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RESEARCH ARTICLE

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Efficacy of a TAP block versus an anterior QLB for laparoscopic inguinal hernia repair: A randomised controlled trial

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Abstract

Background: Both the transversus abdominis plane (TAP) block and the anterior quadratus lumborum block (QLB) have been shown effective in reducing postoperative pain after laparoscopic inguinal hernia repair. Our hypothesis was that there is no difference in analgesic effect between the two blocks for this procedure.

Methods: In this prospective, double-blind, randomised controlled study, 60 adult patients undergoing laparoscopic inguinal hernia repair were equally randomly assigned to either a preoperative TAP block or an anterior QLB. The primary outcome was oral morphine equivalent (OME) consumption at 4 h postoperatively. Secondary outcomes were OME consumption at 24, 48 h and 7 days, pain scores at rest and when coughing, nausea, and level of sedation measured at 1, 2, 3, 24, and 48 h and 7 days postoperatively.

Results: Fifty-three patients completed the study. There was no significant difference in OME consumption at 4 h postoperatively, TAP group (10.3 ± 7.85 mg) (mean ± SD) versus the anterior QLB group (10.9 ± 10.85 mg) ($p = .713$). The pain scores were similar at rest and when coughing during the 7 day observation period, as were the level of sedation and incidence of nausea. There were no cases of serious side-effects or muscle weakness of the thigh on the same side as the block.

Conclusion: There is no difference in OME consumption, pain, nausea or sedation between the TAP and the anterior QLB. Thus, the choice between the two blocks in a clinical setting of laparoscopic inguinal hernia repair should be based on other aspects, such as skills, practicalities, and potential risks.

KEYWORDS
Anterior QLB, Fascial blocks, Inguinal hernia, Regional anaesthesia, TAP block

The work was performed at Ostfold Hospital Trust Moss, Peer Gynts vei 78, 1535 Moss.

Editorial Comment

It is not well established which of the blocks, transversus abdominis plane (TAP) block or the anterior quadratus lumborum block (QLB), is superior regarding analgesia for laparoscopic hernia repair. In this trial, analgesic effects were compared, showing no differences in post-operative pain, opioid consumption, nausea, or sedation.

1 | INTRODUCTION

Inguinal hernia is a frequent condition, often requiring surgery. One-third of all men and one out of 30 women will be diagnosed with an inguinal hernia during their lifetimes.[1] Inguinal hernia repair is an operation associated with significant postoperative pain and a risk of the development of long-term postoperative pain.[2]

The neuronal afferent from the abdominal wall and the groin pass through the transversus abdominis plane (TAP) and merges into the thoracolumbar nerves of T6 to L1. Regional anaesthesia targeting the T6 to L1 nerves has the potential to inhibit the majority of the nociceptive stimulus from a laparoscopic inguinal hernia repair.[3]

Both the TAP block and the anterior Quadratus lumborum (QLB) have been shown to reduce postoperative pain and opioid consumption after laparoscopic inguinal hernia repair.[4–6] The TAP block can be performed using several approaches: subcostal, lateral and posterior.[6] Ensuring adequate spread of local anaesthetic may be a challenge, and multiple injections are recommended in order to cover somatic innervation of the entire anterior abdominal wall.[7] Visceral nociception is not covered with the TAP block, except in some reports of the posterior approach.[8]

The anterior QLB is performed in the fascial layer between the QL muscle and the psoas muscle.[9] The advantage of the anterior QLB is the more posterior and possibly more dependent paravertebral spread as compared to more superficial blocks, such as the TAP block and the lateral QLB.[9] Because the anterior QLB in some studies show the paravertebral spread, it may also provide more reliable visceral coverage.[10] However, because the injection site of the anterior QLB lies anatomically deeper and in closer proximity to the abdominal viscera, the anterior QLB has been regarded as more demanding to perform compared with the TAP block.[11] Reported complications for both the TAP and the anterior QLB are visceral injury, local anaesthesia toxicity, risk of bleeding in anticoagulated patients, as well as weakness of the quadriceps musculature.[6,11,12] However, it is not well established if any of these blocks are superior regarding analgesia in the clinical setting of laparoscopic hernia repair.[13]

The purpose of this study was to compare the analgesic effect of a TAP block versus an anterior QLB after laparoscopic hernia repair. Our hypothesis was that there is no difference in analgesic effect between these two blocks. The primary outcome was oral morphine equivalent (OME) analgesic rescue consumption at 0–4 h postoperatively, whereas secondary outcomes (OME rescue consumption, pain scores, nausea, level of sedation) were studied during the first week.

