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Original Contribution

Interpectoral-pectoserratus plane (PECS II) block in patients undergoing trans-axillary thoracic outlet decompression surgery; A prospective double-blind, randomized, placebo-controlled clinical trial

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ABSTRACT

Study objective: To investigate if an interpectoral-pectoserratus plane (PECS II) block decreases postoperative pain, postoperative nausea and vomiting and improves quality of recovery in patients with neurogenic thoracic outlet syndrome (NTOS) undergoing trans-axillary thoracic outlet decompression surgery.
Design: A prospective single center double blinded randomized placebo-controlled trial.
Setting: Perioperative period; operating room, post anesthesia care unit (PACU) and hospital ward.
Patients: Seventy patients with NTOS, undergoing trans-axillary thoracic outlet decompression surgery.
Interventions: Patients were randomized to an interventional arm, receiving the block with 40 ml ropivacaine 0.5% (concentration was adjusted if the patient's weight was <66 kg), and a placebo group, receiving a sham block with 40 ml NaCl 0.9%. The interpectoral-pectoserratus plane block was performed ultrasound guided; the first injection below the pectoral minor muscle and the second below the pectoral major muscle. The hospitals' pharmacist prepared the study medication and was the only person able to see the randomization result. The study was blinded for patients, researchers and medical personnel.
Measurements: Primary outcome parameters were postoperative pain, measured by numeric rating scale on the PACU (start and end) and on the ward on postoperative day (POD) 0 and 1, and postoperative morphine consumption, measured on the PACU and on the ward during the first 24 h. Secondary outcome parameters were postoperative nausea and vomiting, and quality of recovery.
Main results: There was no statistically significant difference in NRS on the PACU at the start (ropivacaine 4.9 ± 3.2 vs placebo 6.2 ± 3.0, $p = .07$), at the end (ropivacaine 4.0 ± 1.7 vs placebo 3.9 ± 1.7, $p = .77$), on the ward on POD 0 (ropivacaine 4.6 ± 2.0 vs placebo 4.6 ± 2.0, $p = 1.00$) or POD 1 (ropivacaine 3.9 ± 1.8 vs placebo 3.6 ± 2.0, $p = .53$). There was no difference in postoperative morphine consumption at the PACU (ropivacaine 11.0 mg ± 6.5 vs placebo 10.8 mg ± 4.8, $p = .91$) or on the ward (ropivacaine 11.6 mg ± 8.5 vs placebo 9.6 mg ± 9.4, $p = .39$).
Conclusions: The interpectoral-pectoserratus plane block is not effective for postoperative analgesia in patients with NTOS undergoing trans-axillary thoracic outlet decompression surgery.

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1. Introduction

Postoperative analgesia after trans-axillary thoracic outlet decompression (TATOD) is challenging due to the extensive nature of the surgery and the complex innervation of the axillary region [1]. Pain is the most prevalent symptom in neurogenic thoracic outlet syndrome (NTOS) and up to 25% of all patients take opioids or antidepressants on a daily base [2,3]. This limits the possibilities of oral/systemic pain relief in the postoperative period. Usually, TATOD is the preferred primary surgical approach in NTOS. The surgery is performed to relieve the compression on the brachial plexus at the thoracic outlet [1,2,4,5]. Postoperative analgesia regimen is based mostly on additional oral and systemic opioids. These additional opioids (on top of the opioids the patient preoperatively already uses daily), do not always make the patient sufficiently comfortable, but can result in more discomfort due to side-effects like nausea, vomitus, drowsiness and respiratory depression. It reduces the quality of recovery and leads to worse patient experience and longer hospital stay [6–8].

