The use of pectoral nerve block type II in patients undergoing trans-axillary thoracic outlet decompression.

Published: 22-04-2020
Last updated: 08-04-2024

To be able to further investigate the benefit of these interfascial plane blocks we want to perform a randomized controlled trial. Since the effect on postoperative pain of PECS II was similar to PECS I + ESB, we only use the PECS II as an...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON49807

Source
ToetsingOnline

Brief title
BLOCKTOS

Condition

- Spinal cord and nerve root disorders

Synonym
pectoral minor syndrome, Thoracic inlet syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina onderzoeksfonds

Intervention

Keyword: Neurogenic thoracic outlet syndrome (NTOS), PECS block type II (PECS 2), Trans-axillary outlet decompression (TATOD)

Outcome measures

Primary outcome

Primary Objective:

The primary objective of this trial is to determine the effect of a PECS II block in trans-axillary thoracic outlet decompression (TATOD) on postoperative pain compared with standard treatment (paracetamol, NSAID and opioid*s) for patients diagnosed with neurogenic thoracic outlet syndrome (NTOS).

Pain is measured using the Numeric Rated Scale (NRS) for pain. This is a psychometric response scale in which patients are asked to rate their pain from 0 to 10 (no pain to extreme pain). This scale is a validated and generally accepted tool to measure pain.
Opioid use is measured in Morphine Equivalent Dose (MED). This is a generally accepted tool to quantify opioid use in patients. We will focus on the total opioid consumption on the PACU and on the ward during the first 6 and 24 hrs postoperatively.

Secondary outcome

Secondary Objective(s):

A secondary objective is to determine the effect of a PECS II block in TATOD on postoperative nausea and vomitus (PONV) and other opioid induced side-effects

such as drowsiness, respiratory depression and urinary retention compared with standard treatment (paracetamol, NSAID and opioid*s) for patients diagnosed with NTOS.

At last, we will determine the effect of a PECS II block in TATOD on the Quality of Recovery scale (QoR-15) compared with standard treatment (paracetamol, NSAID and opioid*s) for patients diagnosed with NTOS.
The QoR-15 is a recently developed patient-reported outcome measurement (PROM) of postoperative quality of recovery. [26]

Study description

Background summary

Thoracic Outlet Syndrome (TOS) is a group of potentially disabling conditions thought to be caused by the compression of neurovascular structures going to the upper extremity. [2-5] This leads to pain, paresthesia and/or muscle weakness in the neck, shoulder arm and/or hand.[2] The neurovascular bundle, consisting of the subclavian artery, vein and brachial plexus, travels inform the neuraxis to the arm through the thoracic outlet and can be compressed at 3 possible locations: the interscalene triangle, the costoclavicular space or the pectoralis minor space. [2]
Three distinct types of TOS exist: arterial (ATOS), venous (VTOS) and neurogenic (NTOS) thoracic outlet syndrome, by compression of respectively artery, vein or plexus. [2] Mixed TOS (a combination of ATOS, VTOS or NTOS) exists, but incidence is low. In certain cases * especially when patients do not improve with physiotherapy * surgery can be performed to treat the compression and release the neurovascular structures at the thoracic outlet. [2, 6, 7] Surgery consists out of first rib resection with partial scalenectomy and lysis of either the plexus (NTOS), vein (VTOS) or artery (ATOS). Several approaches (trans-axillary, supraclavicular, infraclavicular, paraclavicular, dorsal and transthoracic) are used for surgical decompression. [8] In our center, we perform a trans-axillary thoracic outlet decompression (TATOD) in most primary cases of arterial, venous or neurogenic TOS. Supra-, infra- and paraclavicular approaches are reserved for specific indications, beyond the scope of this protocol.

Postoperative analgesia in TATOD is difficult due to the extensive nature of the surgery, the complex innervation of the axillary region and the limited possibilities of oral pain relief in patients already using oral pain relief on a daily base in most cases. [9, 10] Most postoperative TOD-patients are treated with opioids, however, at the cost of introducing side-effects like nausea, vomitus, drowsiness and respiratory depression. This might lead to worse patient experience and longer hospital stay. [11, 12]

Regional anesthesia techniques such as thoracic paravertebral, thoracic epidural and interscalene brachial plexus block could be part of a multimodal analgesic approach. They reduce postoperative pain and reduce the need for opioids..[9, 13-18] These techniques however, might have their own complications (diaphragmatic hemiparesis from ipsilateral phrenic nerve block, pneumothorax, permanent neurologic injury, blockade of vagus, recurrent laryngeal, and cervical sympathetic nerves (Horner's syndrome), pneumothorax, epidural or subarachnoid injection, vertebral artery injection, intravascular injection, unintentional dural puncture, epidural hematoma and epidural abcess). New regional anesthesia techniques such as the interfascial plane blocks, study-subject in this protocol, might provide an easier alternative to provide regional anesthesia with a very low risk of complications[1, 10, 19-21].