2 | METHODS

The study had a prospective, double-blinded (patients and outcome assessor), randomised controlled study design, with two study arms. The study adheres to the Helsinki declaration, and was approved by the Norwegian Regional Committee for Medical and Health Research Ethics (ref.no. 2016/138). The trial was registered at Clinicaltrials.gov (Trial registration number NCT03023462; 1 March 2017) before patient enrolment. Eligible patients received written and oral information from an anaesthesiologist prior to inclusion, and a signed informed consent form was obtained from all patients. The full trial protocol can be obtained upon request. The manuscript adheres to the Consolidated Standards of Reporting Trials guidelines (CONSORT 2010) for reporting of parallel-group randomised trials.

2.1 | Setting and participants

The study was performed at a county hospital with a catchment area of approximately 320,000 inhabitants. Patients who were scheduled for an elective laparoscopic unilateral inguinal hernia repair and fulfilled the inclusion criteria were invited to participate. The inclusion criteria were: age > 18 years, Body Mass Index (BMI) between 20 and 35, American Society of Anaesthesiologists (ASA) classification from I to III. Exclusion criteria were: inability to speak or understand the Norwegian language; inability to adhere to the protocol; prior inguinal hernia operation on the same side; allergy to latex, local anaesthesia or opioids; chronic pain prior to surgery demanding daily opioids; addiction to medication or alcohol; liver or kidney failure; local infection at the site of injection; systemic infection; atrioventricular (AV) block 2–3; and pregnancy.

2.2 | Intervention

All patients received pre-operative multimodal analgesia consisting of oral paracetamol 2 g and diclofenac 100 mg at least 1 h before the start of surgery, in-line with standard practice. Reduced doses of 1.5 g and 50 mg respectively were given if weight < 70 kg or age > 70 - years as per hospital standard.

All patients were monitored with standard American Society of Anaesthesiologists (ASA) surveillance (SpO2, NIBP, ECG and ETCO2) during the intervention, pre- and postoperatively.

The first author, who was well experienced with both the TAP block and the anterior QLB, performed all block procedures. All

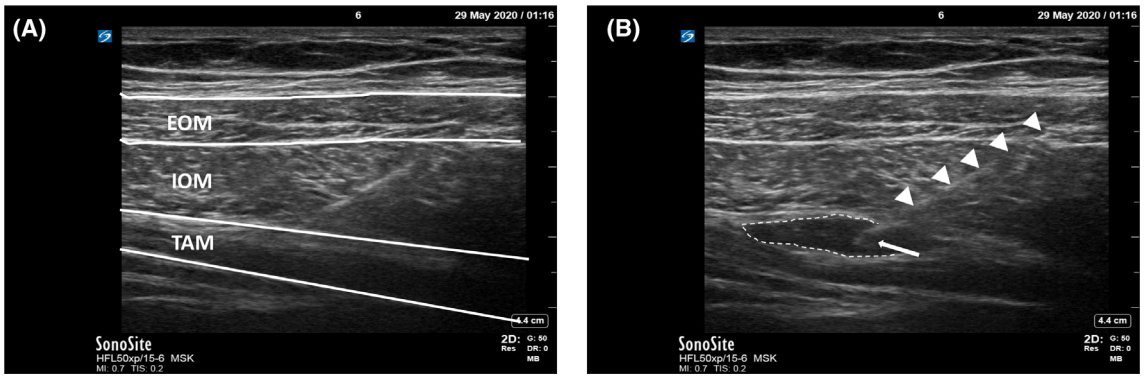

FIGURE 1 Ultrasound image of a medial transversus abdominis (TAP) block. White triangles indicate needle trajectory and the small white arrow indicates position of needle tip and local anaesthetic deposition. Abbreviations; external oblique muscle (EOM), internal oblique muscle (IOM) and transversus abdominis muscle (TAM).