Regional anesthesia techniques reduce postoperative pain, reduce the need for opioids and thereby the opioid related side-effects in thoracic, breast and shoulder surgery [9–12]. Therefore, they could be part of a multimodal analgesic approach to improve the quality of recovery. Neuraxial techniques, such as thoracic epidural or paravertebral analgesia, have their own complications (such as hypotension, unintentional dural puncture, epidural hematoma or abscess), while new regional anesthesia techniques such as the thoracic interfascial plane blocks are easy alternatives to provide regional anesthesia with a very low risk of complications [13–16]. In TATOD surgery, the target sensory nerves to block are branches of the brachial plexus and upper intercostal nerves. A interpectoral-pectoserratus plane block affects the medial and lateral pectoral nerves, the intercostobrachial nerve, the lateral cutaneous part of the III–VI intercostal nerves and reaches the long thoracic nerve [17].

In current literature, conflicting results on the use of myo-fascial blocks in thoracic outlet surgery are reported. Henshaw et al. found no improvement in postoperative pain scores or opioid consumption when adding an interpectoral-pectoserratus plane block to general anesthesia [18]. A previous retrospective analysis of our own results indicated a significant reduction in postoperative pain and opioid consumption for patients treated with an interpectoral-pectoserratus plane block compared to patients without [19]. These conflicting results based on retrospective studies underlined the need for a prospective randomized controlled study.

We hypothesized that an interpectoral-pectoserratus plane block in TATOD surgery decreases postoperative pain and opioid consumption compared with standard treatment for patients diagnosed with NTOS. Secondary, we hypothesized that this block decreases postoperative nausea and vomiting and improves quality of recovery.

This trial was registered at http://www.clinicaltrials.gov prior to subject enrollment on July 15th 2020 with identifier: NCT04471545.

2. Materials and methods

2.1. Trial design

This is a prospective double-blinded randomized [1:1] placebo-controlled parallel-group study. Approval was obtained by the local Research Ethics Board (Medical Research Ethics Committees United, R20.007). The trial was registered on http://Clinicaltrials.gov on November 21st 2018 (Identifier NCT04471545). There were no changes made to the study protocol after trial commencement. An independent data monitoring committee monitored the protocol-adherence. This report was written following the CONSORT guidelines.

2.2. Participants

Patient enrollment started on August 1st 2020 and was completed on October 31st 2021. Patients that were seen at the outpatient clinic of a high-volume TOS-center for NTOS and scheduled for TATOD after multidisciplinary consultation were eligible for inclusion.

Patients were included in the study when they (1) had been diagnosed with NTOS, (2) were selected for a trans-axillary thoracic outlet decompression (TATOD) by the TOS multidisciplinary workgroup, (3) were fit for surgery, defined as ASA (American Society of Anesthesiologists) classification of I, II or III, (4), 18 years of age or older, (5) sufficient in speaking and writing the Dutch language, (6) had normal liver and renal function and (7) signed informed consent. Patients were excluded from the study when they had (1) a history of TOD surgery (redo-surgery), (2) arterial thoracic outlet syndrome (ATOS) or venous thoracic outlet syndrome (VTOS), (3) ASA $\geq$ 4, (4) kidney or liver failure with contra-indication for non-steroidal anti-inflammatory drug (NSAID) or acetaminophen, (5) mental retardation, (6) pregnancy, (7) chronic strong opioid use (>3 administrations per week or continuous transdermal therapy, longer than the last 3 months) or (8) an allergy to one or more medications used in the study including ropivacaine, dexamethasone, propofol, sufentanil, succinylcholine, acetaminophen, NSAID, morphine, granisetron.

2.3. Interventions

2.3.1. Preoperative management

Before surgery patients received a pre-emptive dose of 1000 mg acetaminophen as part of the perioperative pain management.

