Pilot Study for Posterior Quadratus Lumborum Block in Myomectomy: A Randomized Controlled Trial

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Abstract

Background

Uterine fibroids affect 20-40% reproductive age women in the United States. Gynecologic surgeons now perform roughly 65,000 myomectomies each year. The quadratus lumborum block (QLB) is an effective block for laparoscopic pelvic surgery, urologic surgery, hip hemiarthroplasty, femoral neck fracture repairs, and cesarean sections. No clinical trials have yet assessed the QLB in patients receiving laparoscopic myomectomies. We evaluated the effectiveness of the posterior QLB in reducing post-operative pain and morphine milligram equivalent (MME) consumption in patients undergoing laparoscopic myomectomies.

Methods

This was a single center, single-blinded, randomized, controlled study conducted from February 5, 2019 and June 6, 2020. Twenty-seven patients undergoing laparoscopic myomectomy were enrolled, and randomized to the QLB group or control group. Patients in the QLB group received bilateral posterior QLBs. Patients in the control group did not receive a block. MME use at 24 hours following surgery was our primary outcome. MME at other timepoints, as well as post-operative numeric rating scale (NRS) pain score and patient satisfaction were our secondary outcomes. Results are presented as mean ± SD.

Results

We recruited 26 patients, 21 of whom were included in our analysis. Total mean MME consumption was similar between the QLB group and the control group (24.7 ± 8.5 mg, vs. 26.8 ± 12.1 mg respectively; p=0.653). MME consumption was also similar among both groups for intraoperative consumption, total PACU consumption, and at 6, 24, and 48 hours after the end of surgery. Mean NRS pain scores were reduced at 6 hours postoperatively in the QLB groups compared to the control groups (2.0 ± 2.0 vs. 4.6 ± 2.3 respectively; p = 0.007). There was no difference in NRS pain scores at any other time point.

Conclusion

This pilot study provides evidence the QLB may be useful in patients receiving laparoscopic myomectomies. Further studies with a larger sample size will be valuable to determine the effectiveness of this block in laparoscopic myomectomy.

Trial Registration

Our trial is registered with ClinicalTrials.gov on May 2, 2019 with the corresponding identifier NCT03935815

Background

Uterine fibroids affect 20–40% of women during reproductive years.(1, 2) The indications for laparoscopic myomectomy have grown with improved laparoscopic technique and an increasing demand for fertility sparing interventions.(3, 4) Because there are 65,000 myomectomies performed in the United States each year,(5) there is a growing patient population that could potentially benefit from regional anesthesia in an effort to minimize opioid use and its associated adverse effects such as nausea, pruritis, and respiration depression. Patients that elect for these procedures are often young women who are already at risk for post-operative nausea given their demographics and type of surgery and may benefit from regional anesthesia to reduce that risk.

The quadratus lumborum block (QLB) is an abdominal plane block similar to both the erector spinae plane block and the transversus abdominus plane block. Its analgesic effect is through local anesthetic deposition that covers the thoracolumbar fascia and possibly the thoracic paravertebral space.(6–9) The QLB has been used for cesarean sections, hip hemiarthroplasty, femoral neck fracture repairs, laparoscopic pelvic surgery, and urologic surgery(10), and we hypothesize, could benefit gynecological surgeries as well.

Until this point, there are no studies specifically assessing the effectiveness of the QLB for postoperative pain control following laparoscopic myomectomies. We performed a single center, single-blinded, randomized, controlled study to establish the QLB's effectiveness in mitigating postoperative pain in patients undergoing laparoscopic myomectomies. Our primary measure is morphine milligram equivalents (MME) at 24 hours following surgery. Secondary timepoints include MME, at PACU discharge, and at 6, and 48-hours after the end of surgery, numeric rating scale (NRS) pain scores at time 0, 1, 2, 3, 6, 24, and 48-hours after the end of surgery, and patient satisfaction. We hypothesized that patients in the posterior QLB group will have lower total MME and NRS pain scores than patients in the control group.