The axillary region is innervated by the thoracic spinal nerves and branches of the brachial plexus. (Figure 1) The thoracic spinal nerve divides into two rami (ventral and dorsal) when it exits the intervertebral foramen. (figure 2.) The dorsal ramus passes through the costotransverse foramen and divides into a lateral and medial branch. The medial branch ends into a posterior cutaneous branch. The ventral ramus becomes the intercostal nerve which ends as the anterior cutaneous branch. The lateral cutaneous branch also arises from the intercostal nerve at the lateral part of the thoracic wall. [22] The spinal nerves provide sensibility to the thoracic wall at the dorsal, lateral and ventral part of the thorax through the intercostal nerves. The brachial plexus gives rise to the lateral and medial pectoral nerves, long thoracic nerve and the thoracodorsal nerve. They supply the pectoral major muscle, pectoral minor muscle, the serratus anterior muscle and the latissimus dorsi muscle. respectively. Especially the pectoral nerves have nociceptive functions.

The pectoral nerve blocks (PECS I and PECS II) were first introduced by Blanco et al. in 2011 as a novel technique of postoperative analgesia in breast surgery. [8, 17] These ultrasound-guided interfascial plane blocks are administered between de pectoralis major and minor muscles (PECS I) or in addition between the pectoralis minor and serratus anterior muscle (PECS II) at the level of the third rib. PECS I blocks the lateral and medial pectoral nerves, provided by the brachial plexus and the intercostobrachial nerve. [8, 18, 20, 21] This block provides pain relief in the area of the pectoral major muscle and is used in breast surgery, breast expander surgery, catheter surgery and pacemaker insertion. [22]. In PECS II a second injection is performed

between pectoralis minor and serratus anterior muscles. This blocks the lateral branches of at least the T2-T4 spinal nerves and the long thoracic nerve, as well as the intercostobrachial nerve and the lateral and medial pectoral nerves from the PECS I deposit. This block provides pain relief of the pectoral and axillary region and is suitable for more extensive surgery: mastectomy, axillary clearance. [22-25] The use of this plane block has been researched extensively in breast surgery, however has also been described in thoracic surgery, cardiac surgery and chronic thoracic pain cases. [16, 17, 21-24] PECS blocks are able to relief postoperative pain more effectively than traditional analgesics and diminishes the use of opioids postoperative.[25] This technique is simple to perform and safe. There is only a very small risk of a puncture hematoma (0.4%). [1]

In current literature, no evidence can be found about the use of myo-fascial blocks in thoracic outlet surgery. In our center, we already performed a retrospective analyses of 20 patients that received interfascial plane blocks. This retrospective case-control study was approved by the Medical Research Ethics Committees United (W18.227). In 10 patients we performed a combination of a PECS I and ESB. In 10 patients we performed a PECS II. These patients were compared to 20 control patients that did not receive an interfascial plane block before surgery. In this study we found a significant reduction in postoperative pain and opioid consumption for patients treated with either the PECS I+ESB or PECS II compared to patients without a interfascial plane block undergoing thoracic outlet decompression. There was a trend for less nausea and vomiting, however non-significant.

Study objective

To be able to further investigate the benefit of these interfascial plane blocks we want to perform a randomized controlled trial. Since the effect on postoperative pain of PECS II was similar to PECS I + ESB, we only use the PECS II as an anesthetic technique since this only involves one injection.

Study design

This is a single center (TOS expert center Catharina Hospital Eindhoven) double blinded randomized controlled trial. Patients with NTOS that are planned by the vascular surgeon for TATOD will be randomized into 2 groups: patients that receive a supplementary PECS II block next to standard postoperative pain treatment protocol (intervention) and patients that receive a supplementary placebo block with normal saline next to standard postoperative pain treatment protocol (controls).
Since the local anesthetic (Ropivacaine 0.5%) is a generally accepted medicine in daily practice, this study is not an investigational product trial.

Intervention

Standard treatment:
Patients are admitted to the ward and given a pre-emptive dose of paracetamol as part of the perioperative pain management. Upon arrival into the operating theatre, all patients are given an IV access.
Standard ASA (American Society of Anesthesiologists) monitoring is applied. After completion of the sign-in procedure, general anesthesia (GA) is induced, using standard anesthesia protocol. This standardized protocol contains sufentanil, propofol and succinylcholine. All patients receive standard PONV prophylaxis during surgery consisting of granisetron 1mg and dexamethasone 4mg. After induction of GA, the PECS II is performed as described below. Randomisation and preparation of the medication is done by the hospital pharmacy. Surgery is started approximately 10 min after finalizing the block (after disinfecting and draping the patient).

