Randomized controlled trial of a quadratus lumborum block with liposomal bupivacaine for postoperative analgesia in laparoscopic donor nephrectomy

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Clinical trial registration number: NCT03294109.

Abstract
Perioperative pain management is an important consideration in early recovery and patient satisfaction following laparoscopic donor nephrectomy. Transmuscular quadratus lumborum block has been described to reduce pain and opioid usage following several abdominal surgeries. In this prospective single-blind randomized controlled trial, we compared 52 patients who adhered to our institutional donor nephrectomy Early Recovery After Surgery pathway, which includes a laparoscopic-guided transversus abdominus plane block, to 40 patients who additionally received a transmuscular quadratus lumborum block with liposomal bupivacaine. Compared to control patients, those who received the block spent longer in the operating room prior to the surgical start (65.4 vs. 51.6 min, \( P < .001 \)). Both groups had similar total hospital length of stay (33.3 h vs. 34.4 h, \( P = .61 \)). Pain scores from postoperative days 0–30, number of patients requiring opioids, postoperative nausea, and pain management satisfaction were similar between both groups. Patients who received the block consumed less opioid on postoperative day 1 compared to controls (\( P = .006 \)). No complications were attributable to the block. The quadratus lumborum block provides a safe pain management adjunct for some patients, and may reduce opioid use in the early postoperative period when combined with our standard institutional protocol for kidney donors.

KEYWORDS
clinical trial, donor nephrectomy, donors and donation: living

1 INTRODUCTION

Since the first successful living donor kidney transplant between identical twins, the special nature of donor nephrectomy and the anesthetic management has been debated.1 Extensive efforts have been made to improve the safety and reduce the morbidity of kidney donation. Laparoscopic kidney donation has become the standard of care for most transplant programs, as it is associated with similar graft outcomes yet decreased postoperative pain and earlier recovery compared to open nephrectomy.2,3 In addition to improvements in surgical
technique, perioperative pain management has been important in improving the patient experience of living donation. Following donor nephrectomy surgery, moderate pain is usually controlled with narcotic medications, and intravenous ketorolac may also be used to further optimize pain control. Regional anesthetic techniques can also be utilized to improve pain and reduce narcotic use. The quadratus lumborum (QL) block was first described in 2007, and since has been used to reduce pain and narcotic use in a wide variety of surgeries including Cesarean section, hip arthroplasty, and laparotomy. In laparoscopic donor nephrectomy, repeated QL block has shown comparable postoperative pain scores and sensory blockade to continuous epidural analgesia.

We hypothesized that administering a long-acting bupivacaine transmuscular QL block could improve postoperative pain control and promote faster return to normal activities in patients undergoing laparoscopic donor nephrectomy at our institution. We conducted the current single-blind randomized controlled clinical trial to evaluate the effectiveness of a liposomal bupivacaine transmuscular QL block in addition to our standard early recovery after surgery (ERAS) protocol, which includes a laparoscopic guided surgeon-administered bilateral transversus abdominis plane (TAP) block close to the abdominal fascia incision. The primary outcome measured was postoperative pain scores measured on a visual analog scale. Secondary outcomes measured were pain medication requirements, pain management satisfaction, postoperative nausea and vomiting, and complications associated with QL block.

2 | METHODS

2.1 | Patient acquisition

This is a single-blind randomized controlled trial in patients greater than 18 years of age who agreed to proceed with laparoscopic donor nephrectomy between February 2018 and January 2020 at a single institution. Patients were invited to participate in the study at the time of their surgical evaluation to assess their living donor candidacy. Patients were enrolled by a study coordinator who was not part of the surgical team, and enrolled participants were instructed by the coordinator to complete electronic study questionnaires using the Urology Patient Data Waystation (UPDW). When surgery was scheduled, each patient was randomized (alternating, blocked randomization) to either the QL block group to receive liposomal bupivacaine transmuscular QL block in addition to our institutional ERAS for donor nephrectomy or to the control group to receive only ERAS. Randomization maintained equal numbers of participants in each group by sex because historically more living donors are female and also there may be an increased risk of post-anesthesia nausea in females. Surgeons and house staff were unblinded because they were not involved in collection of the data. Additionally, per hospital policy the surgeon or resident is required to be present with the patient in the operating room at all times, and the block was administered after the patient was under anesthesia. All staff who administered questionnaires were blinded. Outside of the operating room, all nursing staff who cared for the patients were also blinded. All patients in both study groups wore a wristband indicating they were not to receive any additional local anesthetic during their hospitalization. The study was approved by the UCLA Institutional Review Board and listed with ClinicalTrials.gov (NCT03294109).