Methods

The Institutional Review Board (IRB) at UCLA provided prospective ethical approval for this study. Our IRB number is 18–000825. Our trial is registered with ClinicalTrials.gov on 05/01/2019 with the corresponding identifier NCT03935815. We designed our study following the CONSORT guidelines.(11)

This trial was a single center, single-blinded, randomized, controlled study. Randomization was performed by a third-party statistician via a random number generator, and treatment allocations were placed in sealed opaque sequenced envelopes. We obtained written informed consent for study participation in patients who were scheduled for laparoscopic myomectomy. We included patients aged 18-years or older and were ASA 1 or 2. We excluded patients with congenital coagulopathy, anatomical abnormalities, localized infections, and patients who used anticoagulants or were non-English speaking For opioid conversion to MME, we used guidelines outlined by the Centers for Disease Control in the United States.(12)

Study Protocol

Study personnel obtained informed consent for all patients for regional anesthesia and participation in the study preoperatively. All patients received 1000mg of oral acetaminophen prior to surgery. General anesthesia was induced with lidocaine, fentanyl limited to 100mcg, propofol, and rocuronium. Patient then underwent endotracheal intubation, and general anesthesia was maintained with sevoflurane and fentanyl as needed. Patients were then randomized to QLB block or control group based on allocation from sealed envelopes. For post-operative nausea and vomiting (PONV) prophylaxis all patients received dexamethasone 10mg IV and ondansetron 4mg IV (13) All patients received 15mg IV ketorolac at the end of the case. For postoperative pain control, patients were allowed hydromorphone 0.2mg IV and oxycodone 5mg po for mild pain, hydromorphone 0.4mg and oxycodone 10mg for moderate pain, or fentanyl 25mcg for severe pain. Additionally, patients were allowed to use acetaminophen and ibuprofen on discharge for further analgesia.

Block Method

For study patients, we performed bilateral QLB 2 or posterior blocks, where deposition of local anesthetic is between the posterior portion of the quadratum lumborum muscle (QLM) and erector spinae muscles. Anesthesiologists on the regional anesthesiology service performed the blocks, with the patients positioned supine. After ensuring asepsis of the site, a 2–5 MHz curvilinear or 5–10 MHz linear probe (rC60xi, L38xi, Sonosite SII, FUJIFILM-Sonosite, Tokyo, Japan) was selected as appropriate to acquire adequate visualization. After identifying the three abdominal wall muscles with the ultrasound, the probe was then moved posteriorly to identify the QLM. Using a 21G 100 mm insulated needle (Stimuplex®, BBraun, Mesulngen Germany), 30 mL of 0.25% ropivacaine was injected by hydrodissecting the lumbar interfascial triangle with an in-plane approach. In the control group, patients did not receive the QLB.

Outcome Measures

Our primary measure is morphine milligram equivalents (MME) at 24 hours following surgery. Secondary timepoints include MME, at PACU discharge, and at 6, and 48-hours after the end of surgery, numeric rating scale (NRS) pain scores at time 0, 1, 2, 3, 6, 24, and 48-hours after the end of surgery, and patient satisfaction as measured on a 10-point scale ranging from 1–10 where 1 is completely unsatisfied and 10 is completely satisfied, and presence of nausea or vomiting headache, dysuria, dizziness, visual or auditory disturbances, muscle pain, and abdominal numbness.

Statistical Analysis

Patient characteristics and study variables were compared between the QLB group and the control group using the t-test for continuous variables and the chi-square test for categorical variables. Analyses were carried out using IBM SPSS V25 (Armonk, NY) and p-values less than 0.05 were considered statistically significant. In order to compare NRS Pain scores between groups over time, we used the Generalized estimating equations (GEE) modeling framework to properly account for the repeated measures design of the study, with terms for time, group, and the group*time interaction. We used a similar modeling approach for MOE usage. P-values were extracted at each pairwise time comparison to formally compare

the groups. This analysis was run using ‘proc genmod’ from SAS V9.4 (SAS Institute, Cary, NC). P-values less than 0.05 were considered statistically significant.

Results

Between March 28, 2019 and June 6, 2020, 26 patients were recruited and randomized to either the QLB or control group. Twenty-one patients were included in the final data analysis because 5 patients were lost to follow-op and thus excluded (Fig. 1). Baseline patient characteristics are shown in Table 1.