Intervention arm: PECS II block with ropivacaine:
The patient is in supine position. A high frequency linear probe (Philips CX50, liniar probe 12-5) is placed horizontally at the level of the third rib and vertically below the lateral third of the clavicle. Then the probe is rotated 45 degrees clockwise. The corresponding ultrasound image shows the pectoralis major and minor muscles and the pectoral branch of the thoraco-acromial artery in the interfascial plane between both muscles. The needle is introduced in-plane from medial to lateral and advanced medial from the thoraco-acromial artery
until the needle tip reaches the facial plane underneath the pectoralis minor muscle. Due to anatomical variability, this plane may be between the pectoralis minor muscle and the
serratus anterior muscle or between the pectoralis minor muscle and the intercostals.
There, we inject 20 ml Ropivacaine 0,5%. The higher volume ensures that the injectate reaches axilla and blocks the intercostobrachial nerve. [28]Then, the needle is pulled back to the facial plane between the pectoralis major muscle and pectoralis minor muscle where the second injection is made, also with 20 ml Ropivacaine 0,5% This is shown in Figure 1 with a double yellow arrow. The procedure is completed after confirming lateral spread of the injected fluid in both fascial planes. Care is taken that the maximal dose of 3 mg/kg ropivacaine is not exceeded. In patients with a weigh of less than 66 kg, the total ropivacaine dosis is reduced accordingly, while the total volume is maintained to ensure that the axilla is reached.

Control arm: PECS II block with placebo
In the control group, the exact same procedure is followed. However, the injection will be performed using 40 ml of NaCl 0,9%.

Postoperative treatment:

At the PACU (post anesthesia care unit) and surgical ward, post-surgical pain management is performed according to the hospital's postoperative pain protocol. At the PACU, 1 gram of metamizol IV is given once (unless the patient has contra-indications for the use of NSAID*s) and IV boluses of morphine (1mg/ml) are titrated until pain relief with NRS < 4 was achieved. The maximum amount of morphine is decided by the attending anesthesiol-ogist. If morphine titration is insufficient, ketamine (maximum of 0.25 mg/kg) is given to re-duce postoperative pain.. Patients are discharged from the PACU if Aldrete*s score * 8, NRS scores < 3 and postoperative nausea or vomiting was absent or treated. At the surgi-cal ward, patients are treated with paracetamol 3d1000mg, naproxen 2d500 mg (unless there are contraindications for the use of NSAID*s), PCA morphine / droperidol. After 24 hours, PCA morphine / droperidol will be discontinued and switched to oxycodone 5mg maximum of 6 tablets per day and oxycodone slow release 10 mg twice daily.

All patients receive a bladder scan before discharge to the ward as part of the standard postoperative care.
A medical assessment is documented routinely twice daily. We will calculate total morphine consumption during PACU stay and on the ward during the first 6 hours, 24 and 48 hours. All medication administration is documented in the patient*s clinical file.

This study will be performed during the hospitalization period of patients. Length of stay is 1,8 days on average.

Study burden and risks

All patients will undergo ultrasound guided injection, after induction of anaesthesia. The ad-ministration of the injection does not invoke any extra physical discomfort. Possible complica-tions include hematoma and pneumothorax, however, the risk is very low (<1%)[1]. In the in-tervention group, we expect less pain, a reduced need for pain medication and less postopera-tive nausea and vomitus. We do not expect an altered postoperative course in the control group. Patients will be asked to fill out a questionnaire. Extra blood samples, site visits, physi-cal examinations or other test will not be done in this study.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ

NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with NTOS
- Selected for a trans-axillary thoracic outlet decompression (TATOD) by the TOS multidisciplinary workgroup.
- Fit for surgery, defined as ASA (American Society of Anesthesiologists) Classification of I, II or III.
- 18 years of age or older
- Sufficient in speaking and writing the Dutch language
- Normal liver and renal function
- Informed consent

Exclusion criteria

- Patients with a history of TOD (Redo-surgery)
- Patients with ATOS or VTOS
- ASA * 4
- Kidney or liver failure with contra-indication for NSAID or paracetamol
- Mental retardation
- Pregnancy
- Patients with chronic strong opioid use (>3 administrations per week or

continuous transdermal therapie, longer than the last 3 months)
- Allergy to one or more medications used in the study including, ropivacaine, dexamethasone, propofol, sufentanil, succinylcholine,
paracetamol, NSAID, morphine, granisetron

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2020
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-08-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL72737.100.20