


Posterior quadratus lumborum block versus epidural analgesia for postoperative pain management after open radical cystectomy: A randomized clinical trial

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Abstract

Background: In open abdominal surgery, continuous epidural analgesia is commonly used method for postoperative analgesia. However, ultrasound (US)-guided fascial plane blocks may be a reasonable alternative.

Methods: In this randomized controlled trial, we compared posterior quadratus lumborum block (QLB) with epidural analgesia for postoperative pain after open radical cystectomy (ORC). Adult patients aged 18–85 with bladder cancer (BC) scheduled for open RC were randomized in two groups. Exclusion criteria were complicated diabetes mellitus type I, lack of cooperation, and persistent pain for reasons other than BC. In one group, a bilateral US-guided single injection posterior QLB was performed with 3.75 mg/ml ropivacaine 20 ml/side. In the other group, continuous epidural analgesia with ropivacaine was used. Basic analgesia was oral paracetamol 1000 mg three times daily, and long-acting opioid twice daily in both groups. All patients had patient-controlled rescue analgesia with oxycodone. Postoperative cumulative rescue opioid consumption was recorded for the day of surgery, and the following 2 postoperative days (POD 0–2). Secondary outcomes were postoperative pain and nausea and vomiting.

Results: In total, 20 patients (QLB), and 19 patients (epidural analgesia) groups, were included in the analyses. Cumulative rescue opioid consumption on POD 0, being of duration 9–12 h, was 14 mg (7.6–33.3) in the QLB group versus 6.1 mg (2.0–16.1) in the epidural analgesia group, $p = 0.089$, and as doses, 8 doses (3.6–15.7) versus 4 doses (1.3–8.5), $p = .057$. On POD 1 consumption was 25.3 mg (11.0–52.9) versus 18.0 mg (14.4–43.7), $p = .749$, and as doses 12 (5.5–23.0) versus 10 (8–20), $p > .9$, respectively. On POD 2 consumption was 19.1 mg (7.9–31.0) versus 18.0 mg (5.4–27.6) $p = .749$, and as doses 8.5 (5.2–14.7) versus 11 (3.0–18.0) $p > .9$, respectively.

Andrus Korgvee and Erik Veskimäe contributed equally to this work.

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Conclusion: Opioid consumption did not differ significantly between posterior QLB and an epidural infusion with ropivacaine for the first 2 postoperative days following RC. *Trial registration:* [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03328988) identifier NCT03328988.

KEYWORDS

cystectomy, epidural analgesia, opiate consumption, postoperative pain, quadratus lumborum block

Editorial Comment

This trial investigated single dose posterior quadratus lumborum block versus epidural analgesia with ropivacaine for analgesia after open cystectomy. No differences in opioid usage and pain were found between groups, but a relatively low number of patient were included, and pain levels were low which may have influenced trial results. The reader must also consider the external validity, as no opioid was used in the epidural infusion.

1 | INTRODUCTION

Bladder cancer (BC) is a common urinary tract malignancy¹ and approximately one-third of patients require more intensive radical treatment, with radical cystectomy (RC) being the most prevalent.² RC is a morbid procedure with a 90-day complication rate of approximately 60%³ and a 90-day mortality rate of up to 9%.⁴ Implementing the enhanced recovery after surgery (ERAS) protocol reduces postoperative complication and mortality rates.⁵ A part of perioperative care includes adequate pain treatment, which usually involves epidural analgesia.⁶ Although epidural analgesia is commonly used method after open abdominal surgery, it has been reported to be associated with increased risk for postoperative complications, hospital readmissions, and longer hospitalizations in patients who undergo RC.⁷ Quadratus lumborum block (QLB) is an ultrasound (US) guided truncal fascial plane block. First described in 2009, several variations of QLB (according to novel nomenclature⁸: lateral, posterior, and anterior QLB approaches) have since been described.^{9–13} Many studies have shown that QLB is a reasonable choice for abdominal surgery, as it produces sufficient analgesia without increasing the severity of side-effects.¹⁴ However, to date, very few studies have compared QLB to epidural analgesia.^{15–18} The aim of this study is therefore to compare bilateral single injection posterior QLB to continuous epidural analgesia (Epidural) for postoperative analgesia after open radical cystectomy (ORC).