Table 1
Baseline characteristics of patients receiving bilateral quadratus lumborum blocks and sham (control). Results are presented as mean (SD) for age, BMI and duration of surgery. ASA, American Society of Anesthesiologists; BMI, body mass index, QLB, Quadratus Lumborum Block

	Table 1. Patient Characteristics	
	QLB (14)	Control (7)
Age	37.6 (7.1)	42.6 (7.6)
BMI	28.0 (6.8)	29.3 (6.9)
Sex (female)	100%	100%
ASA I	8 (57%)	2 (28%)
ASA II	6 (43%)	5 (71%)
Duration of Surgery (hours)	4.1 (0.8)	4.1 (1.3)

Total mean MME consumption (mean ± standard deviation) between the QLB group and the control group were not significantly different at 24 hours (22.3 ± 8.0 mg vs. 24.9 ± 4.5 mg, p = 0.555). MME consumption were also similar among both groups for intraoperative consumption, total PACU consumption, and at 6, 24, and 48 hours (Table 2).

Table 2
Morphine Milligram Equivalent Consumption

Time (hours)	QLB (n = 14)	Control (n = 7)	P-value (t-test)
Intraop	13.5 (7.5)	13.8 (5.0)	0.917
PACU MME	5.3 (2.6)	8.0 (8.5)	0.275
MME 6 hours	1.3 (1.6)	0.8 (0.8)	0.542
MME 7–24 hours	2.2 (2.0)	2.1 (2.9)	0.968
MME 25–48 hours	2.5 (2.1)	1.9 (1.9)	0.574
MME Total at 24 Hours	22.3 (8.0)	24.9 (4.5)	0.555
MME Totals	24.7 (8.5)	26.8(12.1)	0.653
Satisfaction	7.1 (2.7)	5.6 (1.4)	0.187

Table 2. Morphine milligram equivalent consumption (MME) in the control and QLB groups. The above values are represented as mean (SD). Generalized Estimating Equation was also used with similar results but was not presented in the above figure. QLB, Quadratus Lumborum Block; MME, morphine milligram equivalents; PACU, Post-Anesthesia Care Unit.

Generalized estimating equation showed a significant decrease in MME consumption over time in both groups ($p = 0.013$), but the rate of decline in MME consumption was not significantly different between the two groups ($p = 0.666$).

Mean NRS pain scores (mean ± standard deviation) were reduced at 6 hours postoperatively in the QLB groups compared to the control groups (2.0 ± 2.0 vs. 4.6 ± 2.3 respectively; $p = 0.007$). NRS pain scores immediately postoperatively, at PACU discharge, and at 1, 2, 3, 4, 24, and 48 hours were not different (Table 3).

Table 3
NRS Pain Scores (hours)

Time (hours)	QLB (n = 14)	Control (n = 7)	P-value (t-test)
0	5.4 (4.0)	4.9 (3.7)	0.753
1	4.8 (3.1)	4.7 (3.2)	0.961
2	4.9 (2.8)	5.3 (2.7)	0.74
3	3.6 (2.3)	4.9 (2.0)	0.228
6	2.0 (2.0)	4.6 (2.3)	0.017
24	4.9 (2.2)	4.9 (1.6)	0.945
48	4.7 (1.7)	3.7 (0.8)	0.183
PACU DC	2.7 (2.1)	3.0 (1.5)	0.749

Table 3. Post-operative NRS pain scores in both groups over time. The above values are represented as mean (SD). Generalized Estimating Equation was also used with similar results but was not presented in the above figure. NRS, Numeric Rating Scale; QLB, Quadratus Lumborum Block; PACU DC, Post-anesthesia Care Unit Discharge.

Patients in the QLB group had a higher incidence of abdominal numbness than patients in the control group (9 [64%] vs. 0 [0%] respectively; p = .007). The groups were similar in incidence of post-operative nausea or vomiting, dizziness, headache, dysuria, auditory disturbances, visual disturbances, or muscle pain at injection site (Table 4).

