series we could reduce the incidence of post thoracotomy complication to 16.7% using fast track protocol whilst the incidence was 56.7% in conservative method group. Duration of ICU and hospital stay also decreased significantly in fast track treatment group compared to conservative treatment group.

Our study is consistent with some studies in the literature where better results and postoperative vital capacity have been reported using fast track regimen

treatment compared to systemic opioids. We were not able to record FEV1 and FVC of patients in ICU after surgery. Therefore, we could not obtain statistical data and could not compare the 2 groups in this respect.

Mortality rate of up to 7.5% has been reported in the literature (2). Mortality of our studied groups was almost 1.7% depending on the extent of surgery and pulmonary function and omitting ASA class IV patients from the study.

Limitations:

- We had a small under study population and further multicenter studies with a larger sample size are required to confirm our results.
- Degree of pain and pain scores were not determined in this randomized clinical trial.
- Our patients were not followed up after being discharged from the hospital.

CONCLUSION

Fast track protocol using fentanyl and Marcaine combined with multimodal treatments provides better pain relief after thoracic surgery and reduces the incidence of pulmonary complications such as atelectasis and prolonged air leak significantly.

Conflict of interest: The authors have no conflict of interest related to this article.

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