2.3.2. Intraoperative management

General anesthesia was induced using a standardized anesthesia protocol containing 0.1–0.2 μg/kg sufentanil, 1–2 mg/kg propofol and 1 mg/kg succinylcholine. All patients received standard postoperative nausea and vomiting (PONV) prophylaxis consisting of granisetron 1 mg and dexamethasone 8 mg. After induction of general anesthesia, the interpectoral-pectoserratus plane block was performed as we previously described [19]. Briefly, the patient was in supine position. A high frequency linear probe (L12–5) connected to a CX50 ultrasound system (Philips, the Netherlands) was used and placed horizontally at the level of the third rib and vertically below the lateral third of the clavicle. Then the probe was rotated 45 degrees counter clockwise. The corresponding ultrasound image showed the pectoralis major and minor muscles and the pectoral branch of the thoraco-acromial artery in the interfascial plane between both muscles. The needle was introduced in-plane from medial to lateral and advanced just medial from the thoraco-acromial artery until the needle tip reached the facial plane underneath the pectoralis minor muscle. This lateral approach blocks the intercostobrachial nerve more reliably than a medial approach [17]. 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, 20 ml of either ropivacaine 0.5% (intervention arm) or NaCl 0.9% (control arm) was injected. Then, the needle was retracted to the facial plane between the pectoralis major muscle and pectoralis minor muscle where the second injection was made, also with 20 ml of either ropivacaine 0.5% (intervention arm) or NaCl 0.9% (control arm). The higher volume ensures that the injectate reached axilla and blocked the intercostobrachial nerve [17]. The procedure was completed after confirming lateral spread of the injected fluid in both fascial planes. Care was taken that the maximal dose of 3 mg/kg ropivacaine was not exceeded. In patients with a weigh of <66 kg, the total ropivacaine dose was reduced accordingly, while the total volume was maintained at 40 ml to ensure that the axilla was reached. The anesthesiologists that participated in the study were experienced in regional anesthesia techniques and in particular interpectoral-pectoserratus plane blocks.

2.3.3. Postoperative management

At the post anesthesia care unit (PACU) and surgical ward, post-surgical pain management was performed according to the hospital's postoperative pain protocol. At the PACU, 1000 mg of metamizol IV was given once and IV boluses of morphine (1 mg/ml) were titrated until pain relief with NRS < 4 was achieved. The maximum amount of morphine was decided by the attending anesthesiologist. If numeric rating scale (NRS) <4 was not achieved, intravenous ketamine was titrated up to 10 mg. Patients were discharged from the PACU if Aldrete score ≥ 8, NRS scores <3 and postoperative nausea or vomiting was absent or treated. At the surgical ward, patients were treated with acetaminophen 3d1000mg, naproxen 2d500 mg, Patient Controlled Analgesia (PCA) with morphine (1 mg/ml) and droperidol (0.04 mg/ml). After 24 h, PCA morphine / droperidol was discontinued and switched to oxycodone 5 mg maximum of 6 tablets per day.

2.4. Outcomes

Primary study endpoint was postoperative pain. NRS score was assessed on the PACU immediately after surgery and when leaving the PACU, on the ward in the morning and in the evening (assessed at rest and when moving). Postoperative cumulative morphine-equivalent consumption was measured on the PACU and on the ward every 24 h until discharge. Secondary study endpoints were PONV and quality of recovery. PONV was assessed at the PACU and daily on the surgical ward until discharge. Nausea was measured with a validated numeric rating scale going from 0 (no nausea) to 10 (extreme nausea) [20]. Vomiting was registered as yes or no. Quality of recovery was assessed by the Quality of Recovery Scale – 15 (QoR-15). This validated questionnaire for quality of recovery was used twice daily during hospital admission, starting on the evening after surgery [21]. Other study parameters were drowsiness (defined as a feeling of being sleepy and lethargic), urinary retention with the need for urinary catheter insertion, time to mobilization (until sitting in a chair and until walking), length of hospital stay (LOS), the total operative time (recorded as total time spent in the operating room), anesthetic time, surgical time and complications related to surgery (e.g. bleeding, surgical site infection) or related to pain treatment (e.g. local anesthetic toxicity). There were no changes to the trial outcomes after the trial commended.

2.5. Sample size

Sample size calculation was based on the primary endpoint: NRS scores at PACU arrival since the interpectoral-pectoserratus plane block only lasts between 6 and 18 h. In our retrospective study, patients without a block had a mean NRS score of 6.4 with standard deviation of 1.7. Patients with an interpectoral-pectoserratus plane block had a mean NRS score of 4.9 with a standard deviation of 2.2. Using the program Pass (PASS 2020 Power Analysis and Sample Size Software (2020); NCSS, LLC. Kaysville, Utah, USA, http://ncss.com/software/pass), a sample size of 29 in each arm was calculated to reach a power of 80% with an alpha of 0.05% to detect a difference of 1.5 in NRS. A difference of 1.5 NRS is deemed clinically significant [22]. To allow potential dropout, we included 35 patients in each arm. There was no interim analysis.

