The Beneficial Effect of Transversus Abdominis Plane Block After Laparoscopic Cholecystectomy in Day-Case Surgery: A Randomized Clinical Trial

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BACKGROUND: Laparoscopic cholecystectomy is associated with postoperative pain of moderate intensity in the early postoperative period. Recent randomized trials have demonstrated the efficacy of transversus abdominis plane (TAP) block in providing postoperative analgesia after abdominal surgery. We hypothesized that a TAP block may reduce pain while coughing and at rest for the first 24 postoperative hours, opioid consumption, and opioid side effects in patients undergoing laparoscopic cholecystectomy in day-case surgery.

METHODS: In this randomized, double-blind study, 80 patients undergoing laparoscopic cholecystectomy in our day-case surgery unit were allocated to receive either bilateral ultrasound-guided posterior TAP blocks (20 mL 0.5% ropivacaine) or placebo blocks. Postoperative pain treatment consisted of oral acetaminophen 1000 mg, oral ibuprofen 400 mg × 3, IV morphine (0–2 hours postoperatively), and oral ketobemidone (2–24 hours postoperatively). The primary outcome was postoperative pain scores while coughing calculated as area under the curve for the first 24 postoperative hours (AUC/24 h). Secondary outcomes were pain scores at rest (AUC/24 h), opioid consumption, and side effects. Patients were assessed 0, 2, 4, 6, 8, and 24 hours postoperatively. Group-wise comparisons of visual analog scale (VAS) pain (AUC/24 h) were performed with the 2-sample t test. Morphine and ketobemidone consumption were compared with the Mann-Whitney test for unpaired data. Categorical data were analyzed using the χ² test.

RESULTS: The primary outcome variable, VAS pain scores while coughing (AUC/24 h), was significantly reduced in the TAP versus the placebo group (P = 0.04); group TAP: 26 mm (SD 13) (weighted average level) versus group placebo: 34 (18) (95% confidence interval): 0.5–15 mm). VAS pain scores at rest (AUC/24 h) showed no significant difference between groups. Median morphine consumption (0–2 hours postoperatively) was 7.5 mg (interquartile range: 5–10 mg) in the placebo group compared with 5 mg (interquartile range: 0–5 mg) in the TAP group (P < 0.001). The odds ratio of a random patient in group TAP having less morphine consumption than a random patient in group placebo was P (group TAP < group placebo) = 0.26 (confidence interval: 0.15, 0.37) where 0.5 represents no difference between groups. There were no between-group differences in total ketobemidone consumption, levels of nausea and sedation, number of patients vomiting, or consumption of ondansetron.

CONCLUSIONS: TAP block after laparoscopic cholecystectomy may have some beneficial effect in reducing pain while coughing and on opioid requirements, but this effect is probably rather small. (Anesth Analg 2012;115:527–33)

Transversus abdominis plane (TAP) block is a regional anesthetic technique that blocks neural afferents of the anterolateral abdominal wall. With the aid of ultrasound (US) or anatomical landmark guidance, local anesthetic is injected into the transversus abdominis fascial plane, where the nerves from T6 to L1 are located. Randomized controlled trials have demonstrated the efficacy of a TAP block in providing postoperative analgesia for up to 24 hours after abdominal surgery but mainly for lower abdominal surgery. The transversus abdominis plane (TAP) block is a regional anesthetic technique that blocks neural afferents of the anterolateral abdominal wall. With the aid of ultrasound (US) or anatomical landmark guidance, local anesthetic is injected into the transversus abdominis fascial plane, where the nerves from T6 to L1 are located. Randomized controlled trials have demonstrated the efficacy of a TAP block in providing postoperative analgesia for up to 24 hours after abdominal surgery but mainly for lower abdominal surgery. 1,10 Postoperative pain is most intense on the day of surgery and the following day. For ambulatory surgical procedures, pain and other sequelae to surgery and anesthesia may prevent same-day discharge. Traditional treatment with opioids increases the likelihood of side effects such as nausea and sedation. A TAP block, which may provide up to 24 hours of analgesia, may therefore be an interesting analgesic option in this population.
However, it has been questioned whether a TAP blockade at the umbilical level can provide analgesia in an upper abdominal surgical procedure such as laparoscopic cholecystectomy. Two published trials with relatively few patients (group size 18 and 21) have tested a TAP blockade in this population. However, one trial suffered from an unusual surgical access, because all laparoscopic ports were below the umbilicus and the other from an insufficient description of both blinding as well as pain scores. Consequently, it remains to be clarified whether a TAP block is a relevant analgesic treatment in this population with upper abdominal surgery.