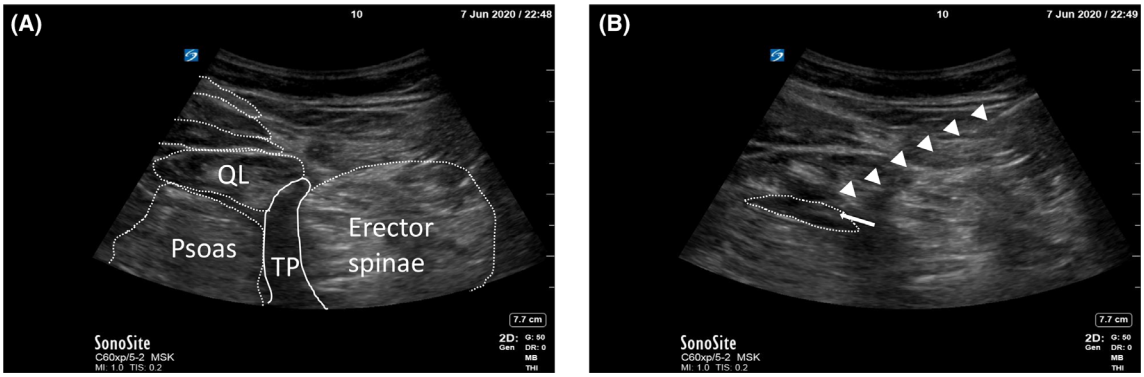

FIGURE 2 Ultrasound image of an anterior quadratus lumborum block (QLB). White triangles indicate needle trajectory and the small white arrow indicates position of needle tip and local anaesthetic deposition. Abbreviations; Quadratus lumborum (QL) and transverse process (TP).

patients were taken to the post-anaesthesia care unit (PACU) prior to surgery. All patients were given the option of sedation with midazolam 1–2 mg and/or alfentanil 0.5–1.0 mg before receiving their allocated block, at least 30 mins before the induction of anaesthesia.

The skin was prepared thrice with chlorhexidine 5 mg/ml with added phenol red. All procedures were performed under ultrasound-guidance (X-porte ultrasound system, Fujifilm, Sonosite, Bothell, Washington, USA) using Stimuplex Ultra 360, 20 G, 100 mm needles (Braun) applying the in-plane technique. In the TAP blocks, the patients were supine and the linear probe transducer (Sonosite HFL50xp) was placed between the iliac crest and the costal margin in the anterior axillary line in the manner of a lateral TAP.[6] The muscular layers of the three abdominal muscles (external- and internal oblique as well as transversus abdominis) were identified. The needle tip was visualised in the fascial plane between the transversus abdominis and the internal oblique muscle. Then, incremental doses of 7.5 mg/ml ropivacaine were injected after negative aspiration tests, reaching a total of 20 ml (Figure 1).

The anterior QLB was performed using the Shamrock method with the patients placed in the lateral decubitus position with the intervention side upward.[14] A curvilinear probe (Sonosite C60XP) was placed in the transverse position above the iliac crest at the level of the posterior axillary line. The needle was advanced from posterior to anterior through the QL muscle. Upon visualisation of the needle tip in the fascial plane between the anterior part of the QL and the psoas muscle, incremental doses of 7.5 mg/ml ropivacaine were injected after negative aspiration tests to a total of 20 ml (Figure 2).

General anaesthesia was provided with target-controlled infusions (TCI) of propofol and remifentanil in both groups. -The plasma target level for propofol and remifentanil was titrated after a clinical response at the discretion of the nurse anaesthetist nurse (the nurse was blinded to the group allocation). Endotracheal intubation was performed after endotracheal spray with 50 mg of lidocaine, according to local procedures. All patients were ventilated with volume control mode (6–8 ml/kg) and oxygen–fresh gas mixture to keep the end-tidal CO_2 between 4,5–6, and the pulse oximeter reading above 98%. The fresh gas flow was set to 1,1 L/min. No muscle relaxant was used throughout the procedure. All patients received ondansetron 4 mg, dexamethasone 8 mg and oxycodone 5 mg iv before the completion of surgery.