2 | METHODS

2.1 | Ethics

This was a prospective single centre randomized controlled parallel-group study that was conducted at Tampere University Hospital, in accordance with the Declaration of Helsinki. Ethical approval was provided by the Regional Ethics Committee of the Expert Responsibility area of Tampere University Hospital (Chairperson Prof. Amos

Pasternack), on February 23, 2017 (Approval number: R17008). The study was registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03328988), on May 5, 2017 (identifier NCT03328988). Recruitment to the study was scheduled from April 27, 2017 to August 2020.

2.2 | Participants

Eligible participants were adult patients aged 18–85 with BC and who were scheduled for ORC. Exclusion criteria were complicated diabetes mellitus type I, lack of cooperation skills, and persistent pain for reasons other than BC.

2.2.1 | Perioperative management

Patient received 1000 mg of acetaminophen 1 h preoperatively and it was continued three times daily until ambulation.

According to the study protocol, all patients received target-controlled infusion (TCI) effect-site concentration anesthesia with propofol and remifentanyl. The Schnider model for propofol and the Minto model for remifentanyl were started with effect site targets 5 µg/ml and 5 ng/ml, respectively, and adjusted according to depth on anesthesia (Entropy™, RE/SE target 40–50). Furthermore, full relaxation with rocuronium until the end of operation was used. To maintain blood pressure (BP) of $\pm 20\%$ from patient normal values, norepinephrine infusion 2 µg/kg/h was started at the same time as TCI. Fluid therapy was performed with crystalloid infusion 0.5 ml/kg/h until bladder removal and 3 ml/kg/h until the end of operation. Crystalloid boluses 250 ml were given if clinical signs of hypovolemia and/or pulse pressure variation of >15 were observed.

Operation technique was standardized and performed through infraumbilical incision. In males, cystoprostatectomy also included removal of the seminal vesicles and in female patients, anterior pelvic exenteration included the uterus, fallopian tubes, and anterior vaginal wall, when necessary. Pelvic lymph node dissection included

obturator, internal, and external iliac chains to the level of the ureteric crossing of the common iliac artery. Bricker technique was used for incontinent ileal conduit, and Studer method for a neobladder.

2.3 | Interventions

Patients were randomly assigned to receive QLB or continuous epidural analgesia for postoperative analgesia after ORC.

2.3.1 | Quadratus lumborum block

Bilateral US-guided single injection posterior QLB, described by Blanco et al.¹⁰ was performed before emergence from anesthesia. Patients were first turned in the lateral position and the skin was prepared with antiseptic solution. A Flex Focus 800 US machine with convex array 6–2 MHz transducer and Stimuplex Ultra 360 8 cm needle were used. The target point for the needle tip was the posterior border of the quadratus lumborum muscle. The correct location was confirmed with injection of a small amount of saline. Thereafter, 20 ml of ropivacaine 3.75 mg/ml was injected. The same procedure was repeated on the other side.

2.3.2 | Epidural analgesia

An epidural catheter was placed before anesthesia induction. Patients were placed in the lateral position and the skin was prepared with antiseptic solution. The skin was then anesthetized with lidocaine 10 mg/ml with adrenaline. The loss of resistance technique and a Tuohy G18 needle were used to place the epidural catheter at the thoracic level of T9–T12. Lidocaine 10 mg/ml with adrenaline 3 ml into the catheter was used as a test dose.

Ropivacaine 1.5 mg/ml without opioid was used for continuous epidural infusion after operation. Before emergence from anesthesia, the epidural catheter was activated with a bolus of 1 ml/10 kg of ideal weight. Thereafter infusion was started with rate 4–5 ml/h and adjusted between 2 and 8 ml/h, with 3–5 ml boluses on demand, according to pain scores and response.

All the blocks were performed by two highly experienced anesthesiologists in epidural and US-guided fascial plane blocks (A.K. and M-L.K.)