The aim of this prospective, double-blind, randomized, placebo-controlled study was therefore to investigate the effect of a TAP block on postoperative pain scores while coughing calculated as area under the curve for the first 24 hours (AUC/24 h) (primary outcome), pain scores at rest (AUC/24 h), opioid consumption, and opioid side effects (secondary outcomes) in patients undergoing laparoscopic cholecystectomy in day-case surgery.

**METHODS**

The study was performed at the Day-Case Surgery Unit at Glostrup University Hospital, Copenhagen, Denmark. It was conducted in compliance with guidelines for Good Clinical Practice (GCP) and was monitored by the Copenhagen University Hospital GCP unit. Furthermore, the design and the description of the study are in accordance with the Consolidated Standards of Reporting Clinical Trials. Approvals were obtained from the Regional Ethics Committee, the Danish Medicine Agency, and the Danish Data Protection Agency. The study was registered at www.clinicaltrials.gov (NCT01046071) on January 8, 2010.

**Participants**

Adult patients (18–75 years) with ASA physical status I to III scheduled for laparoscopic cholecystectomy as day-case surgery were included in the study. Exclusion criteria were as follows: body mass index <18 or >35 kg/m², inability to understand Danish, relevant drug allergy, pregnancy, alcohol or drug abuse, daily opioid intake, consumption of pain medications within 24 hours before surgery, and infection at the injection site.

Patients received both written and oral information regarding the trial. Signed informed consent was obtained from all patients.

**Routine Care**

All patients received a standardized anesthetic regimen. Anesthesia was induced with remifentanil 0.4 mL/kg/h (0.6 mg/mL) and propofol. This was followed by the insertion of an I-gel supraglottic airway (Intersurgical Inc., Lithuania). Anesthesia was maintained with propofol (variable rate) and remifentanil (fixed rate 0.4 mL/kg/h). Ten minutes before the end of surgery, all patients received IV sufentanil 0.2 μg/kg.

The laparoscopic procedure was achieved using 4 ports: three 5-mm ports and one 10-mm port placed supraumbilically. Pneumoperitoneum was established with a Veress needle technique; intraperitoneal pressure was maintained at 12 mm Hg. The gallbladder was retracted via a port site cranial to the umbilicus. This port site was closed with resorbable sutures in the fascia and all port sites were closed with nonresorbable sutures in the skin.

A standardized postoperative analgesic regimen was used consisting of oral acetaminophen 1000 mg every 6 hours and oral ibuprofen 400 mg every 6 hours, initiated 30 minutes before surgery. For the first 2 hours at the postoperative care unit, IV morphine was given by a nurse on request of the patient. The initial morphine dose was 5 mg and the following doses were 2.5 mg with a minimum of 10 minutes between doses. From 2 to 24 hours, oral ketobemidone 2.5 mg was taken based on the patient’s own decision but with a minimum prescribed time interval between doses of 1 hour. For nausea scores of at least moderate intensity, ondansetron was given until discharge (first dose 4 mg IV followed by 1 mg IV).

**Blinding and Randomization**

The study was randomized, double-blind, and placebo-controlled. The patients were randomly assigned to receive a TAP block with either 20 mL of ropivacaine 0.5% bilaterally (study group) or with 20 mL of isotonic saline 0.9% bilaterally (placebo group).