Table 4
Adverse Effects

	QLB (n = 14)	Sham (n = 7)	P Value
Abdominal Numbness	64.3%	0%	0.007
Nausea or Vomiting	35.7%	14.3%	0.613
Dizziness	28.6%	14.3%	0.624
Headache	35.7%	28.6%	1
Dysuria	35.7%	14.3%	0.613
Auditory Disturbances	0%	0%	1
Visual Disturbances	14.3%	0%	0.533
Pain at injection site	38.5%	42.9%	1

Table 4. Incidence of adverse effects between the two groups. The above values were analyzed using a chi-squared test with the relevant P-values to the right.

Discussion

To our knowledge, this is the first prospective, randomized, controlled study to assess the utility of the QLB for postoperative pain control in patients undergoing laparoscopic myomectomy. While MME was not reduced in the QLB group compared to the control group, NRS pain scores were reduced at 6 hours postoperatively.

Inadequate pain control is a common reason for delays in discharge and unintended postoperative admissions.(14–16) As more operations are performed in the outpatient setting, prioritizing perioperative pain management is paramount for prompt discharge. Our study showed reduced NRS pain scores at 6 hours, which may be beneficial for discharging patients early in the ambulatory setting. Pain relief at this timepoint is consistent with a recent meta-analysis of 12 trials and 924 patients also showed improved NRS scores between 4 and 6 hour in patients post-cesarean section.(17) However, our study was underpowered to make recommendations, so further studies will be required to determine the QLB's true effectiveness.

Our original power analysis dictated a sample size of 60 patients with 30 in each group, but the primary surgeon involved in the study left the institution, so we were only able to enroll 26 patients in total before the study ended prematurely. With 5 patients excluded from the study, and data from only 21 patients, the main limitation of this study was small sample size. While this study was underpowered, the preliminary data warrants a follow up study with adequate sample size. A second limitation was our inability to assess block success through dermatomal and myotomal means because the block was placed after induction of general anesthesia and assessing the patients while awake would have risked unblinding them. Lastly, our study did not include a sham for the controls. While this block has been demonstrated to be safe and effective in a multitude of surgeries, performing a QLB for laparoscopic myomectomies has not yet been studied. Given potential block complications like hematoma formation, bowel perforation, and renal injury, exposing patients to this level of harm was considered unnecessary and chosen not to be performed.

The QLB group was found to have a significantly higher incidence of abdominal numbness compared to the control group, which was expected given the block's coverage location. There was no difference in the incidence of PONV, dizziness, headache, dysuria, auditory or visual disturbances between the QLB and control group, lending weight to the safety of this block.

A multimodal approach of analgesics was applied to patients of both groups, with the use of non-opioid adjuncts including acetaminophen, ketorolac, and ibuprofen. It is difficult to ascertain the analgesic effect of these non-opioid analgesics on MME values and NRS pain scores. Similar future studies may benefit from a scheduled non-opioid regimen that would allow more precise comparison between groups, but given most patients used non-opioid adjuncts at home, this may be challenging to implement.

Conclusion

This pilot study provides evidence the QLB may be effective at reducing NRS pain scores in patients receiving laparoscopic myomectomies. Further studies with a larger sample size will be valuable to determine the effectiveness of this block in laparoscopic myomectomy.

Abbreviations

QLB = Quadratus Lumborum Block

MME = Morphine milligram equivalents

IRB = Institutional Review Board

NRS = Numeric Rating Scale

PACU = Post-Anesthesia Care Unit

GEE = Generalized Estimating Equation

Declarations

Ethics approval and consent to participate

The Institutional Review Board at UCLA provided prospective ethical approval for this study. Our IRB number is 18-000825. Informed consent was provided for all patients in the study. This study was performed in accordance with the relevant guidelines and regulations set fourth by UCLA's IRB.

Consent for publication

Not applicable

Availability of data and materials

The dataset supporting the conclusions of this article is available from the corresponding author upon request

Competing Interests

The authors declare that they have no competing interests

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Author Contributions

CL analyzed and interpreted patient data resulting from the clinical trial. CL also wrote the initial manuscript draft.

NN designed the original research proposal and helped draft the original research proposal including interventions and patient populations. NN also assisted with review of the manuscript and data.

TG helped perform statistical analyses as well as wrote the statistics section for the manuscript.