2.6. Randomization

The randomization table and random allocation sequence were created before the start of the trial by using Research Manager (Deventer, the Netherlands) by a person not involved in the research or treatment of the patients. Patients were allocated to the interventional or placebo arm accordingly. Allocation ratio was 1:1 and randomly variable block sizes of 2, 4 or 8 were used.

2.7. Blinding

The hospitals' pharmacist prepared the study medication and was the only person able to see the randomization result. The study medication (ropivacaine or placebo) was prepared in two 20 ml syringes and appeared similar. The study medication was labeled “BLOCKTOS study medication: ropivacaine or NaCl 0.9%”. The patients name and date of birth were printed on the medication-label. The allocation sequence was thus concealed from patients, health care providers, data collectors and treatment team. There were no compromises in blinding; it was not necessary to unblind any participant at any point during the conduct of the study. An independent data and safety monitoring board annually reviewed the safety data.

2.8. Statistical methods

All data were collected from the study file that contained questions on the surgical procedure, anesthesia, medical assessment on the PACU and surgical ward. The study file was completed by the patient, anesthesiologist, PACU nurse and acute pain service nurse. All medication administration was documented and derived from electronic patient records. Data registration was performed during the hospitalization period of the patients.

The primary analysis was intention-to-treat and involved all patients who were randomly assigned. Continuous variables were presented as mean and standard deviation (SD) with 95% confidence interval around the difference in means or median and interquartile range (IQR), depending on normality. Normality was assessed by determining the skewness and kurtosis. If they both were between -1 and $+1$, the data was considered normally distributed. Categorical variables were reported as numbers and percentages. Differences in normal distributed continuous variables were compared with the Student *t*-test, differences in not-normal distributed continuous variables were compared with the Mann-Whitney *U* test. Differences in categorical variables were reported with the Chi square test, but in case of small numbers, data were analyzed with Fisher's exact test. For NRS scales, the two-sided 95% confidence interval was calculated for each group. To compare outcomes within one group and between the two groups at serial timepoints a repeated measures ANOVA was used, with a Bonferroni correction to correct for multiple testing. A Cox proportional hazards regression analysis was used to compare time to mobilization (sitting in a chair and walking) between both groups. For patients who did not sit or walk during hospital stay, the time of discharge was used for censoring. A *p*-value of 0.05 or below was considered as statistically significant. Statistical analyses were performed using SPSS, version 25 (SPSS Inc., Chicago IL, USA).

2.9. Nomenclature

Recently, a consensus study by the American and European Society of Regional Anesthesia introduced a new standardized nomenclature in chest wall blocks [23]. Pectoral nerve block I and II were renamed into the more anatomically descriptive ‘interpectoral’ or ‘superficial pectoralis’ plane block, and the ‘pectoserratus’ or ‘deep pectoralis’ plane block. Since this nomenclature change happened during the inclusion period of this study we therefore use the term interpectoral-pectoserratus plane block and added PECS II in title and abstract for clarification and indexation purposes.

3. Results

In total 110 patients were assessed for eligibility between August 2020 and October 2021. Eleven patients did not meet the inclusion criteria. The first 70 patients that underwent surgery, were randomized and analyzed. No patients were lost to follow-up.

3.1. Study population

Baseline characteristics are summarized in Table 1. Both groups had comparable baseline characteristics (Table 1).

3.2. Primary outcome analysis

At the start of patients' recovery at the PACU, NRS scores in the ropivacaine group (4.9 ± 3.2) tended to be lower than in the placebo group (6.2 ± 3.0) but did not reach statistical significance ($p = .07$, 95% CI of difference in means −0.1–2.8). (Table 2).

