Cutaneous sensory block area of the anterior transversus abdominis plane (TAP) block
A series of prospectively collected data in a standard day surgery population

Protocol code: CSBA-TAP
ClinicalTrials.gov: NCT05826093

Authors: CB Salmonsen, CA Bertelsen, J Kleif, C Rothe, KW Lange
Table of Contents

Introduction ................................................................. 3
Purpose .................................................................................. 4
Hypothesis ................................................................................ 4
Design ...................................................................................... 4
Sample size ................................................................................. 4
Outcomes .................................................................................. 4
Variables .................................................................................. 4
Demographic variables .......................................................... 4
Perioperative variables .......................................................... 5
Postoperative variables .......................................................... 5
Participants ................................................................................. 5
Inclusion criteria ........................................................................ 5
Exclusion criteria ......................................................................... 5
Intervention ............................................................................... 5
Procedure ............................................................................... 6
Recruitment of participants and informed consent....................... 6
US-TAP – procedure (posterior TAP-block) ................................ 6
L-TAP – procedure (sub-costal/anterior dual TAP-block) ......... 7
PACU ...................................................................................... 7
Methods .................................................................................. 8
Demographic variables .......................................................... 8
Size and location of cutaneous sensory block area ....................... 8
Risks, side effects and disadvantages ....................................... 8
Time frame ............................................................................... 9
Ethics ....................................................................................... 9
Guidelines concerning verbal information of participants and obtaining informed consent ....................... 9
Data collection and handling of data ....................................... 10
Statistical analysis .................................................................... 10
Publications .............................................................................. 10
Conflict of interest .................................................................... 11
Abbreviations: ........................................................................... 11
References .................................................................................. 11

Protocol code: Version 0.1.2 – 2020-08-28
Introduction
During the last decade, great advances in regional analgesia have been achieved, particularly following the introduction of ultrasound-guided regional analgesia. Several ultrasound-guided abdominal wall blocks are being administered to adults for a wide range of surgical procedures. In Denmark, the transversus abdominis plane (TAP) block has been implemented as the primary analgesic modality in many minimally invasive procedures replacing epidural analgesia. TAP block has evolved as a safe, simple, and inexpensive intervention incorporated into many postoperative pathways to achieve opioid-sparing analgesia after surgery.

Several techniques are currently used to apply TAP blocks, including blinded ‘pop’ technique using anatomical landmarks, ultrasound-guided (US-TAP), and transcutaneous laparoscopic assisted TAP (L-TAP) blocks. The L-TAP block was first described in 2011 during laparoscopic nephrectomies. There are several advantages of L-TAP including the ease of performance, less dependency on specialized skills or equipment and avoidance of intraperitoneal infiltration.

When using an anaesthetic block technique, it is important to know the characteristics of the block in terms of sensory and motor effect as well as block duration. The posterior TAP block has previously been described to provide pain relief to the T7 to L2 dermatomes. Most studies have examined the efficacy of the TAP block using measurements such as perceived pain and postoperative analgesic consumption. To our knowledge, only one study has examined the cutaneous block area of the posterior TAP block. This study found that the posterior TAP block resulted in a non-dermatomal cutaneous sensory block area (CSBA) with a lesser medial and a larger lateral area of effect, calling into question the previous perception of the dermatomal anaesthetic effect of the TAP block. No cutaneous mapping has been done for the lateral and anterior/subcostal TAP blocks.
At Nordsjællands Hospital Hillerød we will conduct a descriptive study measuring the CSBA in patients undergoing laparoscopic cholecystectomies in a day surgery setting, during the implementation of TAP blocks as a part of pain management in day surgery care.

Purpose
To examine and describe the CSBA of the anterior/subcostal ultrasound guided TAP block and the anterior laparoscopic-assisted TAP block in patients undergoing elective laparoscopic cholecystectomy in a day surgery setting.

Design
Prospectively collected data in a standard population of patients undergoing elective laparoscopic cholecystectomy in a day surgery setting.

Sample size
30 patients in each group will be sufficient for us to estimate the general location and size of the CSBA of the anterior US- and L-TAP blocks. With a sample size of 30 it is possible to achieve a good estimate of the mean and spread in normally distributed data.

Outcomes
- Size of the CSBA of the anterior ultrasound guided TAP block
- Location of the CSBA of the anterior ultrasound guided TAP block
- Size of the CSBA of the anterior laparoscopic-assisted TAP block
- Location of the CSBA of the anterior laparoscopic-assisted TAP block.

