Ultrasound-guided Continuous Thoracic Paravertebral Block Improves Patients Quality of Recovery After Open Hepatectomy: A Randomized, Double-blind, Placebo-controlled Trial

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Received: May 14, 2021; accepted Sep 28, 2021. Published online Mar 3, 2022.
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This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

This article has been accepted for publication but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record.

Please cite this article as: Cui XL, Xu Nan, Zhang ZY, et al. Ultrasound-guided continuous thoracic paravertebral block improves patients quality of recovery after open hepatectomy: a randomized, double-blind, placebo-controlled trial. Chin Med Sci J 2022, 37(1): 003934. Doi: 10.24920/003934.
Keywords: thoracic paravertebral block; hepatectomy; quality of recovery; ropivacaine

Abstract

Background Ultrasound-guided continuous thoracic paravertebral block can provide pain-relieving and opioid-sparing effects in patients receiving open hepatectomy. We hypothesize that these effects may improve the quality of recovery (QoR) after open hepatectomy.

Methods Seventy-six patients undergoing open hepatectomy were randomized to receive a continuous thoracic paravertebral block with ropivacaine (CTPVB group) or normal saline (control group). All patients received patient-controlled intravenous analgesia with morphine postoperatively for 48 hours. The primary outcome was the global Chinese 15-item Quality of Recovery score on postoperative day 7, which was statistically analyzed using Student’s t-test.

Results Thirty-six patients in the CTPVB group and 37 in the control group completed the study. Compared to the control group, the CTPVB group had significantly increased global Chinese 15-item Quality of Recovery scores (133.14 ± 12.97 vs. 122.62 ± 14.89, P = 0.002) on postoperative day 7. Postoperative pain scores and cumulative morphine consumption were significantly lower for up to 8 and 48 hours (P < 0.05; P = 0.002), respectively, in the CTPVB group.

Conclusion Perioperative CTPVB markably promotes patient’s QoR after open hepatectomy with a profound analgesic effect in the early postoperative period.
INTRODUCTION

Open hepatectomy is a common surgical procedure for liver space-occupying lesions [1, 2]. It is often associated with severe postoperative pain due to traumatic incision and substantial surgical manipulations [1,2], which increases the incidence of postoperative complications and impede patients’ recovery [1-3]. High-dose opioid administration may provide effective pain relief; however, its lower pain scores alone may not be perceived by patients as a more favorable outcome, and drug-related adverse effects may also affect patient perception of quality of recovery (QoR) [4]. Since patient-centered outcomes are increasingly recognized as important indicators of quality of care [5-7], it is meaningful to assess improvement in patient-perceived recovery as an important endpoint to determine the optimal analgesic technique for open hepatectomy.

Regional anesthesia techniques have been shown to provide better acute pain control and improve recovery [5-7] when assessed by the Quality of Recovery (QoR) questionnaire, a high-quality tool used to assess patient perception of recovery after anesthesia and surgery [8]. The analgesic effect of perioperative continuous thoracic paravertebral block (CTPVB) after open hepatectomy has been described previously [9, 10]. However, the impact of this analgesic technique on the QoR after open hepatectomy has not yet been evaluated.

We therefore conducted this prospective, randomized, double-blind, placebo-controlled study to assess patients’ perception of recovery following open hepatectomy with CTPVB using the validated Chinese 15-item QoR (QoR-15C) questionnaire [11]. The primary outcome was the global QoR-15C score on postoperative day (POD) 7.
PATIENTS AND METHODS

Patient recruitment

This study was approved by the Institutional Review Board of Peking Union Medical College Hospital, Beijing, China (#ZS-1031). The study was conducted at Peking Union Medical College Hospital in accordance with the principals of the Helsinki Declaration. Written informed consent was obtained from all participants.

Eligible participants were adult patients aged ≥18 years with an American Society of Anesthesiologists (ASA) physical status score of I - III who underwent elective open hepatectomy with a J-shaped right subcostal incision. The exclusion criteria included: a) known allergies to the study drugs, b) coagulopathy or use of anticoagulants; c) concurrent medication with analgesics; d) history of substance abuse; e) participation in other clinical trial; f) inability to adequately describe postoperative pain due to a language barrier; and g) psychiatric disorders.