In the ropivacaine group, 44% of patients had a first postoperative NRS score < 4 compared to 26% in the placebo group ($p = .11$). At the end of the PACU-stay, on the evening of surgery on the ward and on postoperative day (POD) 1, NRS scores at rest and at movement, were comparable ($F = 0.19$; $p = .66$). (Table 2 and Fig. 1) Opioid use during surgery, at the PACU and during the first 24 h on the ward were comparable. (Table 2).

3.3. Secondary outcome analysis

QoR15 score on POD 0 was 96 ± 25 in the placebo group and 87 ± 20 in the ropivacaine group (p = .07, 95% CI of difference in means −1.0–21.2). On POD 1 QoR15 score was 105 ± 23 in the placebo group and 103 ± 24 in the ropivacaine group ($p = .64$, 95% CI of difference in means −8.9–14.3). There was no difference in postoperative nausea and vomiting at the PACU, on POD 0 and 1. (Table 3).

There was no difference in the need for droperidol at the PACU. (Table 3) Drowsiness, urinary retention with the need for urinary catheter insertion, total operative time, surgical time, anesthesia time, length of PACU stay and length of hospital stay were the same in both groups. (Table 4).

There was no difference in mobilization (in time until chair, and time until walk, ($p = .75$, 95% CI of difference in means −243–175 and $p = .13$, 95% CI of difference in means −428–56 respectively). A Cox proportional hazards analysis showed no difference in time until chair (HR 0.72, 95% CI 0.41–1.25) and time until walk (HR 0.71, 95% CI 0.39–1.28) between both groups. Chest drains were placed equally in both groups ($p = .43$). During the study period, there were no surgical or anesthesiological complications.

Table 1
Demographics of patients receiving an interpectoral-pectoserratus plane block in trans-axillary thoracic outlet decompression (TATOD) surgery for neurogenic thoracic outlet syndrome (NTOS).

Variable	Placebo (N = 35)	Ropivacaine (N = 35)	p-value	Difference in means (95% CI)
Sex (female)	30 (86%)	30 (86%)	1.00	
Age (years)	34 ± 13	40 ± 12	0.06	−6.2 (−12.1 - -0.3)
ASA			0.97	
1	12 (34%)	13 (37%)		
2	21 (60%)	20 (57%)		
3	2 (6%)	2 (6%)		
BMI (kg/m^2)	23.3 (21.7–25.8)	24.7 (22.9–27.4)	0.06	
Preoperative use of acetaminophen	3 (9%)	4 (12%)	1.00	
Preoperative use of NSAID	5 (14%)	9 (26%)	0.23	
Preoperative use of weak opioids	0	2 (6%)	0.49	
Preoperative use of SSRI	5 (14%)	3 (9%)	0.71	

Data are presented as n (%) or mean ± standard deviation (SD) with 95% confidence interval of difference in means or median (interquartile range [IQR]). ASA: American Society of Anesthesiologists. BMI: body mass index. NSAID: non-steroidal anti-inflammatory drug. SSRI: selective serotonin reuptake inhibitor.

Table 2
Primary study parameters: differences in postoperative pain and opioid use of patients receiving an interpectoral-pectoserratus plane block in trans-axillary thoracic outlet decompression (TATOD) surgery for neurogenic thoracic outlet syndrome (NTOS).