The surgical procedure included a transabdominal pre-peritoneal patch plasty (TAPP) repair of an inguinal hernia with three abdominal ports (umbilicus, as well as one port to the right and one to the left of the umbilicus). Prior to the insertion of the laparoscopic ports, the

surgeon infiltrated a total of 10 ml 5 mg/ml ropivacaine subcutaneously. A maximum intra-abdominal pressure of 12 mmHg was used.

In the PACU, experienced PACU nurses observed the patient. Upon complaint of pain or any outward signs of distress, the patients were asked to rate their pain, on a numerical rating scale (NRS) from 0–10 (0 = no pain, 10 = worst imaginary pain). The nurses in the PACU were instructed to offer the patients pain relief (titrated iv oxycodone) if the NRS score was above or at four at rest.

The patients were transferred back to the ward after a minimum of 1 h, where they stayed for a minimum of 3 h before being discharged to home the same day. In the ward, the patients received oral tramadol at 30 mg orally upon demand. After discharge, the patients were instructed to take paracetamol 1 g every 4 h the first 3 days, adding codeine 30 mg if needed. Further pain medication was at the patient's discretion and if any were taken the patients were instructed to register the amount and type of medication. A study nurse contacted the patients by telephone after 24 h, 48 h and 7 days, and asked for the outcome measures.

2.3 | Primary outcome

The primary outcome measure was the total opioid consumption during the first 4 h postoperatively, as measured by OME, converted using an opioid conversion table[15] (S1).

2.4 | Secondary outcomes

Secondary outcomes included pain scores as measured with the Numeric Rating Scale (NRS 0–10) at rest and when coughing, nausea (0 = no nausea, 1 = some nausea, 2 = unable to eat and 3 = vomiting), and the level of sedation (0 = awake, 1 = somnolent, 2 = keeps falling asleep and 3 = only awake when manipulated). These secondary outcomes were measured by the investigator at the time points 1, 2, 3, 24, 48 h and 7 days postoperatively. In addition, the secondary outcomes also included OME consumption (in milligrams) after 24 h, 48 h and 7 days. All patients were observed for any report of side effects, including quadriceps weakness, and all were tested for walking before they left hospital.

2.5 | Sample Size Calculation

We performed a pilot study with 12 patients to calculate OME consumption 4 hours postoperatively among patients receiving TAP blocks for laparoscopic inguinal hernia repair. The mean OME consumption after 4 h was 8.75 mg, with a standard deviation (SD) of 5.93 mg. The sample size for the main study was calculated using these data and the sample size algorithm in STATA. With an $\alpha = 0.05$, an effect size of 80% ($\beta = 0.2$), and a clinically significant minimal difference of interest of 50%, the total sample size was set to 60 patients, with 30 in each arm.

2.6 | Randomisation and blinding

Sixty patients were block-randomised by a computer-generated algorithm from randomization.com. The study allocation was sealed in an opaque envelope by a study nurse, and the envelopes were consecutively numbered from 1 to 60. Before surgery, the anaesthesiologist responsible for administering the block opened the allocation envelope. The group allocation was either a unilateral single-shot TAP block or a unilateral single-shot anterior QLB. The anaesthesiologist administering the block was not blinded and did not participate in any further data collection. All other investigators, staff, and patients were blinded to the group allocation.

2.7 | Statistical analysis

Statistical analyses were conducted using STATA Version 16 (StataCorp 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC). Continuous data with normal distributions after Shapiro–Wilk normality tests are presented as means (SD or range as appropriate), non-normally distributed data and ordinal data are presented as medians with interquartile ranges (25–75). Comparisons of baseline statistics were performed with t-tests for the normally distributed data and Mann–Whitney tests for the non-normally distributed data. A multiple regression analysis with the intervention group, age, and BMI as cofactors were performed to test associations with the primary outcome. A multilevel mixed-effects linear regression model was used to analyse repeated measurements (pain, OME consumption, and sedation scores). The model included time, treatment, and the interaction between the two as fixed effects, as well as the patient indicator and residual variance as random effects. Any significant differences between the groups at any time point were calculated using a linear combination of parameters (lincom). To analyse differences in nausea, the repeated-measures ANOVA was utilised because the mixed model did not converge.