2.3.3 | Additional pain therapy

Before emergence from anesthesia, after remifentanyl infusion was terminated, oxycodone 2–4 mg was given intravenously according to the attending anesthetists estimation taking into consideration patients weight and health status. When the patient started spontaneous breathing, additional oxycodone 1 mg/10 kg ideal weight was given intramuscularly.

Postoperatively, all patients received paracetamol 1000 mg orally or intravenously three times per day, and long-acting oxycodone/naloxone (Targiniq[®]) orally twice per day starting in the postoperative care unit (PACU). The dose was adjusted according to the patient's weight and health status. An intravenous patient-controlled analgesia (PCA) pump with oxycodone 1 mg/ml was programmed with a 0.03 mg/kg (ideal weight) demand dose, a lockout time of 10 min, and a maximum of 6 doses/h.

2.3.4 | Postoperative nausea and vomiting prophylaxis and therapy

For Postoperative nausea and vomiting (PONV) prophylaxis, all patients were given intravenous dexamethasone 5 mg after anesthesia induction and intravenous ondansetron 4 mg before emergence from anesthesia. Additionally, ondansetron and dehydrobenzperidol were prescribed as a rescue PONV therapy.

2.4 | Outcomes

The primary endpoint was postoperative cumulative rescue opioid (intravenous oxycodone) consumption. Postoperative cumulative rescue opioid consumption was recorded daily as doses and milligrams for 3 days (POD 0 is the day of the surgery, and POD 1 and POD 2 are the first 2 postoperative days).

Secondary endpoints were pain scores assessed by numeral rating scale (NRS, from 0 to 10). The NRS was also used for the assessment of PONV. The complications and side effects of each block were evaluated and recorded.

2.5 | Sample size

Sample size calculation was based on postoperative cumulative rescue opioid consumption on the day of the surgery measured as doses/h. As previous literature comparing QLB and epidural analgesia was not available, we assumed that clinically significant difference between the two study groups would be 2 doses/h with an estimated standard deviation of 2 PCA dosed opioid. According to the calculation with power 0.8 and the type I probability 0.05, the sample size 18 patients per group was needed and taking into account eventual dropouts, sample size 22 per group was chosen in this study.

2.6 | Randomization and blinding

Participants were randomized into two groups. Patients in the QLB group received posterior QLB, and patients in the Epidural group received continuous epidural analgesia. Randomization was conducted in a block size of 10 using a computerized randomization sequence by an independent research assistant who also wrote the randomization