Randomization and Blinding

Eligible patients were randomized into CTPVB or control group with a ratio of 1:1 following simple randomization procedures. The random numbers were computerized using the SPSS package (version 22.0; SPSS Inc, Chicago, IL, USA) by a professional statistician who was not involved in the implementation and statistical analysis of the study. Allocation concealment was ensured by the use of sealed, opaque, sequentially numbered envelopes. These assignment envelopes were opened after the inclusion of the patient in the study.
A single experienced anesthesiologist performed all the CTPVBs. Surgery was conducted by the same surgical team blinded to subject allocation using a standardized approach. All the patients, researchers who assessed the postoperative outcomes, acute pain service team, and surgical team were blinded to the group assignments, which were unmasked upon the completion of statistical analysis.

**Perioperative management and anesthesia**

All patients were informed of the postoperative CTPVB and patient-controlled intravenous analgesia (PCIA) schedule the day prior to surgery, with a goal of maintaining pain scores <4 on an 11-point numerical rating scale (NRS; 0: no pain; 10: maximum pain imaginable) using PCIA. Baseline physical and mental health-related quality of life data were measured using the validated Chinese version of the Medical Outcomes Study 36-Item Short-Form questionnaire (SF-36) \[12\]. The Chinese SF-36 physical component summary (PSC) and mental health summary (MCS) domain scores were calculated using a specific scoring algorithm \[13\]. No pre-operative medications were administered.

CTPVB was performed 30 minutes before surgery in a dedicated procedure room. Standard monitoring and peripheral venous access were established to the patient. Intravenous fentanyl and midazolam were titrated based on the patient’s level of comfort. A thoracic paravertebral catheter was placed at the T₈ level under ultrasound guidance using a curvilinear 1 – 5 MHz transducer (CX-50, Philips Inc., USA) in the left lateral position. The in-plane needle insertion approach was used as described by Renes et al. \[14\]. A 21-gauge 10-cm needle (PlexoLongNanoline; Pajunk Inc, Geisingen, Germany) was inserted and positioned at the T₈ paravertebral space between the internal intercostal membrane and the pleura under real-time ultrasound guidance. After a negative aspiration test, 25
ml of 0.5% ropivacaine with 1:200,000 adrenaline was injected over 2 - 3 minutes in the CTPVB group. The control group received 25 ml of 0.9% saline over 2 - 3 minutes. A catheter (PlexoLongNanoline; Pajunk Inc, Geisingen, Germany) was inserted through the needle to a depth of 1 to 2 cm; it was tunneled subcutaneously and secured with Bio-gel to patient’s back. The catheter was connected to a programmable, portable, electronic pulse infusion pump set (Apon ambulatory infusion pump ZZB-I, Jiangsu Apon Medical Technology Co., Ltd.) to deliver a bolus of 0.125 ml/kg every hour over 90s, commencing immediately after surgery. The blinded study solution of either 0.2% ropivacaine or 0.9% saline was set up and commenced by a nurse who was otherwise not involved in the study. To avoid inadvertent unmasking of the allocation, the extent of the sensory block was not tested.