Study medication was prepared by the hospital pharmacy into identical boxes containing either isotonic saline or ropivacaine. The boxes were sealed and marked with the name of the project, the investigators name, and consecutive numbers according to a computer-generated block randomization list prepared by the hospital pharmacy (block size = 10). A nurse (who was not part of the study or who took care of the patient) opened the box and drew the study medication into a neutral syringe. The patients, the anesthesiologists, and staff providing postoperative care were blinded to group assignments. Two of the investigators (PLP, PS) performed all assessments.

**Interventions**

A US-guided TAP block was performed bilaterally before surgical incision by 1 of 2 investigators (PLP, PS). A US probe (Venue 40; GE Healthcare, Waukesha, WI) was placed transversely in the midaxillary line between the iliac crest and the costal margin at the level of the umbilicus. The external oblique, internal oblique, and transversus abdominal muscles and their fascia were visualized. A Pajunk 22-gauge, 80-mm needle (Medizintechnik, Geisingen, Germany) was introduced anteriorly and in the plane of the US probe, and on entering the TAP, 2 mL of isotonic saline was injected to verify the correct position of the needle. After negative aspiration, 20 mL of the study solution was injected and the injectate was seen spreading in the TAP as a dark oval shape. Similarly, another TAP block was performed on the contralateral side.

**Outcomes**

The primary outcome measure of the study was visual analog scale (VAS) pain scores while coughing, estimated as AUC/24 h based on pain scores at 0, 2, 4, 6, 8, and 24 hours postoperatively.

The secondary outcome measures of the study were VAS pain scores at rest (AUC/24 h) based on pain scores at 0, 2, 4, 6, 8, and 24 hours postoperatively, morphine
consumption 0 to 2 hours postoperatively, ketobemidone consumption 2 to 24 hours postoperatively, levels of nausea and sedation based on measurements at 0, 2, 4, 6, 8, and 24 hours postoperatively, number of vomiting episodes, and number of patients vomiting during the first 24 postoperative hours.

Assessment of Outcomes
Before their operation, all patients were instructed in the use of an ungraded 100-mm VAS with 0 = no pain and 100 = worst pain imaginable.

Patients were interviewed at 0, 2, 4, 6, 8, and 24 hours after operation by the investigators either in person or by telephone after discharge. The investigators recorded the patients’ assessments of VAS pain scores at rest and while coughing, opioid consumption, and the patients’ assessments of opioid side effect at each interview.

Opioid consumption was recorded as on-request IV morphine (mg) for the first 2 hours postoperatively and oral ketobemidone (mg) taken by the patients 2 to 24 hours postoperatively.

The severity of both nausea and sedation was assessed by patients on a 4-point scale (none, mild, moderate, and severe). The number of episodes of vomiting (>10 mL) postoperatively at 0–2, 2–4, 4–6, 6–8, and 8–24 hours was reported by the patients. Finally, the number of patients receiving ondansetron was recorded.

Sample Size
We were not able to find any study in laparoscopic cholecystectomy that used VAS pain scores calculated as area under the curve. Therefore, we based our sample size calculation on the highest postoperative VAS score (at 6 hours postoperatively) from a previous study conducted at our day-case surgical unit.13 The anticipated VAS score at 6 hours postoperatively was 50 (SD 25). We considered a 40% reduction in VAS pain scores to be of clinical relevance. With a type I error of 0.05 and a type II error of 0.10, a sample size calculation determined that 68 patients were needed in the study. To allow for dropouts and exclusions, we recruited an additional 12 patients for the study.

Statistical Methods
Statistical analyses were performed using SPSS 19 (SPSS Inc., Chicago, IL) and SAS 9.1 (SAS Institute Inc., Cary, NC, USA). Data are presented as median and interquartile range (IQR) or with mean and SD as appropriate. The Kolmogorov-Smirnov (K-S) test with Lilliefors significance correction was used to test for normality. VAS pain scores at rest and while coughing were calculated as AUC/24 h. VAS pain scores at rest AUC/24 h (K-S: P = 0.20), VAS pain scores while coughing AUC/24 h (K-S: P = 0.20), and pain scores while coughing at 6 hours (K-S: P = 0.094) followed the normal distribution and were compared with the Student t test with unequal variances. Morphine consumption (K-S: P < 0.001) and ketobemidone consumption (K-S: P < 0.001) did not follow a normal distribution and were compared with the Mann-Whitney (M-W) test for unpaired data, and confidence intervals (CIs) were calculated for P (X > Y) using Wilcoxon-Mann-Whitney odds analysis.1a Number of patients vomiting and using ondansetron was analyzed using the χ² test. For comparing side effects (nausea and sedation), numerical values were assigned to the scores from each patient (none = 0, slight = 1, moderate = 2, and severe = 3). Data for sedation (K-S: P < 0.001)