2.2 | Transmuscular quadratus lumborum block technique

After induction of general anesthesia, patients were placed in the lateral decubitus position. For patients randomized to the study group, a curvilinear ultrasound probe was placed in the ipsilateral posterior-axillary line, right above the iliac crest to identify the transversus abdominis, quadratus lumborum, and psoas muscles. Using sterile technique, a 22 gauge nerve block needle was inserted and advanced under ultrasound guidance below the fascia covering of the QL muscle, with the tip of the needle ending between the psoas and QL muscles. Gentle aspiration was performed to confirm position and 20 ml of 1.3% liposomal bupivacaine (Exparel; Pacira Pharmaceuticals, Inc., Parsippany, NJ, USA) mixed with 10 ml of normal saline was injected. The control group had a 22 gauge needle inserted just through the skin in the same location to blind the patients in the control group. A total of three anesthesiologists delivered the blocks in this study. The majority of the QL blocks were performed by S.R., who also supervised the other providers when they administered the block.

2.3 | Surgical technique

Following intubation, all patients were placed in 90-degree lateral flank position. Pneumoperitoneum was established with a Veress needle and a pressure of 15 mmHg was maintained with carbon dioxide. A fully laparoscopic donor nephrectomy was performed with three 5 mm ports positioned along the lateral border of the rectus abdominis muscle, beginning superiorly 1 cm below the costal margin and subsequently spaced one hand’s width apart. An 8–10 cm pfannenstiel incision was created, and a 15 mm port was placed through the incision in the midline to accommodate a stapling device and specimen bag. The 15 mm port was extended to open the fascia in the midline, and the kidney was extracted through the Pfannenstiel incision. For right sided nephrectomies an additional 3 mm port was placed below the xyphoid process to retract the liver. After the kidney was extracted, the midline abdominal fascia was closed. After ensuring adequate hemostasis, pneumoperitoneum was desufflated prior to removal of laparoscopic ports.

2.4 | ERAS pathway for laparoscopic donor nephrectomy patients

The institutional ERAS pathway for donor nephrectomy patients included opioid-sparing anesthesia and triple agent prevention of
postoperative nausea and vomiting with scopolamine, dexamethasone, and ondansetron. After the fascia of the kidney extraction site was closed, the abdomen was reinsufflated with 15 mmHg carbon dioxide. A TAP block of 20 ml (5 ml in each quadrant of the fascia incision) of .25% bupivacaine was injected percutaneously in the pre-peritoneal plane under direct vision with the laparoscopic camera using a 22 gauge needle in a similar fashion to that which has been previously described. Another 10 ml of .25% bupivacaine was injected around the laparoscopic incisions. To maintain blinding and increase safety, patients in both the control and QL block groups received an Exparel wristband after surgery to prevent any further local anesthetic injection during the first 96 h after surgery. Prior to extubation, patients received 30 mg intravenous ketorolac, and this was continued every 8 h for 48 h, or until discharge from the hospital. Additionally, postoperative pain was managed with 650 mg acetaminophen every 6 h, an oral opioid (hydrocodone/acetaminophen, oxycodone, or tramadol) as needed every 4 h for moderate pain, and intravenous hydromorphone as needed for severe pain. The maximum daily acetaminophen dose was limited to 3000 mg. Patients were given a clear liquid diet initially and advanced to a regular diet on the morning of postoperative day 1. Early ambulation on postoperative day 0 was encouraged. The foley catheter that was inserted in the operating room was also discontinued in the morning of postoperative day 1. All patients were discharged with polyethylene glycol for constipation management. The target goal for hospital discharge was postoperative day 1.