After the ultrasound-guided block, a bispectral index (BIS) monitor was connected to the patient, and general anesthesia was induced with intravenous fentanyl (2 μg/kg), propofol (1.5 - 2.0 mg/kg), and rocuronium (0.6 mg/kg). All patients received endotracheal intubation. Anesthesia was maintained with sevoflurane and an O₂-N₂O mixture to maintain the BIS index within 40 - 60. An intravenous infusion of atracurium was administered for muscle relaxation and ceased 30 minutes before the completion of surgery. Intravenous fentanyl in boluses of 1 μg/kg were administered to maintain the patient’s heart rate and/or systolic blood pressure below 120% of pre-operative levels. A standard right or left-lobe hepatectomy was performed by the same surgical team using a J-shaped right subcostal incision. The J-shaped incision consisted of a right subcostal incision with a medio-cranial extension to the xiphoid process and a variable right lateral extension with transection of the oblique abdominal musculature [15]. Thirty minutes prior to skin suturing, all patients received
1 μg/kg of fentanyl for immediate postoperative analgesia and 4 mg of ondansetron and 5 mg of
dexamethasone for prophylactic antiemetic treatment. Upon completion of surgery, sevoflurane and
N₂O were discontinued and the neuromuscular blockade was reversed using neostigmine (50 μg/kg)
and atropine (20 μg/kg). Extubation was carried out when the patients were fully awake. PCIA was
then commenced using a pump set (Gemstar, Hospiria Inc., USA) to deliver boluses of 1.5 - 2 mg of
morphine at a 5-minute lockout interval and without background infusion. The maximal permitted
dosage of morphine was set at 8 mg/h. CTPVB and PCIA were continued until 48 hours after the
surgery in both groups.

Outcomes and data collection
The primary outcome of the study was the QoR, which was assessed with the QoR-15C questionnaire
[11] on POD 7. The QoR-15C is a 15-item questionnaire designed to evaluate the QoR after anesthesia
and surgery, with each item scored on a 5-point Likert scale. The items are grouped according to the
following subscales: 2 on pain, 4 on emotional state, 5 on physical comfort, 2 on patient support, and
2 on physical independence. The global QoR-15C scores range from 0 (extremely poor QoR) to 150
(excellent QoR).

The secondary outcomes included: the QoR-15C score on POD 3; morphine consumption at 8,
24, and 48 hours after surgery; pain at rest and upon activity, as evaluated by the NRS (range, 0 -
10) at 8, 24, and 48 hours after surgery; episodes of postoperative nausea and vomiting (PONV)
within 48 hours; time intervals from the end of surgery to first out-of-bed activity and to resumption
of bowel movements; and postoperative length of hospital stay (LOS). Since we did not use any
adjustment method for the type I error of the multiple secondary outcomes, findings from secondary
outcomes were only interpreted as exploratory results. CTPVB-related adverse events (including inflammation or infection at the site of insertion) and adverse effects caused by local anesthetic agents were also recorded.

**Statistical Analysis**

**Sample size**

We conducted a pilot study with 10 patients in each group; the mean ± SD QoR-15C scores on POD 7 were 114.80 ± 43.21 in the control group and 144.34 ± 42.46 in the CTPVB group. We calculated a sample size of 34 patients per study group to detect a difference in QoR-15C score at an α level of 0.05 with 80% power. We planned to enroll 38 patients per study group to allow for possible dropouts and missing data.

**Variable analysis**

Statistical analyses were performed using SPSS version 22.0 (SPSS Inc, Chicago, Illinois, USA). Variables and demographics that were expected to follow a Gaussian distribution are expressed as mean ± SD or presented as a column-and-standard deviation line and analyzed using the two-tailed Student’s t test. Variables that did not follow a normal distribution are presented as the median (interquartile range, IQR) and analyzed using the Mann–Whitney U test. Categorical data are reported as a proportion or percentage, as appropriate, and were analyzed using the Chi-square test. P-values <0.05 (two-sided) were considered statistically significant.
RESULTS

Demographic, Baseline, and Operative Characteristics

The study flowchart is shown in Figure 1. From November 2018 to May 2019, 80 patients were assessed for eligibility; one patient was excluded due to receiving tramadol and pregabalin tablets for postherpetic neuralgia, and three patients who refused to participate were not included. Finally, 76 patients were randomly assigned to the CTPVB group or the control group. Two patients from the CTPVB group were excluded, one due to an unexpected transfer to the ICU and one for suspected extensive sympathetic block because of severe hypotension and bradycardia after the block. One patient from the control group was excluded because the QoR-15C questionnaire was incomplete. Therefore, 73 patients, including 36 in the CTPVB group and 37 in the control group, entered the final analysis. The demographic, baseline, and surgical characteristics of these two groups were comparable ($P > 0.05$) (Table 1). The baseline Chinese SF-36 PSC and MCS domain scores also showed no statistically significant differences ($P > 0.05$).
Table 1. Patient demographic, baseline, and surgical characteristics