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and nausea (K-S: $P < 0.001$) did not follow a normal distribution and were compared with the M-W test. $P < 0.05$ was considered statistically significant.

**RESULTS**

One hundred thirty-six patients were approached for participation in the study from April 2010 to February 2011. Eighty patients were recruited and randomly assigned to their treatment group. However, 6 patients were later excluded resulting in 74 patients in the final analyses (Fig. 1).

All US-guided TAP blocks were performed as described in the Methods section and without any complications. Patients’ characteristics and perioperative data are depicted in Table 1; there were no large differences between groups.

**Primary End Point**

The primary outcome variable, VAS pain scores while coughing, estimated as AUC/24 h, was significantly reduced in group TAP: 26 mm (SD 13) (weighted average level) versus group placebo: 34 (18) (95% CI: 0.5–15 mm) (Fig. 2).

Correlation analysis demonstrated a positive relationship between the 24-hour AUC based on VAS pain scores while coughing (primary outcome), morphine consumption, and ketobemidone consumption in both groups. Spearman correlation ($\rho$) for morphine was 0.370 (95% CI: 0.075–0.639) in the TAP block group and 0.501 (95% CI: 0.176–0.734) in the placebo group. Correlations for ketobemidone consumption were $\rho = 0.0408$ (95% CI: 0.131–0.650) in the TAP block group and $\rho = 0.684$ (95% CI: 0.448–0.828) in the placebo group. Correlation analysis demonstrated a positive correlation between the 24-hour AUC based on VAS pain scores while coughing and number of vomiting episodes; $\rho = 0.467$ (95% CI: 0.178–0.710) in the placebo group only (Fig. 3).

**Secondary End Points**

**Pain Scores**

For the 24-hour AUC based on VAS pain scores at rest, no significant difference between treatment groups was demonstrated (group TAP 19 [10] versus group placebo 23 [13] [$P = 0.16$]). VAS pain scores at rest at each time point are presented in Figure 4.

Our sample size calculation was based on VAS pain scores at 6 hours postoperatively because we did not find any study in laparoscopic cholecystectomy that used VAS pain scores calculated as area under the curve. VAS pain scores while coughing at 6 hours were not significantly reduced in the TAP group, 26 mm (SD 19), compared with the placebo group, 34 mm (SD 19) (95% CI: −0.2 to 18 mm) ($P = 0.05$).

**Opioid Consumption**

Median morphine consumption (0–2 hours postoperatively) was 7.5 mg (IQR: 5–10 mg) in the placebo group compared with 5 mg (IQR: 0–5 mg) in the TAP group ($P < 0.001$). The odds ratio of a random patient in group TAP having less morphine consumption than a random patient in group placebo was $P$ (group TAP < group placebo) = 0.26 (CI: 0.15, 0.37) where 0.5 represents no difference between groups. There was no significant difference between groups for total ketobemidone consumption 2 to 24 hours postoperatively. Median ketobemidone consumption was 0 mg (0–2.5 mg) in the TAP group compared with 2.5 mg (0–5 mg) in the placebo group ($P$ [group TAP < group placebo]) = 0.42 (CI: 0.30–0.53).

**Side Effects**

Levels of sedation, nausea, number of patients vomiting, number of vomiting episodes, and consumption of ondansetron were not significantly different between groups (Table 2).