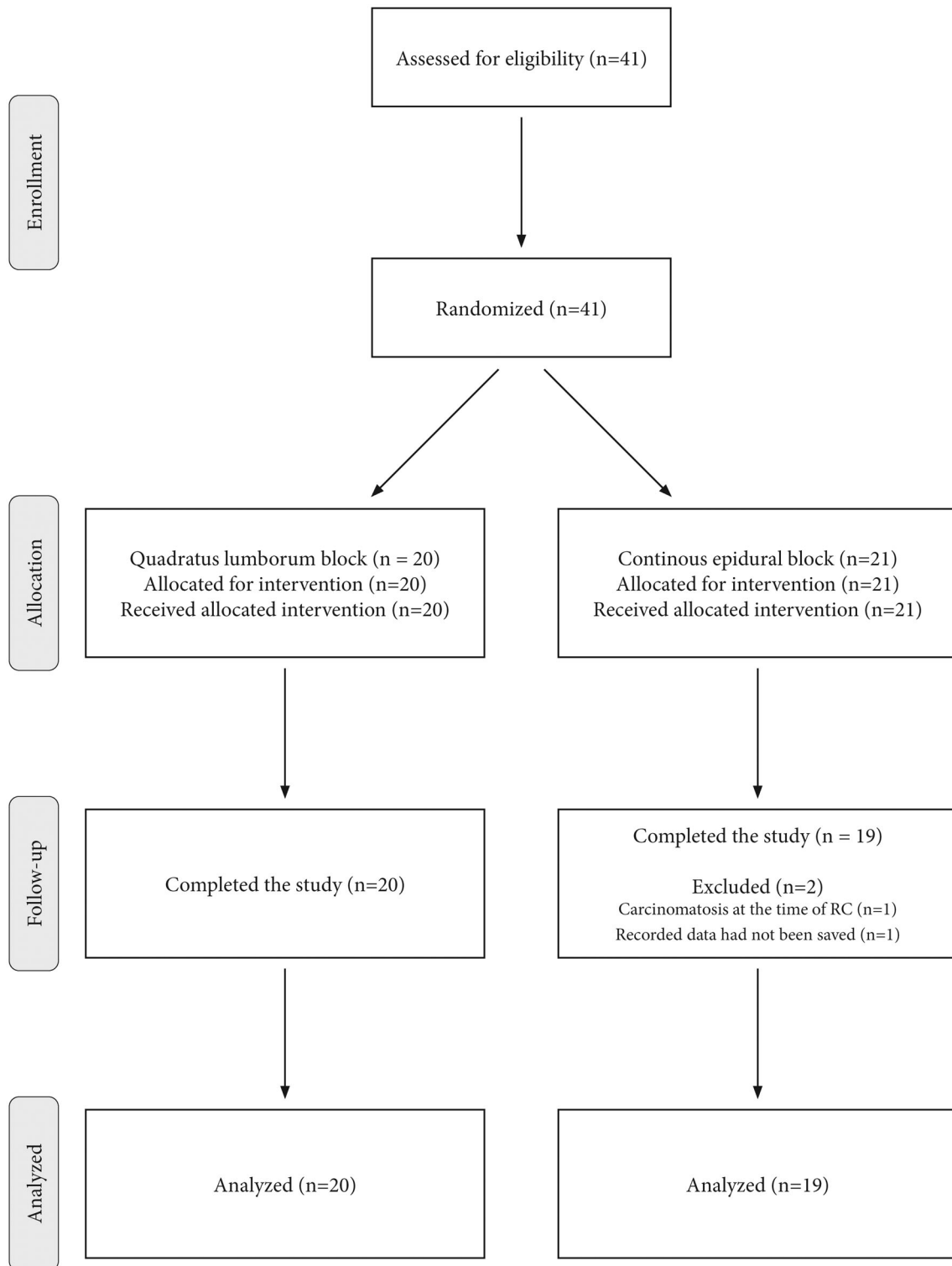


FIGURE 1 Flowchart of the study

allocation number for each participant on paper and concealed it in an opaque envelope. The envelope was opened by the anesthesiologist appointed to perform the epidural or QLB procedure. Blinding participants, care providers, and those evaluating pain, analgesia, and PONV at the bedside was not possible, as the analgesic procedures were technically so different.

2.7 | Statistical methods

Statistical analyses were performed using SPSS Statistics version 26 for Windows (IBM Corp, Armonk, NY). Summary measurements were expressed as means with standard deviations or as medians with 25th–75th percentile unless otherwise stated. Continuous variables

were analyzed using Student's *t*-test or Mann–Whitney *U*-test, the latter for non-normally distributed data. Chi-square or Fisher's exact test was used for categorical variables. Two-tailed *p* values were reported, and a *p*-value <.05 was deemed statistically significant.

Primary outcome was postoperative cumulative rescue opioid consumption. The data were recorded as cumulative daily doses (N and mg at POD 0, POD 1, and POD 2), which were compared between the two study groups. Additional analyses were performed in pain scores and PONV. All analyses were performed according to the grouping based on the intention-to-treat protocol.

3 | RESULTS

Forty-one consecutive ORC patients were enrolled in this trial. The trial was terminated before reaching the planned sample size (22 per group), as the operation technique used in our hospital changed from ORC to robotic cystectomy. In total, 20 patients were allocated to the QLB group and 21 patients to the epidural group. All enrolled patients received the intended intervention. Two patients were excluded after enrolment from the epidural group before analysis: in one patient, the operation plan changed to inoperable BC, and in one patient, the recorded data had not been saved. The flowchart of the study is presented in Figure 1.

Baseline characteristics are presented in Table 1.

Two groups appeared similar except that slightly more females were included in the Epidural group (8 females in the Epidural group vs. 2 in the QLB group).