Variable	Placebo (N = 35)	Ropivacaine (N = 35)	p-value	Difference in means (95%CI)
NRS PACU start	6.2 ± 3.0	4.9 ± 3.2	0.07	1.3 (−0.1–2.8)
NRS PACU end	3.9 ± 1.7	4.0 ± 1.7	0.77	−0.1 (−0.9–0.7
NRS at rest POD 0 evening	4.6 ± 2.0	4.6 ± 2.0	1.00	0.0 (−1.0–1.0)
NRS movement POD 0 evening	6.6 ± 2.2	6.7 ± 2.4	0.82	−0.1 (−1.3–1.0)
NRS at rest POD 1 morning	3.6 ± 2.0	3.9 ± 1.8	0.53	−0.3 (−1.2–0.6)
NRS movement POD 1 morning	5.9 ± 2.1	6.3 ± 1.6	0.48	−0.3 (−1.3–0.6)
Sufentanil during surgery (mcg)	30.8 ± 8.9	31.0 ± 10.6	0.93	−0.2 (−4.9–4.5)
Morphine during surgery (mg)	2.4 ± 3.4	2.0 ± 2.5	0.58	0.4 (−1.0–1.8)
OME during surgery	44.4 ± 12.0	43.1 ± 15.5	0.77	1.0 (−5.7–7.7)
Morphine at PACU (mg)	10.8 ± 4.8	11.0 ± 6.5	0.91	−0.2 (−3.2–2.8)
Morphine during first 24 h (mg)	9.6 ± 9.4	11.6 ± 8.5	0.39	−1.9 (−6.4–2.5)

Data shown as mean ± standard deviation (SD) with 95% confidence interval of difference in means. NRS: Numerical Rating Scale. PACU: Post Anesthesia Care Unit. POD: Postoperative Day. OME: oral morphine equivalents.

4. Discussion

In this prospective double-blinded randomized study, the interpectoral-pectoserratus plane block did not decrease postoperative pain, opioid need and nausea and vomiting, nor did it increase quality of recovery in TATOD surgery for NTOS patients.

For a long time, the challenge of postoperative care for patients undergoing TATOD surgery has been acknowledged and several strategies to improve postoperative pain and quality of recovery for this group of patients have been reported. In 2017 Wooster et al. showed with a PCA morphine based regimen a length of stay of 4.3 days with a median pain score of 6 that was improved to 2.6 days of hospitalization and a mean pain score of 4 after introduction of a more multimodal analgetic treatment with acetaminophen, NSAID and Valium [24]. Further research on postoperative pain is mainly focussed on different regional anesthesia techniques. In 2021 Guffey et al. compared the erector spinae plane block to continuous perineural local anesthetic infusion but did not see any reduction in pain scores and reported a length of stay of 3 days in both groups [25]. Kavala et al. studied T1/T2 single shot paravertebral analgesia and reported a reduction in opioid need and discharge after 57 instead of 66 h postoperatively [26]. Retrospective studies and a case series on the interpectoral-pectoserratus block reported both positive and negative results [18,19,27]. The research group of Julie Freischlag has previously pointed out the need to prospectively investigate this further [18]. Our current study is the first prospective study. The effect of the interpectoral-serratus plane block in our study is in line with the retrospective analysis by Henshaw but is the opposite of the result of our retrospective analysis and underlines the risk of bias in retrospective studies [18,19].

Hospital LOS, in our study only a secondary outcome parameter, was 1.3 days. In general, our patients are discharged around noon the first post-operative day after neurological screening for complications and removal of the chest drain. As discharge depends on these surgery related factors, even comfortable patient will not be discharged earlier. Therefore, the interpectoral-pectoserratus plane block cannot have any impact on the LOS.