2.5 Postoperative data collection

The primary objective of the study was to determine the degree of pain control in patients receiving a long-acting transmuscular QL block in addition to a short-acting TAP block compared to TAP block alone. Postoperative day 3 was chosen as our primary endpoint timepoint. We rationalized that liposomal bupivacaine may be effective for up to 72 h, and therefore we would most like identify a noticeable reduction in pain within the first 3 days after administration compared to those who did not receive a TQL. For the duration of the patients’ hospitalization, the nurse caring for them prompted them to indicate their pain level through a numeric visual analog scale of 0 through 10, and this was recorded by the nurse in the electronic medical record (EMR). For data collected after discharge (postoperative days 3, 5, 10, and 30), patients viewed and reported the visual analog scale themselves through the UPDW server.

Secondary objectives were to determine postoperative opioid requirements, postoperative nausea and vomiting, patient satisfaction, and complication rates in both groups. Total opioid and other analgesic medication doses were collected from the EMR and patient reported doses in UPDW by electronic survey after discharge. The incidence of nausea or vomiting was extracted from nursing notes and queried via electronic surveys. The Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R), a validated instrument to measure inpatient pain management quality, was administered on postoperative day 1. The questionnaire was presented to patients by a blinded study nurse 18–24 h postoperatively. The study nurse provided the patient with a tablet computer and the patient entered their scores electronically after reading the questionnaire. The study nurse remained present while the patient filled out the questionnaire and was available for any questions. Post-discharge, which is typically 1–2 days following surgery, patients were sent surveys delivered by the UPDW server 3, 5, 10, 30, and 90 days postsurgery. If patients did not respond to the 90 days postsurgery, the study team contacted patients to attempt to have the exit survey completed. Complications were documented in the EMR by the anesthesia pain service, urology service, and nurses. Approximately 8 to 10 days postsurgery, the patients had a follow-up visit in the transplant clinic.

2.6 Statistical analysis

Patient characteristics and study variables were summarized using mean or frequency as appropriate for each group. They were then formally assessed for differences using t-tests for continuous variables or chi-square tests for categorical measures. The association between milligram morphine equivalent ranges and groups was assessed using the Cochran-Armitage test. Statistical analyses were carried out using IBM SPSS v26 (Armonk, NY). P-values < .05 were considered statistically significant.

An a priori power calculation was computed during the design phase of the study. After reviewing the current pain literature as well as what we felt was a clinically significant effect for the block, we thought it was reasonable to assume a reduction in pain scores of approximately 30%. A sample size of 37 per group gives adequate power (>80%) to detect differences as small as 29% (mean control = 7, mean treated = 5, SD = 3) using a two-sample t-test, two-tailed, alpha = .05. We then targeted 50 versus 50 to be conservative, in order to account for potential exclusions and loss of follow-up on certain patients. The study concluded with 52 versus 40 patients for control and QL block groups, respectively.

3 RESULTS

Of the 170 potential living kidney donors who were invited to participate in the study, 103 patients (71 female, 32 male) underwent randomization to receive either the QL block or no QL block. Eleven patients were excluded after randomization if they did not complete the preoperative electronic survey or if surgery was canceled, leaving 92 patients who underwent laparoscopic donor nephrectomy. Forty patients received a transmuscular QL block and 52 patients received the institutional ERAS protocol only. (Figure 1).