All male patients had similar surgical approach, but surgical range varied in female patients dependent on clinical T-stage, patients preferences and history of previous operations. Two patients in the epidural group underwent removal of the uterus, salpingo-oophorectomy, and resection of anterior vaginal wall. One patient in both groups had isolated salpingo-oophorectomy. Cysto-urethrectomy without gynecological organ removal was done to five patients in Epidural group and one patient in QLB group (Table S1).

3.1 | Primary outcome

In Figure 2A, the cumulative postoperative rescue oxycodone consumption is presented as total milligrams during the whole follow up period. No statistically significant differences were observed between the groups. On POD 0, varying of duration 9–12 h depending on the length of operation, rescue opioid consumption was 14 mg (7.6–33.3) in the QLB group versus 6.1 mg (2.0–16.1) in the epidural group, *p* = .089. On POD 1, consumptions were 25.3 mg (11.0–52.9) in the QLB group versus 18.0 mg (14.4–43.7) in the epidural group, *p* = .749, and on POD 2 19.1 mg (7.9–31.0) versus 18.0 mg (5.4–27.6) *p* = .749, respectively.

Rescue opioid consumption, reported as doses per day, are presented in Figure 2B. It was on POD 0 8 doses (3.6–15.7) in the QLB group versus 4 doses (1.3–8.5) in the epidural group, *p* = .057. On POD 1 consumptions were 12 (5.5–23.0) in the QLB group versus

10^{8–20} in the epidural group, *p* > .9, and on POD 2 8.5 (5.2–14.7) versus 11 (3.0–18.0) *p* > .9, respectively.

During the following period, cumulative rescue opioid consumption was 37.0 (24.2–89.1) versus 32.0 (14.0–59.8), *p* = .134 on days POD 0–1 and 57.2 (34.2–111.9) versus 54.0 (23.4–70.0), *p* = .365 on days POD 0–2 (Figure 3).

3.2 | Secondary outcomes

The results of the secondary outcomes are presented in Table 2.

Postoperative pain scores were comparable between the groups at 2 h and at 24 h being 3.0 ± 2.2 in the QLB group versus 1.8 ± 2.4 in the Epidural group, *p* = .061 and 1.3 ± 1.3 versus 1.0 ± 1.1, *p* = .55, respectively. At 4 h, patients in the epidural group had significantly lower NRS pain scores compared to the QLB group (0.7 ± 2.1 vs 2.3 ± 1.8, *p* = .002).

Postoperative nausea and vomiting at 24 h postoperatively were detected in four patients in the QLB group and in three patients in the Epidural group, *p* > .9.

3.3 | Side effects and complications

Seven patients in the Epidural and two patients in the QLB group needed norepinephrine infusion for hemodynamic support postoperatively in the PACU (*p* = .065). No other side effects or complications were observed.

4 | DISCUSSION

In this study, we compared cumulative rescue opioid consumption between bilateral US-guided single injection QLB and continuous

TABLE 1 Baseline characteristics

Variable	QLB	Epidural
Number of patients	20	19
Age (years)	74.5 (68.2–78.7)	74 (63.0–77.0)
Gender Male (%)	18 (90)	11 (57.9)
BMI (kg/m ²)	24.5 (23.1–26.6)	24.6 (21.0–31.6)
ASA (1/2/3)	1/5/14	1/4/14
Propofol (mg/kg/h)	7.1 (6.0–9.0)	7.3 (6.2–8.3)
Remifentanyl (µg/kg/h)	6.6 (6.3–7.2)	6.3 (5.3–7.3)
Perioperative crystalloids (ml/kg/h)	4.7 (4.1–5.5)	4.6 (3.6–6.7)
Noradrenalin in recovery room yes (%)	2 (10)	7 (36)
Days in hospital	10 (9–13)	12 (9–12)

Note: Data are presented as median IQR, counts (%).

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; Epidural, continuous epidural analgesia; QLB, quadratus lumborum block.