3 | RESULTS

Patients were enrolled from 05.09.2019 to 30.06.2020. Of 161 patients screened for eligibility, 60 patients were included and randomised, of which 53 completed the in-hospital study protocol. None of these were lost to further post-discharge data collection. See CONSORT flow diagram (Figure 3). Seven patients were excluded after inclusion because of conversion from laparoscopic surgery to open surgery.

There were no significant differences between the groups with respect to demographic data: age, weight, body mass index (BMI), gender, ASA classification, surgical duration, or intraoperative medication. Table 1 presents an overview of patients' characteristics and perioperative information.

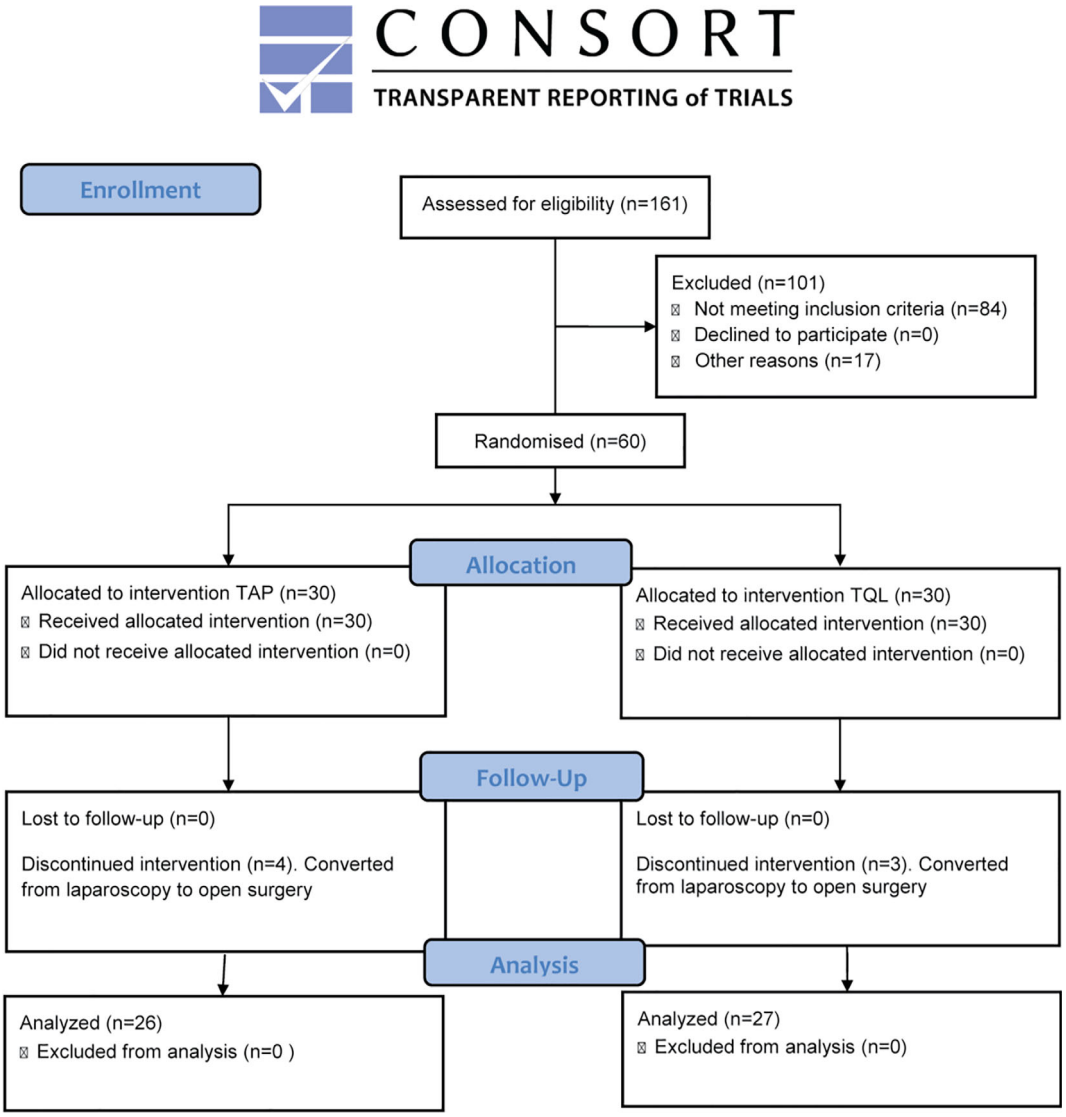

FIGURE 3 CONSORT flow diagram.