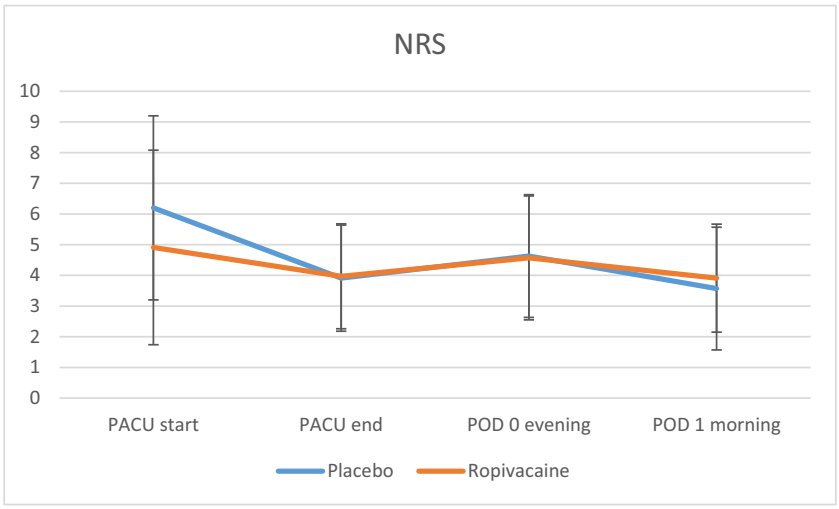

Fig. 1. Differences in postoperative pain at rest of patients receiving an interpectoral-pectoserratus plane block in trans-axillary thoracic outlet decompression (TATOD) surgery for neurogenic thoracic outlet syndrome (NTOS).
NRS: Numeric Rating Scale. PACU: Post Anesthesia Care Unit. POD: Postoperative Day.

Table 3
Secondary outcome parameters; quality of recovery, nausea and vomiting of patients receiving an interpectoral-pectoserratus plane block in trans-axillary thoracic outlet decompression (TATOD) surgery for neurogenic thoracic outlet syndrome (NTOS).

Variable	Placebo (N = 35)	Ropivacaine (N = 35)	p-value	Difference in means (95% CI)
QoR-15 POD 0	96 ± 25	87 ± 20	0.07	10.1 (−1.0–21.2)
QoR-15 POD 1	105 ± 23	103 ± 24	0.64	2.7 (−8.9–14.3)
Nausea PACU start			0.11	
0	34 (97%)	29 (85%)		
1–3	1 (3%)	5 (15%)		
Nausea PACU end			0.45	
0	27 (79%)	24 (71%)		
1–3	4 (12%)	4 (12%)		
>4	2 (6%)	6 (17%)		
Nausea POD 0			0.51	
0	15 (46%)	15 (44%)		
1–3	8 (24%)	5 (15%)		
>4	10 (30%)	14 (41%)		
Nausea POD 1			0.25	
0	23 (67%)	25 (76%)		
1–3	3 (9%)	5 (15%)		
>4	8 (24%)	3 (9%)		
Vomiting PACU (yes)	1 (3%)	1 (3%)	1.00	
Vomiting POD 0 (yes)	13 (37%)	10 (29%)	0.50	
Vomiting POD 1 (yes)	3 (9%)	3 (9%)	1.00	
Droperidol at PACU (yes)	3 (9%)	5 (15%)	0.71	

Data are presented as n (%) or mean ± standard deviation (SD) with 95% confidence interval of difference in means or median (interquartile range [IQR]). QoR-15: Quality of Recovery- 15 scale. POD: Postoperative Day. PACU: Post Anesthesia Care Unit.

Table 4
Other study parameters of patients receiving an interpectoral-pectoserratus plane block in trans-axillary thoracic outlet decompression (TATOD) surgery for neurogenic thoracic outlet syndrome (NTOS).

Variable	Placebo (N = 35)	Ropivacaine (N = 35)	P-value	Difference in means (95% CI)
Drowsiness POD 0 (yes)	24 (71%)	28 (85%)	0.16	
Drowsiness POD 1 (yes)	15 (44%)	13 (39%)	0.70	
UBC during surgery (yes)	0	0	1.00	
UBC postoperative (yes)	0	1 (3%)	1.00	
Total operative time (min)	126 (115–134)	127 (113–137)	0.74	
Surgical time (min)	85 ± 13	85 ± 16	0.78	−1.0 (−7.9–6.0)
Anesthesia time (min)	32 (29–37)	32 (27–40)	0.81	
Length PACU stay (min)	93 (76–126)	97 (83–114)	0.95	
Length of hospital stay (days)	1 (1–1)	1 (1–1)	1.00	
Length of hospital stay (days, categories)				
1	29 (83%)	32 (91%)	0.71	
2	4 (11%)	2 (6%)		
3	1 (3%)	1 (3%)		
4	1 (3%)	0		
Time until chair (min)	535 ± 373 *N* = 26	569 ± 358 *N* = 24	0.75	−34 (−243–175)
Time until walk hallway (min)	523 ± 346 *N* = 24	709 ± 456 *N* = 21	0.13	−186 (−428–56)
Thoracic drain (yes)	26 (74%)	23 (66%)	0.43	

Data shown as n (%) or mean ± standard deviation (SD) with 95% confidence interval of difference in means or median (IQR). POD: Postoperative Day. UBC: Urinary Bladder Catheter. PACU: Postoperative Anesthesia Care Unit.