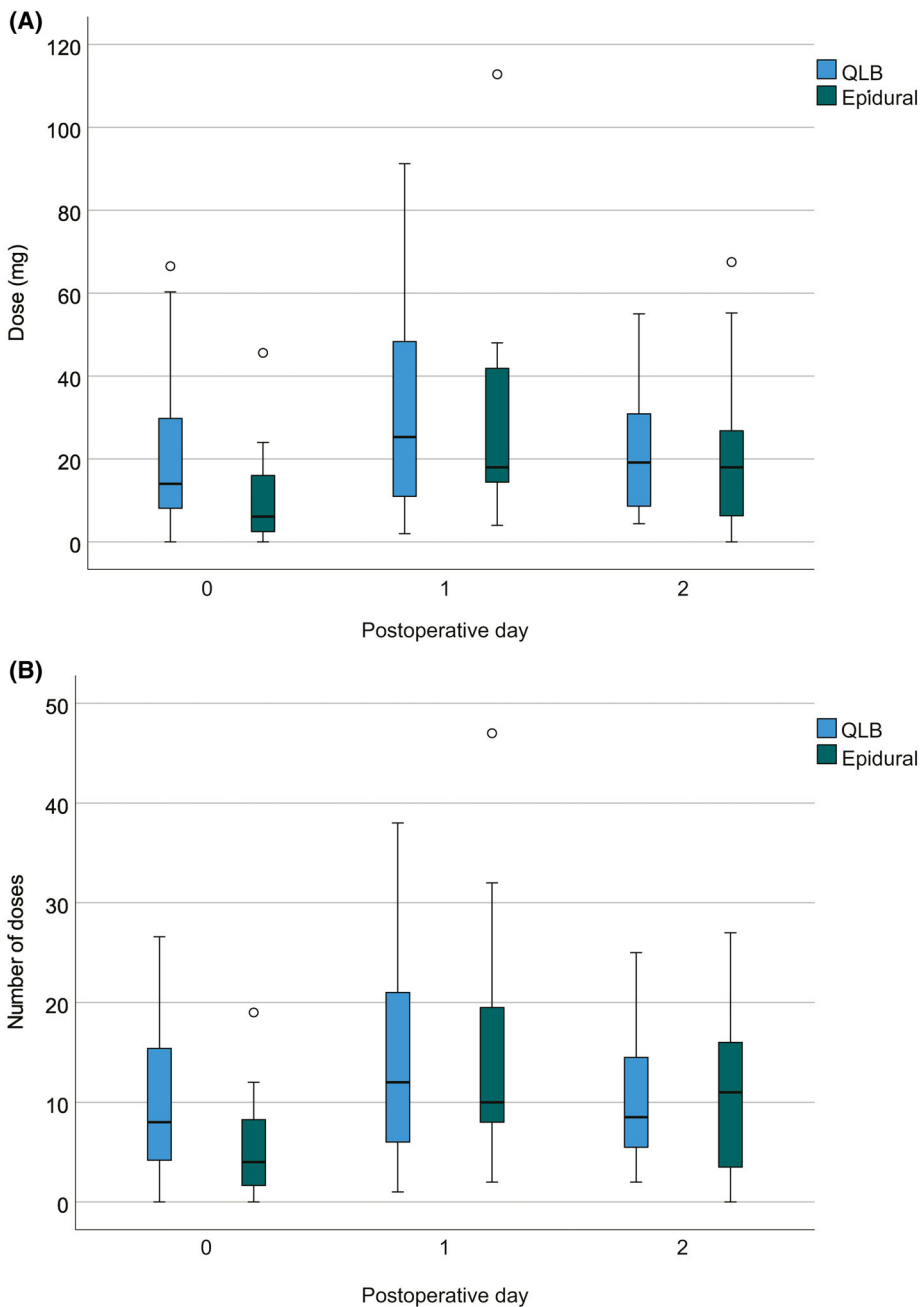


FIGURE 2 Rescue oxycodone consumption on postoperative day 0, 1, and 2, presented as milligrams (median with IQR, A) and doses (median with IQR, B)

epidural analgesia without opioid for postoperative analgesia in ORC patients. PCA for opioid dosing was chosen to allow the patients dose the rescue analgesic independently regardless of the ward's occupancy. We could not find statistically significant differences between the groups in cumulative rescue opioid consumption nor pain scores, nausea, and vomiting during the acute postoperative phase.