|                                | Control (n=37) | CTPVB (n=36) | Statistics | P value |
|--------------------------------|----------------|--------------|------------|---------|
| Age (yr), mean ± SD            | 57.08 ± 9.96   | 55.36 ± 11.20| 0.694      | 0.490   |
| Male/female (n)                | 22/15          | 22/14        | 0.210      | 0.538   |
| Body weight (kg), mean ± SD    | 64.16 ± 9.53   | 65.54 ± 8.62 | -0.648     | 0.519   |
| BMI(kg/m^2), mean ± SD         | 23.31 ± 3.15   | 23.56 ± 3.59 | -0.009     | 0.850   |
| ASA PS I/II/III (n)            | 13/23/1        | 18/17/1      | 0.014      | 0.907   |

Educational background


|                                    |    |    |        |        |
|------------------------------------|----|----|--------|--------|
| < University*/≥ university* (n)     | 23/14 | 24/12 | 0.161  | 0.808  |
| History of previous surgery, yes/no (n) | 20/17 | 17/19 | 0.341  | 0.642  |
| Medical insurance, yes/no (n)      | 32/5  | 33/3  | 0.502  | 0.711  |
| SF-36 PCS scores, mean ± SD        | 45.75 ± 9.52 | 48.24 ± 9.70 | -1.119 | 0.218  |
| SF-36 MCS scores, mean ± SD        | 48.01 ± 9.94 | 49.94 ± 7.76 | -0.925 | 0.334  |
| Preoperative pain NRS score, median (IQR) | 0 (0 to 1.5) | 0 (0 to 1.75) | 716.0  | 0.761  |
| Duration of surgery (h), mean ± SD | 3.00 ± 1.09  | 2.87 ± 0.91  | 0.297  | 0.578  |

BMI, body mass index; PS, physical status; SF-36, Medical Outcomes Study 36-Item Short-Form questionnaire; PCS, physical component summary; MCS, mental component summary; SD, standard deviation; ns, non-significant. *Primary school, middle school, or high school. † University or postgraduate education.

**QoR**

Patient-reported global and dimensional QoR-15C scores on PODs 3 and 7 are shown in Figure 2. The primary outcome (the global QoR-15C score on POD 7) was significantly higher in the CTPVB group than in the control group [(133.14 ± 12.97) vs. (122.62 ± 14.89); mean difference (95% CI): -10.52 (-17.04 to -3.99); P = 0.002]. The global QoR-15C score on POD 3 was also significantly higher in the CTPVB group [(115.64 ± 21.70) vs. (103.46 ± 19.00); mean difference (95% CI): -12.18 (-21.45 to -2.91); P = 0.011]. The dimensional score of pain on POD 3 [(16.61 ± 2.90) vs. (13.84 ± 5.70); mean difference (95% CI): -2.77 (-4.89 to -0.66); P = 0.011] and the emotional state on POD 7 [(37.19 ± 3.10) vs. (33.65 ± 7.52); mean difference (95% CI): -3.55 (-5.90 to -1.09);
were significantly higher in the CTPVB group than in the control group, respectively. The dimensional score of physical independence on POD 3 [(10.03 ± 6.73) vs. (6.58 ± 5.16); mean difference (95% CI): -3.46 (-6.25 to -0.67); \( P = 0.016 \)] and POD 7 [(14.42 ± 4.42) vs. (11.49 ± 4.30); mean difference (95% CI): -2.93 (-4.96 to -0.90); \( P = 0.005 \)] were also significantly higher in the CTPVB group than in the control group, respectively. There was no significant difference in the domain scores relating to physical comfort, psychological support, or their sub-domain scores on POD 3 or 7 between these two groups (\( P > 0.05 \)).