The demographics of the study patients are shown in Table 1. Patients in the QL block group appeared slightly older (mean age 45.5 in control vs. 50.9 in QL block) but otherwise the groups were well balanced among gender (69.2% female in control vs. 70.0% female in QL block), BMI (25.8 kg/m² vs. 24.9 kg/m²), and laterality of surgery (9.6% vs. 12.5% right sided nephrectomy). There was similar
| N | Control | QL Block |
|---|---------|----------|
| **Patient characteristics** | | |
| Age (SD) | 45.5 (13.1) | 50.9 (11.4) |
| Female, n (%) | 36 (69.2) | 28 (70.0) |
| BMI (SD) | 25.8 (3.2) | 24.9 (3.5) |
| Right side nephrectomy, n (%) | 5 (9.6) | 5 (12.5) |
| **Education, n (%)** | | |
| Some High School | 0 (0) | 1 (2.5) |
| High School | 1 (1.9) | 3 (7.5) |
| Some College | 14 (26.9) | 8 (20.0) |
| College Graduate | 18 (34.6) | 13 (32.5) |
| Some Graduate School | 3 (5.8) | 1 (2.5) |
| Graduate Professional | 16 (30.8) | 14 (35.0) |
| **Race, n (%)** | | |
| White | 33 (63.5) | 27 (67.5) |
| Black | 0 (0) | 2 (5.0) |
| Hispanic | 9 (17.3) | 3 (7.5) |
| Asian | 6 (11.5) | 6 (15.0) |
| Other | 4 (7.7) | 2 (5.0) |
| **Relationship, n (%)** | | |
| Single | 14 (26.9) | 7 (17.5) |
| Married | 33 (63.5) | 29 (72.5) |
| Divorced | 3 (5.8) | 4 (10.0) |
| Widow | 2 (3.8) | 0 (0.0) |
| **Employment, n (%)** | | |
| Full time | 34 (65.4) | 24 (60.0) |
| Part time | 7 (13.5) | 4 (10.0) |
| Homemaker | 5 (9.6) | 5 (12.5) |
| Retired | 4 (7.7) | 7 (17.5) |
| Student | 1 (1.9) | 0 (0.0) |
| Unemployed | 0 (0.0) | 0 (0.0) |
| Other | 1 (1.9) | 0 (0.0) |
| **Donating for, n (%)** | | |
| Parent | 4 (7.7) | 5 (12.5) |
| Child | 2 (3.8) | 4 (10.0) |
| Sibling | 4 (7.7) | 4 (10.0) |
| Other relative | 5 (9.6) | 3 (7.5) |
| Spouse | 7 (13.5) | 6 (15.0) |
| Non-biological relative | 4 (7.7) | 5 (12.5) |
| Friend | 17 (32.7) | 9 (22.5) |
| Unknown | 9 (17.3) | 4 (10.0) |
| **Operative characteristics** | | |
| Preparation and positioning time, min (SD) | 51.6 (7.8) | 65.4 (9.6) | <.001 |
| Total OR time, min (SD) | 219.6 (33) | 229.2 (23.4) | .13 |
| Length of stay, h (SD) | 33.3 (8.6) | 34.4 (11.6) | .61 |
Pain scores were similar between the two groups immediately post-operatively (3.96 vs. 3.27, \( P = .49 \)), at postoperative day (POD) 3 (4.62 vs. 4.20, \( P = .40 \)), POD 5 (3.82 vs. 3.55, \( P = .51 \)), POD 10 (2.49 vs. 2.69, \( P = .59 \)), and POD 30 (1.64 vs. 1.78, \( P = .56 \)). Due to potential departures from normality in the pain score data, as a sensitivity analysis, we also ran the Wilcoxon test (results not shown) and obtained the same conclusions as the t-test. Both groups tapered opioid use in a similar fashion. By POD 5, only 21% of control patients and 23% of patients who received the block still required an opioid for pain control, and by POD 10 only one patient reported opioid use (Figure 2). The response distribution of education level, race, relationship status, employment status, and relationship status to the recipient between patients in the two groups.