ORC patients are usually elderly people with several comorbidities and with a high risk of peri- and post-operative complications.¹⁹ Therefore, it is recommended that the ERAS protocol⁶ is used to minimize complications and to reduce the length of hospital stay. According to the ERAS protocol for RC, epidural analgesia is strongly recommended because of its superiority to systemic opioids in pain management. Additionally, according to the literature in patients who

undergo general abdominal surgery, epidural analgesia has been reported to be associated with a faster return of gut function, fewer respiratory failures, and reduced pain scores without reduced morbidity or improved recovery compared with alternative analgesic methods.^{20,21}

However, the superiority of epidural use has been questioned in studies on RC patients. In the study of Miller and colleagues⁷ it was reported that epidural analgesia was associated with increased risk for perioperative complications, hospital readmission, and longer hospitalization without any improvement in disease-specific survival in this patient population. In all, due to contraindications and challenges with epidural catheter use, alternative regional analgesia methods are now mandatory.

FIGURE 3 Postoperative cumulative rescue oxycodone consumption on postoperative days 0–2, presented as milligrams (median with IQR)

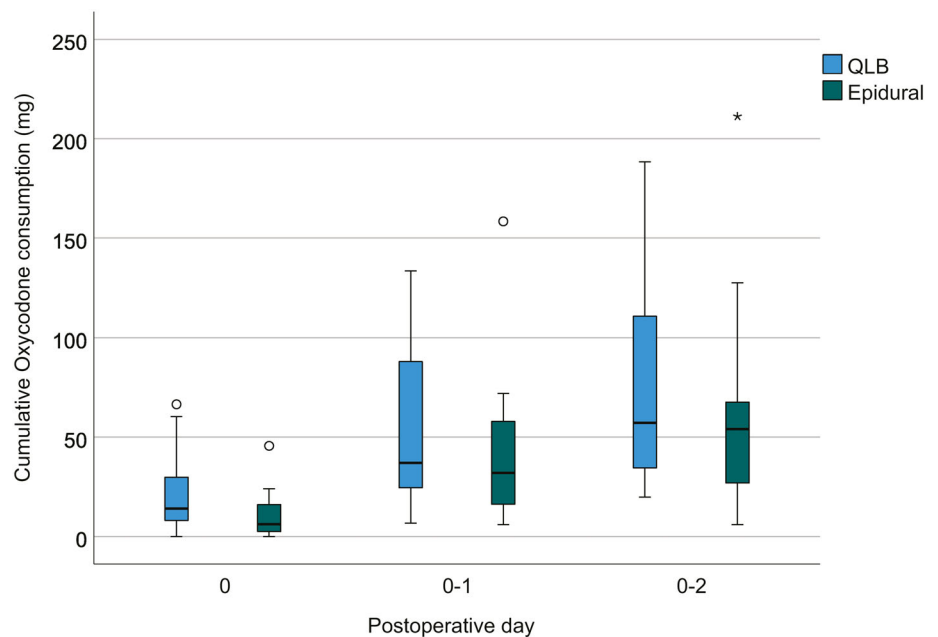


TABLE 2 Secondary outcomes: pain scores and PONV (NRS)

Variable	QLB	Epidural	p-value
Pain score, 2 h	3.0 ± 2.2	1.8 ± 2.4	.061
Pain score, 4 h	2.3 ± 1.8	0.7 ± 2.1	.002
Pain score, 24 h	1.3 ± 1.3	1.0 ± 1.1	.55
PONV, yes (%)	4 (20)	3 (15.8)	>.9

Note: Data are presented as mean ± SD and counts (%).

Abbreviations: Epidural, continuous epidural analgesia; PONV, postoperative nausea and vomiting; NRS, numeric rating scale; QLB, quadratus lumborum block.

