Analgesia in patients undergoing thoracotomy: Epidural versus paravertebral technique. A randomized, double-blind, prospective study

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Background: Pain control after thoracotomy prevents postsurgical complications and improves respiratory function. The gold standard for post-thoracotomy analgesia is the epidural catheter. The aim of this study was to compare it with a new technique that involves placement of a catheter in the paravertebral space at the end of surgery under a surgeon's direct vision.

Methods: From November 2011 to June 2012, 52 patients were randomized into 2 groups depending on catheter placement: an epidural catheter for group A and a paravertebral catheter for group B. At 12, 24, 48, and 72 hours after surgery, the following parameters were recorded: (1) pain control using the patient's completion of a visual analog scale module, (2) respiratory function using forced expiratory volume in 1 second and ambient air saturation, and (3) blood cortisol values as an index of systemic reaction to pain.

Results: Statistically significant differences (P < .05) were found in favor of group B for both cough and rest pain control (P = .002 and .002, respectively) and respiratory function in terms of forced expiratory volume in 1 second and ambient air saturation levels (P = .023 and .001, respectively). No statistically significant differences were found in blood cortisol trends between the 2 groups (P > .05). Collateral effects such as vomiting, nausea, low pressure, or urinary retention were observed only in group A. No collateral effects were recorded in the paravertebral group.

Conclusions: According to our data, drugs administered through a paravertebral catheter are very effective. Moreover, it does not present contraindications to its positioning or collateral effects. More studies are necessary to confirm data we collected. (J Thorac Cardiovasc Surg 2014;147:469-74)

Pain after standard thoracotomy is often present and associated with severe complications, such as atelectasis. This can also develop into a severe pneumonia due to retention of secretions.¹⁻³ Pain prevents effective coughing, deep breathing, and a patient's mobility. Generally, strong pain after surgery increases perioperative morbidity and may also lead to chronic pain.⁴⁻⁶ At present, various techniques are proposed and used to prevent thoracic pain after thoracotomy. Among these, the most common is thoracic epidural anesthesia (EA), considered to be the gold standard.⁷⁻⁹

Our study compares the efficacy of EA with a technique that consists of the placement of a catheter in the

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Copyright © 2014 by The American Association for Thoracic Surgery http://dx.doi.org/10.1016/j.jtcvs.2013.09.024 paravertebral space, resulting in paravertebral anesthesia (PA).

This technique was previously proposed and tested almost 20 years ago but never became very popular in clinical practice.^{10,11} The most interesting and recent article on this topic presents a systemic review and meta-analysis of 10 randomized trials by Davies and colleagues,¹² including 520 adult patients. PA resulted the same in terms of pain control, but was better as concerns contraindications and adverse effects in comparison with EA. However, the studies were of moderate quality because they did not use uniform populations regarding positioning techniques, drugs used, and largely because there were no blinding.

An EA catheter is usually placed by an anesthesiologist immediately before surgery when the patient is awake, using local anesthesia to prevent positioning pain. This method is contraindicated for patients taking anticoagulant or antiplatelet drugs that cannot be suspended for the perioperative period or for those who have coagulopathies.^{13,14} Moreover, this technique may result in dangerous risks during placement, including dural perforation, spinal cord hematoma, spinal infection, or abscess.^{15,16} During treatment some adverse effects may occur, including hypotension, urinary retention, nausea, vomiting, or itching.¹⁷⁻¹⁹ On the contrary, the PA catheter does not

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Abbreviations and Acronyms

- EA = epidural anesthesia
- FEV1 =forced expiratory volume in 1 second
- PA = paravertebral anesthesia
- VAS = visual analog scale

present any contraindications during placement and, due to the drugs used and to the anatomical space where they are administered, it has no side effects. Two different approaches for placing the catheter in the paravertebral space are used: a blind approach, also known as an anesthetic approach, using the loss of resistance technique first described by Eason and Wyatt,¹⁷ and a de visu approach where the catheter is placed by a surgeon at the end of the thoracotomy.¹⁸

The aim of our study was to investigate if PA is as effective as EA in patients undergoing thoracotomy. Our primary outcome was to compare pain control, both at rest and while coughing, between the 2 groups. Our secondary outcome was to compare surgical stress and respiratory function in these patients.

MATERIALS AND METHODS

The study was approved by the local ethics committee of St Paolo Hospital at the University of Milan (No. 9898). All recruited patients provided informed and written consent to the study. We considered patients who underwent muscle-sparing thoracotomy for surgery due to pulmonary neoplastic diseases, pleuric empyema, lung volume reduction surgery, bronco-pleural fistula, or infectious diseases. Our inclusion and exclusion criteria are reported in Table 1. The study was prospective, randomized, and double-blind.