TABLE 1 Patient characteristics.

	TAP ($N = 26$)	Anterior QLB ($N = 27$)	*p*-value[a]
Age (SD)	55.4 (10.55)	59.4 (13.76)	.24
Weight (range)	82.2 (62–122)	85.9 (65–124)	.36
BMI (range)	25.2 (19.6–35)	26.4 (21.9–34.3)	.22
ASA (I/II/III)	9/16/1	8/18/1	.88
Operation time (IQ)	46 (36–54)	45 (37–51)	.82
Propofol (IQ)	512.3 (410–710)	531 (493–640)	.66
Remifentanil (IQ)	0.82 (0.58–1.06)	0.69 (0.59–0.92)	.29

Note: Age: in years. SD, standard deviation. Weight; in kilograms. BMI, body mass index kg/height(m^2). ASA, The American Society of Anaesthesiologists (ASA) criteria; normal health (I), mild systemic disease (II), severe systemic disease (III), severe systemic disease that is a constant threat to life (IV), moribund patient (V). Operation time; in minutes. IQ, interquartile range 25–75. Propofol/Remifentanil; in milligrams. The data are represented as means (SD/range as appropriate) for continuous data with normal distribution, and median (interquartile range 25–75) for non-normally distributed data.
[a]Comparisons of baseline statistics were performed with *t*-tests for the normally distributed data and Mann–Whitney tests for the non-normally distributed data.