Patients who received the QL block on average required longer positioning and preparation times prior to the start of surgery (65.4 vs. 51.6 min, \( P < .001 \)). However, the total amount of time spend in the operating room was similar between the two groups (219.6 for control vs. 229.2 min for QL block, \( P = .13 \)). Total hospital length of stay was also similar (33.3 h for control vs. 34.4 h for QL block, \( P = .61 \)) (Table 1).
rate for the control group was 100% in the post-anesthesia care unit (PACU), 56% (29/52) on POD 3, 69% (36/52) on POD 5, 71% (37/52) on POD 10, and 75% (39/52) on POD 30. The response rate for the block group was 100% in the PACU, 63% (25/40) on POD3, 78% (31/40) on POD 5, 88% (35/40) on POD10, and 90% (36/40) on POD 30.

Patients who received the QL block consumed lower opioid quantities on postoperative day 0 compared to control patients (P = .006), and 38.5% of the QL block group compared to 15.4% of control patients required no oral opioid medication on postoperative day 0 (Table 2). Total oral opioid consumption was similar between the two groups on postoperative days 1, 3, and 5.

No difference was observed in the number of prophylactic antiemetics administered intraoperatively or rescue antiemetics administered in the recovery room between the control group and those who received the transmuscular QL block (Table 3). Satisfaction with pain management, measured with APS-POQ-R scores, was largely comparable between control and QL block groups (Table 4). Postoperative complications were also similar between the two groups (5.8% in control, 12.5% in QL block, P = .26). All complications were classified as Clavien-Dindo grade I with the exception of a pleural effusion that required drainage in a patient in the control group (Table 5). None of the patients experienced local complications related to the QL and TAP block procedures nor symptoms of local anesthetic toxicity.

4 DISCUSSION

In this single-blind randomized controlled trial of an ipsilateral transmuscular QL block with liposomal bupivacaine in addition to our institutional donor nephrectomy ERAS protocol that includes intraoperative TAP block, both groups on average were discharged from the hospital the following day after surgery, and the majority of patients in both groups discontinued opioid use between 3 and 5 days after surgery. Opioid consumption on postoperative day 0 was lower in the QL block group compared to the control group, but it did not provide a significant benefit in regard to postoperative pain scores, postoperative nausea and vomiting, or patient satisfaction compared to the standard ERAS pathway.

A consensus agreement regarding the specific mechanism of QL block analgesia has not yet been reached. The hypothesis that transmuscular QL block may provide additional analgesic effect in combination with an incisional TAP block was based partially on the observation that QL block may provide more consistent spread of anesthetic into the paravertebral space and reach somatic and sympathetic nerves, and thus provide analgesia for anterior abdominal incisions. Furthermore, visceral analgesia may result from the spread of local anesthetic to the celiac ganglion of the sympathetic trunk. However, a more recent study has suggested that QL block may in fact provide inconsistent spread toward the thoracic paravertebral space, which may partially explain the negative result in our trial. For patients undergoing abdominal or inguinal surgeries, QL block alone may even be superior to TAP block.

In our practice an incisional TAP block with bupivacaine was incorporated into the ERAS protocol for donor nephrectomy partly because it can be easily and quickly administered by the surgeon under direct vision with the laparoscope and therefore does not add a significant amount of time to the procedure. We chose liposomal bupivacaine with the goal of prolonging duration of the effect compared to plain bupivacaine. However, a recent meta-analysis suggests that liposomal bupivacaine may not in fact provide superior pain control compared to non-liposomal bupivacaine for peripheral nerve blocks.

We did not identify any complications that were attributed to the transmuscular QL block in this study. Lower extremity weakness and hypotension have been reported rarely and are thought to be related to anesthetic spread to the paravertebral that may affect lumbar and sympathetic nerves. In our study no patient reported motor weakness; one patient in the QL block group experienced postoperative hypotension but this was thought to be related to acute blood loss rather than an effect of regional anesthesia. The overall complication rate was low and comparable to existing literature for laparoscopic donor nephrectomy outcomes. To our knowledge this was the first study to evaluate the safety of liposomal bupivacaine administration for QL block.
TABLE 3  Postoperative nausea and vomiting treatment in donors who received standard ERAS protocol (control) versus additional quadratus lumborum block

|                          | Control n = 52 | QL block n = 40 | P-value |
|--------------------------|----------------|-----------------|---------|
| Pre-op scopolamine patch, n (%) | 11 (21%) | 9 (23%) | .88     |
| Prophylactic antiemetics administered, mean (SD) | 2.6 (.69) | 2.6 (.68) | .83     |
| Patients requiring rescue antiemetics in PACU, n (%) | 8 (15%) | 6 (15%) | .96     |