Patients were recruited between November 2011 and June 2012 and randomly located by computer-generated randomization in 1 of the following 2 groups: Group A, EA with infusion through the catheter of 0.001% fentanyl (10 μ g/mL) with 0.1% bupivacaine. Group B, PA with infusion of 0.3% naropine (5-10 mL vials 10 mg/mL in 100 cc 0.9% saline solution). Each patient in the 2 groups had simultaneous infusion of paracetamol (1-500 mg vial) 4 times a day and the opportunity to ask for tramadol (1-50 mg/1 mL vial in 100 cc of 0.9% saline if visual analog scale (VAS) score was >6 maximum twice a day). Any other requests by patients to be administered more pain medication were recorded and satisfied.

All patients were pretreated with sublingual morphine. In group A the epidural catheter was placed immediately before surgery according to the standard techniques. The patient was awake and placed in a seated position and the interspace T5/6, T6/7 was detected; using the midline approach and the loss of resistance technique, the catheter was inserted. In group B the paravertebral catheter was placed at the end of surgery using the de visu technique: an 18-gauge Thohy needle was placed through the chest wall at an appropriate site in the same interspace as the thoracotomy incision. The needle's obturator was removed and the catheter passed through and emerged inside the thoracic cavity. A localized extrapleural, paravertebral pocket was then created by placing a gently curved clamp under the parietal pleura at the posterior end or apex of the intercostal incision. Then, the catheter was gently prompted inside the pleural pocket and pushed close to the paravertebral space. Once positioned, a piece of hemostatic sponge was placed at the entrance of the pleural pocket to avoid spreading of medication. The external side of the catheter was then fixed to the skin with a transparent patch. We always placed 2 chest tubes before thoracotomy closure. All surgeries were performed by AB and FR. In each group the catheter was removed on the same day that the final chest tube was removed, between the third and fifth day after surgery, except for 1 patient with prolonged air leaks.

We arbitrarily identified the length of surgery as the period from the arrival of patients in the operating room area to the end of thoracotomy closure. To evaluate pain systemic response blood cortisol was measured 30 minutes after thoracotomy and then at 6, 12, 24, 48, and 72 hours after surgery. Pain level was measured using a VAS, where 0 = indicates no pain and 10 = severe pain, at 6, 12, 24, 48, and 72 hours after surgery. To evaluate pulmonary function at 6, 12, 24, 48, and 72 hours, forced expiratory volume in 1 second (FEV1) and ambient air saturation were measured. Possible drug-related complications such as urinary retention (defined as Foley catheter replacement after initial removal), itching, nausea/vomiting, or postural hypotension were recorded in the postoperative period. We evaluated pain using the VAS scale, both at rest and while coughing, during the 3 months postsurgical clinical control, and recorded the patients' VAS scale answers. All data were recorded by the research fellow (ie, AR). Normally distributed results were compared by Student t test analysis and nonnormally distributed results were compared by Mann-Whitney analysis. The population of the recruited patients was calculated to be sufficient for obtaining statistical significance.

RESULTS

From November 2011 to June 2012, 52 patients were enrolled and randomized for the study. Three patients were excluded from the EA group due to an erroneous location of the catheter and 1 patient was excluded from the PA group because of accidental removal of the catheter. The 2 groups were composed of 24 patients each, 50% and 54% men in the EA and PA groups, respectively. The mean patient age was 78 years in both groups. No statistical significance was found in the demographic traits (ie, weight, height, and body mass index) of the 2 groups (P > .468) (Table 2). No patients in either group had a prior history

TABLE 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age >18 or <80 y	Age <18 or >80 y
Karnofsky performance scale \geq 70%	Coagulopathies
American Society of Anesthesiology	Therapies
Classification <iv< td=""><td></td></iv<>	
Forced expiratory volume in 1 second	Allergies
\geq 50% predicted	
Wegener's granulomatosis (white blood cell	Spinal deformities
$count > 4000/mm^3$)	
Primary systemic chemotherapy (platelet	Neurologic diseases
$count > 100,000/mm^3$)	
Hemoglobin >8.5 g/dL	Psychiatric diseases
Bilirubin <3.0 mg/dL	Past thoracic surgery
Aspartate transaminase <2 times limits	Pre-op thoracic drainage
Creatinine <3.0 mg/dL	Past acute myocardial
	infarction
Carbon dioxide tension <50 mm Hg	Abuse of alcohol or drugs
	Body mass index >30
	Pregnancy

Pre-op, Preoperative.

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