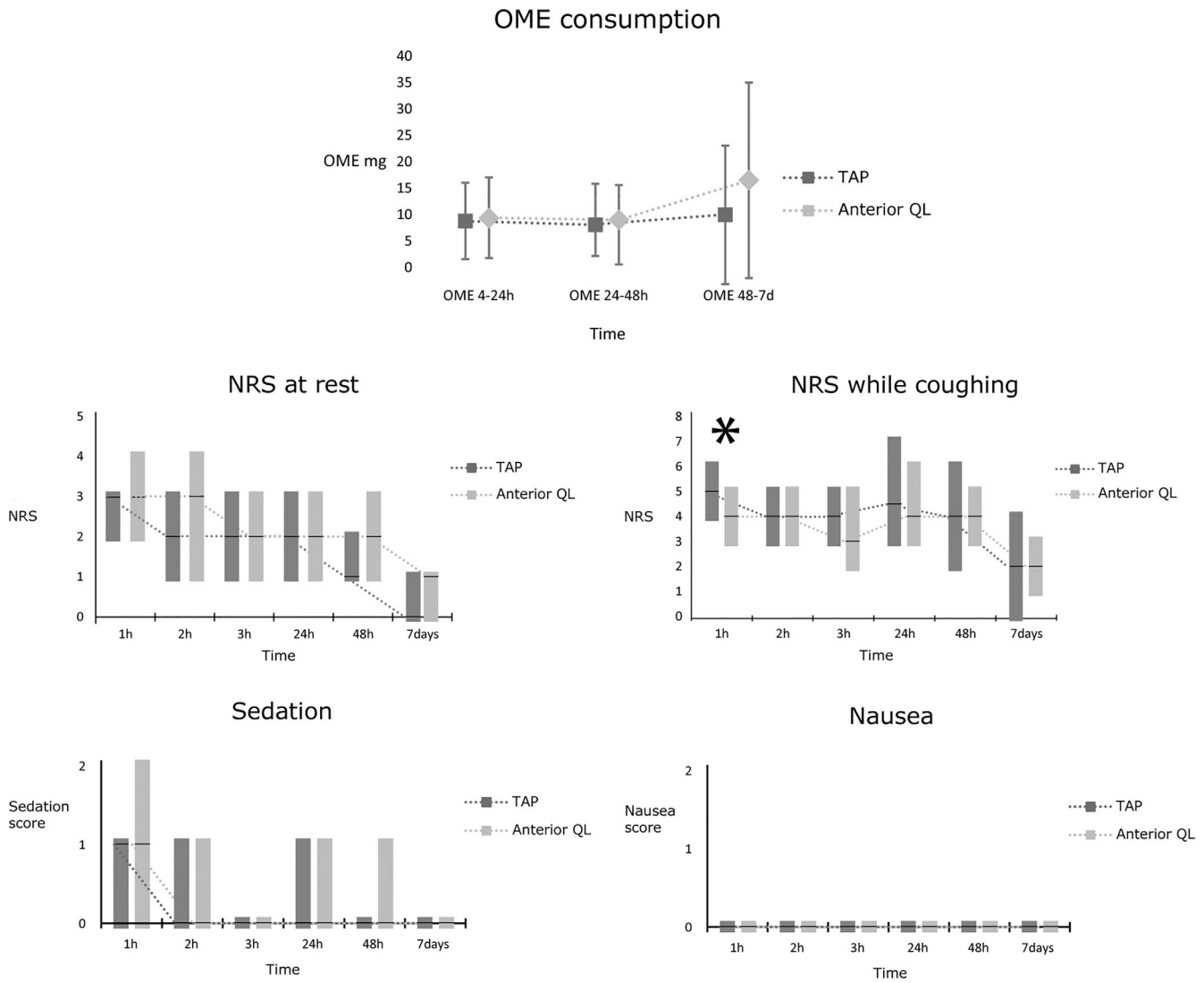

FIGURE 4 OME = Oral morphine equivalents presented in milligrams (mg). *h* = hours. *d* = days. Numerical rating scale (NRS). The data are represented as means with SD for continuous data with normal distribution (OME consumption), and median (interquartile range 25–75) for ordinal data (NRS, sedation and nausea). *p*-values are calculated with linear combination of parameters (lincom) using the results derived from a repeated measures mixed model. The group *p*-value for nausea are calculated using a repeated measures ANOVA. Any significant *p*-values are marked with an asterisk.

3.1 | Outcomes

3.1.1 | Primary outcome

The mean OME consumption 0–4 h postoperatively was similar in the two groups, in the TAP group 10.3 ± 7.85 mg (mean ± SD) versus 10.9 ± 10.85 mg in the anterior QLB group ($p = .713$).

3.1.2 | Secondary outcomes

There were no significant differences in OME consumption, nausea or sedation in any registration during the 7 days observation period. The pain score when coughing was significantly different at 1 h; in the TAP group NRS = 5 (4–6) (median [IQR]) versus in the anterior QLB group NRS = 4 (3–5) ($p = .025$). See Figure 4.

No adverse effects of the blocks were reported by the patients, especially no quadriceps weakness. All patients walked out of the hospital.

4 | DISCUSSION

In this randomised, double blinded study comparing the TAP block versus the anterior QLB in laparoscopic inguinal hernia repair patients, we could not identify any significant differences in OME consumption

at 4 h postoperatively or in any other observed aspect at any time during the 7 days of observation period. Although the pain score when coughing at 1 h postoperatively was significantly different ($p = .025$), this may be regarded as a random finding, due to a high number of registrations and no other indications of any trends of significant group differences in the pain registrations.

Previous studies have shown both the TAP block and the anterior QLB to be effective in lowering postoperative pain score and opioid consumption in inguinal repair.[4,5] Ahmed et al.[5] found that the anterior QLB significantly lowered postoperative pain scores immediately after arrival in the PACU and after 12 h. A meta-analysis looking at the duration of a lateral and a posterior TAP showed a reduction of opioid consumption, rest and dynamic pain up to 48 h.[16]

A reason for the lack of significant differences may be that the patients only received a unilateral block. The surgical technique entails port insertion on both sides of the midline as well as the use of pneumoperitoneum, and with a unilateral block, we would expect some pain from irritation of the pneumoperitoneum despite LA injection of all port sites.[17] Still, deep abdominal unilateral groin pain is expected to dominate in most cases.[18]

Another potential reason for the lack of any significant difference between the two blocks is the baseline multimodal analgesia. Effective multimodal analgesia is an integrated part of modern postoperative pain treatment and lowers opioid consumption and pain scores after surgery.[19] This may obscure the observed effect of the studied interventions.[20] However, any difference between two interventions significant enough to alter clinical practice, should be present on top of simple baseline multimodal analgesia.