SY performed the surgeries

PC helped conduct the study as well as interpreted data and reviewed the manuscript.

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Figures

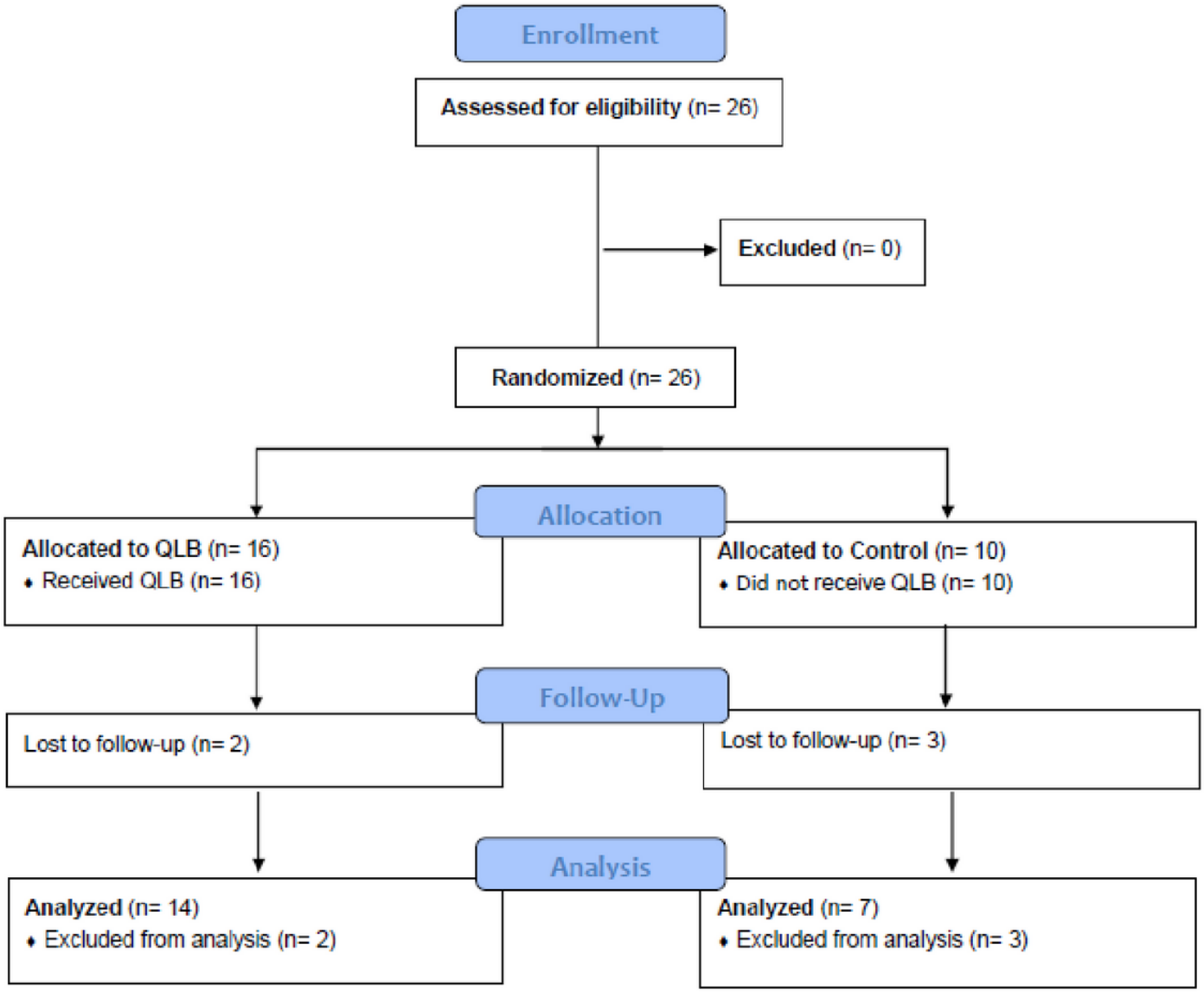

Figure 1

Consolidated Standards of Reporting Trials (CONSORT) flow diagram for enrolled and analyzed patients. QLB, Quadratus Lumborum Block.