The results of this study lead to the question why the interpectoral-pectoserratus plane block did not improve postoperative analgesia and the quality of recovery. A previous retrospective study showed an equal reduction in postoperative pain after PECS 1 + erector spinae plane block and after PECS 2 block [19]. The area to cover with a regional anesthesia technique therefore seemed the thoracic wall and axilla. The axillary nerve, suprascapular nerve and first intercostal nerve are part of the sensory innervation of the axilla but not blocked by the interpectoral-pectoserratus block. Clinically we noted that many patients complained of postoperative posterior shoulder pain. Therefore, a possible explanation may be that not enough sensory nerves of the axilla or not the right sensory nerves were blocked. The complaint of shoulder

pain could be a clue in this search. Also anatomical variations such as a postfixed brachial plexus (eg T1 and T2 are anastomosed to the brachial plexus) could interfere with the extent of the clinical effect of the interpectoral-pectoserratus plane block on postoperative pain in our patients [27]. This may also explain the results of da Costa et al., who combined an interpectoral-pectoserratus plane block with a supraclavicular plexus block, which does provide analgesia of the shoulder [28]. However, a major drawback of this approach is phrenic nerve paresis which occurs in up to 45% of cases after supraclavicular plexus block [29]. Another disadvantage of a brachial plexus block is motor blockade of the arm. Patients are left with an immobile arm for up to 24 h, which may obscure possible complications of surgery and also possibly increase the length of stay.

The limitations in this trial should be discussed. First, the efficacy of the interpectoral-pectoserratus plane block was not tested prior to surgery. We chose to perform the block after induction of general anesthesia for patient comfort. If the block was performed in the preoperative holding area and time was taken for the local anesthetic to start working, it would be clear if some patients did not have a sensory block and thus no working interpectoral-pectoserratus plane block. In this study, this might be a factor of bias. Second, in the design of the study, details about the location of postoperative pain were not registered in a structured way. In searching for reasons to explain the lack of effect of the interpectoral-pectoserratus plane block, more information on the location of postoperative pain would have been helpful. Third, the standard deviations of NRS score at PACU arrival were greater than assumed in the power analysis. This might have contributed to the study being underpowered to detect a difference at this specific time point.

5. Conclusions

This study showed that interpectoral-pectoserratus plane block is not effective for postoperative analgesia in patients with neurogenic thoracic outlet syndrome undergoing trans-axillary thoracic outlet decompression surgery.

Other information

Registration Trial registry: http://www.clinicaltrials.gov; Identifier: NCT04471545

Data sharing

All of the individual participant data collected during the trial, after de-identification including data dictionary defining each field in the set, will be made available to investigators whose proposed use of the data has been approved by an independent review committee. This data will be available immediately following publication without any end date. Proposals should be directed to renee.vd.broek@catharinaziekenhuis.nl with a signed data access agreement.

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CRediT authorship contribution statement

Renee J.C. van den Broek: Conceptualization, Methodology, Data curation, Formal analysis, Funding acquisition, Project administration, Writing – original draft. **Jens Goeteyn:** Conceptualization, Methodology, Funding acquisition, Data curation, Project administration, Writing – original draft. **Saskia Houterman:** Methodology, Formal analysis, Writing – review & editing. **R. Arthur Bouwman:** Conceptualization, Writing – review & editing. **Barbara J.B. Versyck:** Conceptualization, Methodology, Writing – review & editing. **Joep A.W. Teijink:** Conceptualization, Methodology, Writing – review & editing.

Declaration of Competing Interest

Dr. R.A. Bouwman is a clinical consultant for Philips Research (Eindhoven, the Netherlands) since January 2016. The other authors declare no potential conflict of interest.

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