Variables
Demographic variables
- Gender
- Age
- Height
- Weight.

**Perioperative variables**
- Surgical procedure
- US- or L-TAP block applied at the end if anaesthesia.

**Postoperative variables**
- Size of the CSBA
- Location of the CSBA.

**Participants**
All patients planned for laparoscopic cholecystectomy in an elective setting are screened for inclusion.

**Inclusion criteria**
- Planned for elective laparoscopic cholecystectomy in a day surgery setting
- Age ≥ 18 years
- Having given informed verbal and written consent to assessment of the CBSA including photo documentation.

**Exclusion criteria**
- Predictably non-compliant due to language barrier or psychiatric disease
- Patients with a history of abdominal wall surgery including resection of the external oblique muscles, the internal oblique muscles, the transversus abdominis muscles, the rectus abdominis muscles or their fascial components
- Pregnancy
- Patients with sensory deficits of any kind in the skin overlying the thorax and/or abdominal wall

**Intervention**
- **Group A**  Anterior US-TAP with 20 ml ropivacaine 2 mg/ml solution bilaterally
- **Group B**  Anterior L-TAP with 20 ml ropivacaine 2 mg/ml solution bilaterally.
In both groups NO local anaesthetic will be applied around the incisions.

**Procedure**

**Recruitment of participants and informed consent**

All adult patients booked for elective laparoscopic cholecystectomy are pre-screened by Site investigator or Study nurse for participation in the trial. Patients can only be included in the trial if they meet all the inclusion criteria and do not violate any exclusion criteria, want to participate and give informed consent to do so.

Upon admission to the hospital prior to surgery, Investigator makes sure that the patient is informed about the study and gives oral and written consent to participating in the study. They are also informed that participation is voluntary and that they have the right to refuse to participate and to withdraw their participation, samples or data at any time without any consequences.

**US-TAP – procedure (anterior TAP-block)**

During the first phase of the trial the following block will be applied at the end of anaesthesia (group A):

- Sterile procedure is applied to all blocks
- Use of sterile ultrasonic gel and sterile cover for the ultrasonic probe
- Sterile gloves and surgical gowns
- With the patient in supine position the anaesthesiologist uses a linear high frequency ultrasonic transducer placed as shown in Figure 1. The subcostal/anterior approach targets the transverse abdominal plane beneath the costal margin, anywhere between the xiphoid process and the anterosuperior iliac spine. As the block is placed centrally compared to the lateral and posterior block, you will not be able to identify the three layers of the abdominal wall musculature. Going from the skin to the peritoneum you will see: the rectus abdominis muscle and transverse abdominal muscle. The neurovascular plane is located between the rectus abdominis- and the transverse abdominal muscles. A 90-120 mm, 21-gauge needle is used, and the injection is carried out in the direction medial-lateral so that the injection is performed in parallel with the ultrasound...
transducer for better visualization of the needle. The neurovascular plane is sought out and a small amount of local anaesthetic is injected to visualize the spread of local anaesthetic in the correct plane. The correct place for the needle tip is in the TAP about halfway along the overlapping of the rectus abdominis muscle over the transverse abdominal muscle (Figure 1)

- 20 ml of ropivacaine 2 mg/ml / placebo is injected followed by the same procedure on the other side of the patient

L-TAP – procedure (sub-costal/anterior dual TAP-block)
After 30 patients have finished the trial in the US-TAP group the following block will be applied (group B):

- After laparoscopic port placement, a total of four injections are carried out with 10 ml of ropivacaine 2 mg/ml at each injection site using a 90-120 mm, 21-gauge needle
- Bilateral subcostal infiltration between mid-clavicular and central sternal lines and bilateral subcostal infiltration between mid-clavicular and anterior axillary line (see Figure 2 and video).
- The needle tip is visualized laparoscopically passing into the preperitoneal fat without perforating the parietal peritoneum. The needle is then withdrawn so the tip is located just superficially to the posterior rectus sheath / the transverse abdominis fascia (approximately 2-3 mm but more in obese patients) and injection is performed. Confirmation of the correct plane can be visualized by the formation of Doyle’s bulge covered by the transverse abdominal muscle (Appendix X)

Surgery is performed in accordance with department guidelines for laparoscopic cholecystectomy.
There will be NO application of local analgesia before port placement. At the end of surgery there will be NO application of local wound infiltration analgesia.