![Graph showing QoR-15C scores on POD 3 and POD 7 in control and CTPVB groups.](image)

**Figure 2.** Patients’ global and dimensional QoR-15C scores on postoperative days (PODs) 3 and 7 in two groups. QoR-15C, Chinese version of the 15-item Quality of Recovery Questionnaire.
Secondary Outcomes

Compared with the control group, the CTPVB group reported significantly lower median (IQR) pain scores at rest [2.5 (1 - 3) vs. 3 (2 - 4), P = 0.021] and upon activity [3 (2 - 4.25) vs. 4 (3 - 5), P = 0.040] at 8 hours postoperatively (Table 2). However, no significant differences were observed in median (IQR) pain scores at 24 and 48 hours postoperatively (Table 2) (Ps > 0.05). Patients in the CTPVB group consumed significantly less median (IQR) morphine than the control group at 8 [4.25 (2.00 - 7.00) vs. 7.5 (6.00 - 16.00) mg/kg, P < 0.001], 24 [10.25 (4.50 - 18.13) vs. 19.50 (10.50 - 33.00) mg/kg, P < 0.001], and 48 hours [15.75 (6.00 - 28.50) vs. 26.50 (18.00 - 45.00) mg/kg, P = 0.001] postoperatively (Table 2). Outcomes related to postoperative recovery were not significantly different between these two groups, including episodes of PONV within the first 48 hours, time to first out-of-bed activity, time to resumption of bowel movement, and postoperative LOS (Table 2) (Ps > 0.05). No evidence of adverse effects due to local anesthetic agents, hematoma, infection at the site of insertion, or dislocation of the catheter was reported.

Table 2. Data related to postoperative pain and recovery in the study population

| Variables | Control group (n=37) | CTPVB group (n=36) | Statistics | P value |
|-----------|---------------------|--------------------|------------|---------|
| Pain scores at rest (NRS), median (IQR) | | | | |
| 8 h postoperatively | 3 (2 - 4) | 2 (0.25 - 3) | 437.5 | 0.009 |
| 24 h postoperatively | 2 (1.5 - 3) | 2 (1 - 3) | 581.0 | 0.332 |
| 48 h postoperatively | 1 (0 - 2) | 1 (0 - 2) | 617.5 | 0.577 |
DISCUSSION

The primary outcome of our current study was the QoR on POD 7 in CTPVB group and control group. In the CTPVB group, the improved dimensions of QoR included pain, emotional state, and physical independence. Additional benefits of this regional analgesic technique were better opioid-sparing effect for up to 48 hours and reduced pain severity for up to 8 hours.
Opioids are frequently used to treat postoperative pain, but the associated side effects can impede functional recovery \[^{[4]}\]. Therefore, in determining the optimal analgesic technique for open hepatectomy, it is essential to assess improvement in patient-perceived recovery as part of the consumer-centered health care strategies \[^{[4-7]}\]. Regional analgesic techniques have been reported to improve recovery after non-hepatic surgeries \[^{[5-7]}\] when assessed by the QoR questionnaire, a validated, multidimensional assessment tool \[^{[8,11]}\]. CTPVB has been reported to decrease pain severity with an opioid-sparing effect after open hepatectomy \[^{[9,10]}\]. The current study further verified the practical application of CTPVB as an important component of a multimodal analgesia regiment for improving QoR after open hepatectomy.

In our current study, patients who received CTPVB had significantly lower pain scores for up to 8 hours postoperatively; however, the difference between two groups did not persist beyond this period, possibly because we educated patients pre-operatively in the optimal use of postoperative PCIA to maintain NRS scores below 4, which was considered to be ethical in clinical practice. However, we believe that the analgesic effect of CTPVB persisted until 48 hours postoperatively, substantiated by the significantly lower use of morphine in the CTPVB group during this period. Additionally, the overall analgesic effect of CTPVB was evident with the improved pain dimensional score of the QoR-15C until POD 3.