US-guided truncal fascial plane blocks²² have gained popularity for postoperative analgesia in several types of abdominal surgery. One of the most promising of these is QLB, which is thought to also relieve visceral pain.²³ Three different types of QLBs have been described (lateral, posterior, and anterior). According to the systematic review,¹⁴ all QLB approaches have been successfully used for abdominal surgery analgesia. Still, the exact mechanisms of action and the spread of injectate after QLB are under investigation.^{24,25}

In this study, we could not find any statistically significant differences in cumulative rescue opioid consumption between the QLB and Epidural groups. Moreover, the total opioid consumption in this study was in line with previous reports in this patient population.^{26,27} The difference in opioid consumption between the groups was greatest on POD 0, was diminishing on POD 1, and was minimal on POD 2. A possible reason for this may be the timing of the QLB injection before the emergence of anesthesia. The downside of this technique is that the maximum analgesic effect of QLB comes with a delay, which may also be reflected in the higher pain scores in the recovery room observed in this study.

Despite standardized anesthesia and fluid therapy, more patients in the epidural group needed noradrenalin infusion in the PACU, although without any statistical difference. It should be noted,

however, that only two patients in the QLB group needed noradrenalin infusion in the recovery room. The epidural regimen allowed for bolus-doses during PACU stay while single-injection QLB did not. Boluses may have an effect on both the BP and need for rescue analgesics. This may also explain the larger difference of rescue opioid doses on POD 0 than on POD 1 and 2.

According to the results of our study, pain scores remained low during the observation period in both groups. In the recovery room, pain scores at 2 and 4 h postoperatively were low, with slightly higher scores in the QLB group, and statistically significant at 4 h. There was no difference in PONV between the groups, which is in line with equal opioid consumption between the groups.

Epidural analgesia and QLB associated complications are relatively rare when performed with caution by an experienced anesthesiologist. However, epidural analgesia complications may be quite severe and, in the worst case, permanent.²⁸ Conversely, QLB complications are less reported and theoretically not so severe.¹⁴ In our study, no QLB or epidural analgesia related complications were observed.

4.1 | Limitations

First, regarding the sample size calculation, it was based on the need for doses of rescue opioid instead of differences in milligrams. It should be noted that because of the wide variety in the weights of the study patients, results based on doses are more informative than those based on total milligrams. Additionally, due to the scarcity of available studies comparing epidural analgesia and QLB, we had to base our calculations on estimations of the clinically relevant differences between the study groups.

Second, the study was terminated before reaching the sample size goal. However, the number of study patients recruited achieved

the lower limit in sample size calculations ($n = 18$ per group). Additionally, the recruitment period would have been further extended, because of the operation technique changed from ORC to robotic cystectomy in our hospital.

Third, this was a single center study with a limited number of patients. The strengths of the study included the study method (RCT) and that all the blocks were performed by two anesthesiologists highly experienced in US-guided truncal fascial plane blocks. In addition, perioperative treatment followed the same protocol for all patients. Nevertheless, a broader interpretation of results should be done with caution.

Fourth, despite randomization, there was a difference in gender distribution between the study groups (more female patients in the epidural group). However, as BC is approximately four times more common in men than women,²⁹ it is in line with the gender distribution in this study and partly explains the difference in distribution. Therefore, the difference between the study groups could be caused more by chance, and in any case the difference hardly affects the results. Although, there were some differences in surgical technique in women, ultimately most of the patients had isolated cystourethrectomy and only in two patients (both in epidural group) gynecological organs were also removed during the operation.

Fifth, the recording time of rescue opioid consumption on POD 0 varies from 9 to 12 h, depending on the timing and duration of the surgery. However, the results were analyzed as a total consumption of opioids (milligrams and doses) during POD 0 as well as milligrams and doses per h. In both, no statistically significant differences between the groups were observed.

Sixth, it may be considered as a limitation that continuous epidural analgesia allows both adjusting the infusion rate and boluses while single shot QLB does not as discussed above. Also, the duration of QLB varies from 12 to 72 h according to the literature, which is why long-lasting opioid is added to the analgesic standard of practice in our hospital in these patients. Following this regimen some patients may even be overtreated and thus may decrease the sensitivity of the study.

Finally, for better comparability of the total opioid consumption between groups, epidural analgesia was exceptionally established without epidural opioid. This may have diminished the effectivity of epidural analgesia despite the other administration routes of opioids used in this study.

5 | CONCLUSION

In this trial, we did not find that opioid consumption differed significantly between posterior QLB and an epidural infusion with ropivacaine for the first two postoperative days following RC.

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CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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