Erector Spinae Plane (ESP) Block versus Thoracic Epidural Analgesia (TEA) in Video-Assisted Thoracic Surgery (VATS): A Prospective Randomized Open Label Non-Inferiority Trial

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Effective postoperative pain control is an essential and humanitarian need of every surgical procedure. Inadequate pain control may result in increased mortality, delayed recovery and increased hospital costs (1). The optimal perioperative analgesic...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON22453

Source
Nationaal Trial Register

Brief title
ESP VATS

Condition

- Respiratory tract therapeutic procedures

Synonym
lungcancer, postoperative pain

Research involving
Human

Sponsors and support

Primary sponsor: Catharina ziekenhuis Eindhoven
Source(s) of monetary or material Support: We applied for internal funding (Catharina Onderzoeksfonds).

Intervention

Keyword: Video Assisted Thoracic Surgery (VATS) Thoracic Epidural Analgesia (TEA) Erector Spinae Plane block

Explanation

Outcome measures

Primary outcome

The primary outcome of this study is the QoR15 (See section 6.1.) on POD1 and 2 including subscale analysis Comfort; Emotions, Independence, Support and Pain).

Secondary outcome

Secondary endpoints include

- postoperative Visual Analog Scales (VAS) score on day 1 and 2 (assessed at rest and when moving (coughing) in the morning and in the evening)

- Length of hospital stay (LOS),

- requirement of rescue medication

- postoperative morphine-equivalent consumption per day,

- failure of analgesic technique (defined as catheter failure, need for specialist intervention and/ or need for rescue medication) (Table 1)

- the total operative time (recorded as total time spent in the operating room, anesthetic time, surgical time),

- complications related to surgery (e.g. bleeding, surgical site infection, conversion to open procedure),

- complications related to pain treatment (e.g. epidural hematoma and abscess or local anesthetic toxicity)

- duration of bladder catheterization,

- first mobilization to chair and > 20 meters

- 30 days post-surgical evaluation by phone of pain, opioid use and patient satisfaction

Study description

Background summary

This is an investigator-initiated prospective randomized open label non-inferiority trial comparing the thoracic epidural (TEA) with the Erector Spinae Plane block (ESP) as regional anesthesia technique for VATS-surgery. The ESP-block is recently introduced in clinical practice as an easy, safe and reliable alternative to the thoracic epidural. This new technique injects local anesthetic within a plane beneath the erector spinae muscle to achieve analgesia (6).

A total of 90 patients are being randomly allocated to ESP (study group) or TEA (control group). Patients will be followed until 48 hours after surgery or until discharge from the hospital. Primary outcome is the Quality of Recovery 15 (QoR15) score. We hypothesize that the ESP is equally as effective as a TEA, without the disadvantages (bedrest, urinary catheter, rare but serious neurologic adverse events).

Study objective

Effective postoperative pain control is an essential and humanitarian need of every surgical procedure. Inadequate pain control may result in increased mortality, delayed recovery and increased hospital costs (1). The optimal perioperative analgesic strategy is preemptive and involves the combined administration of local anesthetic techniques [local anesthetic infiltration, peripheral nerve blocks, and neuraxial blocks (epidural and paravertebral)], systemic analgesic agents (opioids, acetaminophen, non-steroidal anti-inflammatory drugs, and cyclooxygenase-2-specific inhibitors) and analgesic adjuncts such as steroids, ketamine, α-2 agonists, and anticonvulsants (2). This so-called multimodal approach improves the analgesic effect because of the synergizing effect between the different analgesia techniques and/or drugs.

Up until now, the epidural analgesia is the gold standard local anesthetic technique for VATS surgery (3). However, the invasiveness of this technique, the rare but serious neurologic complications and the failure rates up to 30% (4) have resulted in a search for alternatives. Alternatives include lower thoracic catheter placement, intercostal nerve blocks, paravertebral blocks, intrapleural catheters, local anesthetic infiltration, and systemic analgesia with one or more agents (4). However, none of these techniques were able to replace the thoracic epidural as gold standard due to (5) ‘too technically challenging’ or ‘insufficient analgesia’ (6). Recently the ESP-block has been introduced in clinical practice as an easy, safe and reliable alternative to the thoracic epidural. This new technique injects local anesthetic within a plane beneath the erector spinae muscle to achieve analgesia (6).

The most significant advantage of the ESP-block is its simplicity and safety. The sonoanatomy is easily recognizable and there are no structures at risk of needle injury in the immediate vicinity (6). Case reports describe the successful application of the ESP-block for analgesia after VATS surgery (7,8), but evidence from large trials targeting a specific surgical population is lacking. To test the hypothesis that the ESP block with Continuous ESP Analgesia (ESP) is non-inferior in terms of the quality of recovery as measured by the Quality of Recovery 15 (QoR15) score compared to the thoracic epidural with continuous epidural analgesia (TEA) for patients undergoing elective unilateral VATS.

Study design

Patients will be followed until 48 hours after surgery or until discharge from the hospital. Thirty days after the surgery, patients will be contacted for a telephone survey.

Intervention

Patients will be randomized (1:1) to receive either pain treatment with ESP (the study group) or TEA (the control group). Patients in the intervention group receive continuous ESP analgesia (ESP) with bupivacaine 0.125% and a PCIA pump with morphine. Settings of the continuous ESP analgesia are 10- 15ml/h, settings of the PCIA pump are according to local protocol. When ESP does not provide adequate pain relief, minor adjustments or a manual top-up are allowed. Patients in the control group receive thoracic epidural analgesia (TEA) through a continuous epidural analgesia (CEA) pump with bupivacaine 0.125% + sufentanil 1mcg/ml at 8 - 12ml/h. When CEA does not provide adequate pain relief, minor adjustments or a manual top-up are allowed.

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: (1) Age between 18 and 75 years old, (2) BMI between 20 and 30kg/m 2 , (3) scheduled for elective VATS, and (4) written informed consent.

Exclusion criteria

Exclusion criteria are as follows: (1) ASA status ≥ 4, (2) chronic opioid use (> 3 months of strong opioids, weak opioids such as tramadol are allowed), (3) renal or liver failure inhibiting the systematic use of paracetamol and/or NSAIDs, (4) contraindication for epidural analgesia (e.g. INR or platelets according to local protocol, local infection at the surgery site or puncture site) (5) allergy to study medication, (6) pregnancy, (7) cognitive impairment, (8) insufficient comprehension of the Dutch QoR-40 questionnaire.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	90
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	26-02-2020
Application type:	First submission
Review commission:	Medical Research Ethics Committees United (MEC-U) Postbus 2500 3430 EM Nieuwegein 088 320 8784 info@mec-u.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 48927
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6433
NTR-old	NTR7224

Register	ID
CCMO	NL65158.100.18
OMON	NL-OMON48927

Study results

Summary results

(1) Gupta A, Kaur K, Sharma S, Goyal S, Arora S, Murthy RS. Clinical aspects of acute post-operative pain management & its assessment. J Adv Pharm Technol Res. 2010;1(2):97–108.

(2)Rosero EB, Joshi GP. Preemptive, preventive, multimodal analgesia: what do they really mean? Plast Reconstr Surg. 2014 Oct;134(4 Suppl 2):85S–93S.

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(6)Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The Erector Spinae Plane Block: A Novel Analgesic Technique in Thoracic Neuropathic Pain. Reg Anesth Pain Med. 2016;41(5):621–7.

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