**DISCUSSION**

In this study, we have demonstrated that the application of a TAP block with 20 mL of ropivacaine 0.5% bilaterally in patients undergoing day-case laparoscopic cholecystectomy resulted in reduced pain scores during coughing calculated as the area under the curve for the first 24 hours postoperatively, and reduced morphine consumption in

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**Table 1. Baseline Patient Characteristics and Perioperative Data**

<table>
<thead>
<tr>
<th></th>
<th>TAP Group</th>
<th>Placebo Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>37</td>
<td>37</td>
</tr>
<tr>
<td>Sex (female/male) (n)</td>
<td>28/9</td>
<td>25/12</td>
</tr>
<tr>
<td>Age (y)</td>
<td>42 (13.5)</td>
<td>43 (17.0)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>171 (9.4)</td>
<td>170 (9.4)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>77 (14.5)</td>
<td>76 (13.8)</td>
</tr>
<tr>
<td>Duration of surgery (min)</td>
<td>73 (31.5)</td>
<td>62 (18.3)</td>
</tr>
<tr>
<td>Volume of isotonic sodium chloride (mL)</td>
<td>659 (262)</td>
<td>644 (223)</td>
</tr>
<tr>
<td>Propofol (mg)</td>
<td>681 (169)</td>
<td>683 (142)</td>
</tr>
<tr>
<td>Remifentanil (mg)</td>
<td>2.8 (1.0)</td>
<td>2.4 (0.7)</td>
</tr>
<tr>
<td>Sufentanil (µg)</td>
<td>15.3 (2.8)</td>
<td>15.7 (3.5)</td>
</tr>
</tbody>
</table>

Data are presented as mean (SD) or number. TAP = transversus abdominis plane.
the first 2 postoperative hours. Furthermore, we observed a positive correlation between the highest pain scores while coughing and consumption of morphine and ketobemidone, which supports the primary outcome finding. However, because of large CIs on the difference between groups, the true benefit of a TAP block in laparoscopic cholecystectomy may be small.

The overall 24-hour reduction in pain scores while coughing in the TAP group was primarily attributable to reduced VAS scores from 0 to 8 hours postoperatively. In our pretrial sample size calculation, we considered a 20-mm reduction in pain scores to be of clinical relevance. The actual 24-hour AUC-VAS pain was reduced from 35 to 26 mm, which is 9 mm on the VAS. The reduction may be considered clinically relevant, because most VAS scores at all timepoints in the treatment group were reduced from moderate (\( \geq 30 \) mm) to low pain (\( < 30 \) mm) (Fig. 2). Furthermore, the clinical significance of reduced pain scores has been addressed in 2 previous trials in an emergency department population in which a reduction of 9 mm\(^1\) and 13 mm\(^1\), respectively, could be considered clinically relevant, and did not vary with gender, age, or cause of pain.\(^1\) These findings support the clinical relevance of the results of the present study. However, the minimally relevant reduction in pain score is controversial.\(^1\),\(^2\)

We did not find a significant difference in pain scores at rest between groups, but pain scores at rest were generally low (\( < 30 \) mm) and therefore the study had low sensitivity to detect a difference on this point.\(^1\),\(^2\)

Morphine consumption was significantly reduced from 0 to 2 hours postoperatively, thereby supporting the analgesic effect of the TAP. However, the actual reduction in morphine consumption was low and most likely of no clinical relevance. In general, ketobemidone consumption from 2 to 24 hours was low and we did not find any significant difference between groups. This was not surprising, because a previous study demonstrated low opioid consumption after laparoscopic cholecystectomy.\(^1\) The present study would therefore be expected to have low sensitivity to demonstrate any difference on this outcome. Consequently, we chose pain scores while coughing as our primary outcome measure in the study.

Previously, 2 randomized controlled studies have demonstrated analgesic efficacy of TAP blockade after laparoscopic cholecystectomy.\(^1\),\(^2\) Unfortunately, both studies had
methodological limitations. El-Dawlatly et al. demonstrated a significant reduction in perioperative sufentanil administration as well as 24-hour morphine consumption with a TAP block. Regrettably, neither pain scores nor side effects were assessed in the study. All ports for the laparoscopic procedure were below the umbilicus. Therefore, the study does not adequately answer the question of whether a TAP block is advantageous for laparoscopic cholecystectomy with incision holes in the upper abdominal area, as is most frequently used. Ra et al. demonstrated a reduced use of both ketorolac and fentanyl after administration of a TAP block. Furthermore, pain scores in the treatment group were significantly reduced for 24 hours in their study. However, the study suffers from an insufficient description of randomization and blinding, and it was not stated whether the evaluation of pain scores was conducted at rest or during mobilization.