We did not identify any significant difference in terms of nausea or sedation, which is in line with previous studies.[21,22] No adverse effects of the blocks or muscular weakness were reported by the patients.

In our study, we used 20 ml of ropivacaine at 7.5 mg/mL for both blocks, partly to reduce any potential difference in the systemic effects of the local anaesthetic and also to keep the dose well below the risk of systemic toxicity. Recommended volume for a TAP block is 15–20 ml, while 30 ml has been described for the anterior QLB.[10,23] There is a possibility that the spread to the paravertebral space and the visceral coverage would have been better with a higher anterior QLB volume. Moreover, studies have demonstrated that higher concentrations result in longer block durations.[24] However, we were not able to identify any transient increase in postoperative pain at any time, due to the early resolution of the blocks.

4.1 | Strengths and limitations

A strength of this study is that all blocks were performed by a single experienced anaesthesiologist, only one hospital was involved, and there were highly standardised criteria for all aspects of patient handling.

A limitation may be that the blocks were not tested beyond the confirmation of the accurate spread of the local anaesthesia via ultrasound imaging. The nerves from T9 to L1 communicate freely and form a "TAP plexus," with the considerable inter-individual variation of the dermatomal patterns.[11] The testing of skin sensory changes may therefore be non-reliable in this setting.

Further, we did not provide a patient-controlled analgesia (PCA) pump that could have provided a more objective representation of the patients' need for pain relief, but studies have shown proper nurse-controlled analgesia to be of comparable quality as PCA.[25]

The primary outcome was opioid consumption during the first 4 h. Due to the fact that the patients were discharged to the home shortly after this period, the study design did not allow for accurate estimations on block duration or minor differences in pain at defined time-points after that period. However, our data collection at 24, 48 h and 1 week should be able to spot clinically relevant differences in perceived analgesic block quality by the patients.

As clinicians, we thought that a demanding block such as the anterior QLB (in terms of competence, time spent and potential side effects) should demonstrate a difference of at least 50% efficacy (in terms of OME) versus the less invasive and simpler TAP block in order to be clinically recommended. This may have led to an inappropriate sample size calculation.

Another limitation may be the number of patients who fulfilled the per-protocol criteria, a total of 53 instead of 60, as planned. However, because the results in these 53 patients are very similar, with highly overlapping confidence intervals for almost all variables, we do not believe that including additional patients would have revealed any new significant differences of clinical interest.

It may be discussed whether using the anterior QLB in addition to multimodal laparoscopic hernia repair is appropriate, or if this block should be reserved for more invasive surgeries. Even though a laparoscopic inguinal hernia repair is not a very invasive surgical procedure, it is still associated with significant postoperative pain.[1,2] The anterior QLB block had not been compared to a TAP block previously in this setting, and there was a possibility that it would lend an added postoperative analgesic advantage.

5 | CONCLUSIONS

There were no differences in pain, opioid analgesic rescue consumption, nausea or sedation between the groups. Neither of the blocks resulted in complete pain relief after surgery.

Hence, we conclude that, these blocks have equal analgesic effects after a laparoscopic inguinal hernia repair. The choice of the block should therefore be based on other issues, such as skills, practicalities, and potential risks.

AUTHOR CONTRIBUTION

Marie Sørenstua, Johan Ræder, Jan Sverre Vamnes and Ann-Chatrin Linqvist Leonardsen conceived and designed the study. Marie

Sørenstua performed the blocks, while AS (the study nurse) did the data collection. All authors participated in the manuscript writing and data analysis. Marie Sørenstua, Johan Ræder, Jan Sverre Vamnes and Ann-Chatrin Linqvist Leonardsen read, critically reviewed and edited the manuscript. Marie Sørenstua, Johan Ræder, Jan Sverre Vamnes and Ann-Chatrin Linqvist Leonardsen approved the final manuscript.

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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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