Chen et al. \[^{[9]}\] studied CTPVB with an initial dose of 10 ml of 0.2% ropivacaine administered upon the completion of surgery, followed by an infusion of 0.2% ropivacaine at 6 ml/h for 24 hours after right lobe hepatectomy. They demonstrated a reduction in pain intensity and decreased sufentanil consumption by 20% for 24 hours postoperatively. In our current study, the initial dose of CTPVB
with 25 ml of 0.5% ropivacaine was administered pre-operatively, followed by a 0.2% ropivacaine infusion at 0.125 ml/kg per pulse per hour for 48 hours postoperatively. Consequently, besides an early analgesic effect, morphine consumption decreased by 60.2% at 24 hours and by 40.6% at 48 hours. Thus, the analgesic technique we used provided a more pronounced opioid-sparing effect compared to the technique described by Chen et al. [9]. This was likely due to the larger volume of ropivacaine that we gave with the initial dose, which may have provided a wider thoracic nerve root blockade. Furthermore, the programmed intermittent bolus infusion technique we used may generate higher injection pressures than a continuous infusion, which might have facilitated local anesthetic spread from the catheter tip to the targeted trunks or nerve [16]. However, the risk of epidural spread resulted from large-volume or high-pressure injection should always be a concern for clinical practitioners, although no related side effect was noted in our current case.

Enhanced recovery after surgery (ERAS) protocol has become a popular management modality for contemporary surgical procedures [1,17]. In our current study, we also assessed the physician-perceived ERAS-related endpoints as secondary outcomes, which included episodes of PONV, time to first out-of-bed activity, time to resumption of bowel movement, and postoperative LOS [1,18]; none of these outcomes showed statistically significant differences between CTPVB group and control group. This may be explained by multiple confounding factors, including the use of drugs (e.g. potent anti-emetic drugs including dexamethasone and ondansetron [18]) in our anesthesia regiment. Although our current study was not sufficiently powered to detect a difference in secondary outcomes, the lower raw numbers of both the time to first out-of-bed activity and postoperative LOS in the CTPVB group may suggest potential superiority of CTPVB in speeding up the recovery.
Although CTPVB was a safe procedure without major complications in our current study, one patient in the CTPVB group experienced severe hypotension and bradycardia after the block, which was likely caused by extensive sympathetic block. Upon arrival in the operating room, the patient’s heart rate and blood pressure had dropped significantly. Atropine (0.5 mg) and ephedrine (20 mg) were intravenously administered, followed by a fluid bolus for resuscitation. For safe consideration, the patient was excluded from the study and the surgery was completed successfully. Notably, sympathetic blockade produced by TPVB may unmask hypovolemia [19] and explain the symptomatic hemodynamic instability in the excluded patient.

Our study has several limitations. First, although we used the SF-36 questionnaire (which is a well-validated instrument and reflects health-related quality of life more comprehensively) to assess baseline mental and physical status, we did not obtain baseline QoR values. Second, to enable blinding, we did not assess the sensory blockade level following CTPVB. Hence, failed PVB might have occurred. However, considering that all of the blocks were performed by a single anesthesiologist experienced in performing TPVB and the failure rate of TPVB was low [19, 20], we believe that most blocks were effective. Third, since major hepatectomy is associated with a decrease in ropivacaine clearance by >50% after regional block (TAP block) [21], further studies are required to monitor serum ropivacaine levels after CTPVB. Furthermore, our patients may have used morphine PCIA to relieve pain unrelated to surgery, although we had educated them not to do so. Finally, the unique demographic profile of patients from a single Chinese medical center may not be generalizable to other medical situations. Further extensive multicenter studies are required to validate our findings.
In conclusion, perioperative CTPVB enhances the QoR in patients undergoing open hepatectomy by using a J-shaped right subcostal incision for up to 7 PODs. In addition, this technique provides significant analgesia in the early postoperative period and has an opioid-sparing effect.

ACKNOWLEDGMENTS

We thank the Department of Hepatobiliary Surgery team at Peking Union Medical College Hospital for supporting this research. We also thank Dr. Yuelun Zhang who works at the Central Research Laboratory of Peking Union Medical College Hospital for his help in statistics.

Conflicts of Interest

The authors declare no conflicts of interest.

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