PACU
Between 1 and 1½ hours from the end of anaesthesia, the PACU nurse contacts Investigator. Investigator then contacts the patient at the PACU in order to mark, photograph and register the size and location of the CSBA in cooperation with the patient using the later described method.
If the patient complains of wound pain after the documentation is performed, a local subcutaneous infiltration of the wound area 20 ml ropivacaine 2 mg/ml will be applied by the Investigator or an appointed representative.

The patient then continues to follow standard procedure for the duration of his/her stay.

**Methods**

**Demographic variables**
Data on gender, age, weight, height, ASA score, WHO performance score is registered by Investigator using the electronic medical record (EMR).

**Size and location of cutaneous sensory block area**
The CSBA is assessed bilaterally before patients leave the PACU (approximately 1½h after the end of anaesthesia) using gauze dipped in alcohol. The gauze is then moved at an approximate rate of 2 cm/s from the midsagittal line using a star-shaped approach to indicate sensory changes. Changes are marked on the skin and hereafter a connecting line is drawn to determine the CSBA. A ruler is placed beside the drawn CSBA and the abdomen/CBSA is photographed. The photo is transferred directly to the database in REDcap and the total area is later calculated from the photos using the software SketchAndCalc. The photos will also be used later as a reference to the location of the calculated CSBA. The photos will only include the abdomen.

**Risks, side effects and disadvantages**
This study will pose no further risk to the patients compared to standard treatment.

The only disadvantage in participating will be the time it takes for the patient and Investigator to mark out the CSBA and take the photos.
**Time frame**

The trial will commence once clearance has been given by the Data Protection Agency of the Capital Region of Denmark, and the local ethics committee of the Capital Region of Denmark.

Nordsjællands Hospital Hillerød is expected to include 5–6 patients per week. Approximately 10 weeks should be enough to reach the desired 60 patients to be included.

**Ethics**

This study is conducted as an observational study during the implementation of a new technique as standard treatment at Nordsjællands Hospital Hillerød. The only disadvantage to the patient is the time spent when mapping out the CSBA.

Data collection will be conducted according to the General Data Protection Regulation of the European Union and national laws.

**Guidelines concerning verbal information of participants and obtaining informed consent**

Patients who are scheduled for elective laparoscopic cholecystectomy will be evaluated for participation in the trial. The patients who fulfil the inclusion criteria and who does not fulfil any of the exclusion criteria will be informed verbally:

1) That they are asked to participate in a scientific experiment

2) That the purpose of the study is to examine the perceived effect of the TAP block, a generally accepted treatment for managing postoperative pain

3) That they will be asked certain questions concerning their wellbeing after the operation at a specific time and that photos will be taken of their abdomen

4) That their general treatment plan will not deviate from the standard treatment
5) That they at any point can withdraw their consent without the need to provide a reason

6) That their choice to not participate in the study will not have any negative consequences to their continued treatment.

The verbal information will be given by Investigator or an appointed representative upon admission to the hospital before surgery or during the preadmission information session. During the conversation it will be possible for the patient to ask questions and have time enough to listen and understand the verbal information. The patient will be given an understandable version of the research project without technical and suggesting phrases. The conversation is adapted to the receiver’s individual preconditions concerning age, maturity, experience, etc. Informed verbal and written consent need to be given at the latest before the patient leaves the department for surgery.

Data collection and handling of data
Data will be collected throughout the study and registered in REDcap by Investigator. Data will be managed according to Danish legislation and the European Union’s General Data Protection Regulation.

Statistical analysis
Data will be analysed using R version 3.6.1 or later. Sample size estimation is not relevant because of the observational nature of the study. A $p$ value of less than 0.05 is considered statistically significant.

Publications
All results will be published. The results will be submitted as articles for publication in relevant anaesthesiological journals. First author will be Christopher Blom Salomonsen, second author will be Claus Anders Bertelsen, tertiary author will be Jakob Kleif and last author will be Kai Henrik Wiborg Lange. All authors will have to fulfil the Vancouver criteria for authorship.

When results are available, oral and poster presentations will be published at international congresses as well as national meetings of Danish scientific communities.
Conflict of interest
No conflict of interest declared.

Abbreviations:
ASA: American Society of Anesthesiologists
CSBA: Cutaneous Sensory Block Area
EMR: Electronic Medical Record
ERAS: Enhanced Recovery After Surgery
L-TAP: anterior Laparoscopic assisted TAP block
US-TAP: posterior UltraSound-guided TAP block

References
Appendices

Figure 1:
Ultrasound probe position, needle puncture site, and sonographic image of the subcostal transversus abdominis plane block. Asterisk indicates needle target; RA, rectus abdominis muscle; TA, transversus abdominis muscle.