We compared a TAP block to a placebo block; therefore, we cannot comment on the TAP block analgesic effect compared with that of a local anesthetic infiltration into the abdominal port hole wounds. Local anesthetic infiltration has an expected duration of 0 to 6 hours, and although we found a reduced 24-hour AUC pain score with the TAP block, this result is primarily based on reduced pain scores during the first 8 postoperative hours. Three systematic reviews concluded that local anesthetics have a significant benefit after laparoscopic cholecystectomy, but the effect is small and of doubtful clinical relevance. Furthermore, a recently published, randomized, clinical trial did not find any effect of combined subcutaneous and intraperitoneal installation of levobupivacaine on postoperative pain after laparoscopic cholecystectomy.

Pain scores in our placebo group were low. Therefore, it can be argued that performing a TAP block may be unnecessary in relation to the pain levels and that port infiltration with local anesthetic in combination with a multimodal analgesic treatment may be a better choice. In a multimodal approach, dexamethasone (8 mg) may have a role; 2 clinical studies have demonstrated a positive effect on pain, nausea, and recovery after laparoscopic cholecystectomy.

There are a number of limitations to this study. First, despite block performance with real-time US, we do not know whether all TAP blocks produced a sensory block, because we did not make sensory assessments in order not to unblind the study. Even if a third and independent investigator had tested the sensory levels of the TAP blockade, this would have unblinded the patients and thereby influenced the results of the study. Furthermore, assessment of sensory levels does not necessarily reflect the analgesic effectiveness of the TAP blockade. This is more truly reflected in differences in pain scores or opioid consumption. Second, we have no assessment points from 8 to 24 hours postoperatively. We thought that it was important to document an effect in the early postoperative period, when pain levels are highest. Third, we used the US-guided posterior approach at the umbilical level to perform the TAP block, but this approach may not produce sensory block above the umbilicus. We might have achieved better coverage of the upper port holes for the laparoscopic procedure with a subcostal approach to the TAP block. Fourth, we did not encounter any complications with the TAP block, but complications are rare and our study was underpowered to detect complications. Fifth, port infiltration after laparoscopic cholecystectomy is a standard procedure in many surgical departments. We considered port infiltration as part of the basic analgesic treatment in both study groups, but we discarded this approach in order not to exceed the toxic limit for ropivacaine because surgeons at our institution used up to 50 mL of a local anesthetic for infiltration.

It should be considered whether a TAP block is relevant in the present surgical population. The reduction in pain score from moderate to low while coughing has to be weighed against the cost of a TAP blockade, procedural time (low in experienced hands), and the risk of procedural visceral perforation (low with a US-guided procedure). Finally, because the general improvement in pain scores was approximately 10 to 15 mm on the VAS, it cannot be excluded that a more comprehensive oral multimodal analgesic treatment that includes, e.g., gabapentinoids and glucocorticoids in addition to acetaminophen and nonsteroidal antiinflammatory drugs, will outweigh the benefits of a TAP blockade. Future trials will have to address these questions.

In conclusion, our study showed that patients who received TAP block in addition to a basic analgesic regimen with acetaminophen and ibuprofen after laparoscopic cholecystectomy had reduced pain scores (AUC/24 h) while coughing as well as reduced morphine consumption in the first 2 postoperative hours, but these reductions were rather small. The procedure was without reported complications and may be considered as part of multimodal analgesic treatment for laparoscopic cholecystectomy in day-case surgery. However, the additional analgesic effect of a TAP block in the presence of a vigorous multimodal analgesic regimen should be further explored.

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DISCLOSURES
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Attestation: Pernille Lykke Petersen has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
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