TABLE 4  APS-POQ-R scores of donors who received standard ERAS protocol (control) versus additional quadratus lumborum block

| N                     | Control | QL Block | P-value |
|-----------------------|---------|----------|---------|
| Least pain            | 3.3 (2.4) | 2.8 (2.0) | .35     |
| Most pain             | 7.0 (1.8) | 6.8 (2.5) | .60     |
| How often in pain     | 28% (26) | 32% (25) | .56     |
| Prevented activities in bed | 5.8 (2.7) | 4.4 (2.7) | .02     |
| Prevented activities out of bed | 4.3 (2.6) | 4.7 (2.8) | .58     |
| Prevented falling asleep | 3.8 (2.7) | 3.7 (3.2) | .84     |
| Prevented staying asleep | 3.8 (2.9) | 4.2 (3.4) | .56     |
| Feeling anxious       | 1.7 (2.1) | 2.3 (2.5) | .21     |
| Feeling depressed     | .3 (.8) | .5 (1.1) | .39     |
| Feeling frightened    | .9 (1.6) | .8 (1.6) | .79     |
| Feeling helpless      | 2.0 (2.8) | 2.0 (2.8) | .94     |
| Experienced nausea    | 29 (3.0) | 3.7 (3.5) | .26     |
| Experienced drowsiness | 5.0 (2.6) | 4.7 (2.6) | .64     |
| Experienced itching   | .8 (1.4) | .6 (1.5) | .49     |
| Experienced dizziness | 1.7 (1.9) | 1.8 (2.4) | .71     |
| How much pain relief  | 73% (18) | 74% (20) | .93     |
| Allowed to participate in decisions | 9.1 (1.6) | 9.2 (1.7) | .74     |
| Satisfaction with pain treatments | 9.1 (1.2) | 8.6 (1.9) | .20     |
| Received information about pain treatment options | 1.9 (.2) | 1.9 (.3) | .84     |
| How helpful was information | 8.1 (1.9) | 8.4 (1.8) | .42     |
| Non-medicine pain relief methods | 1.2 (.4) | 1.5 (1.5) | .02     |
| Were non-medicine methods encouraged? | 1.6 (.7) | 1.7 (.7) | .37     |
| Satisfaction with care | 4.8 (.8) | 4.9 (.3) | .26     |

TABLE 5  Postoperative complications

| Complication                                      | Clavien-Dindo classification |
|---------------------------------------------------|-------------------------------|
| **Control Group**                                 |                               |
| 1. Pleural effusion requiring aspiration          | IIIa                          |
| 2. Incisional hematoma                            | I                             |
| 3. Urinary retention                              | I                             |
| **QL Block Group**                                |                               |
| 1. Urinary retention                              | I                             |
| 2. Wound infection                                | I                             |
| 3. Wound seroma                                   | I                             |
| 4. Contralateral flank pain and acute kidney injury (eGFR 55 6 months later) | I                             |
| 5. Postoperative hypotension in setting of acute blood loss | I                             |
Our study has several limitations. First, there was some attrition in the response to postoperative surveys, and data for pain scores and opioid use after hospital discharge was less robust than for inpatient records. Second, while our institutional ERAS pathway includes administration of ketorolac postoperatively, seven patients in the control group and one patient in the block group never received this medication. It is possible this was at the discretion of the surgeon to avoid bleeding complications due to an intraoperative concern. Furthermore, there was variability in the opioid that patients received postoperatively, as some received hydrocodone and others oxycodone, and a small number of patients who did not tolerate either of these medications received tramadol. Nevertheless, we accounted for this variation by calculating morphine milligram equivalent consumption. Finally, we studied the effect of the transmuscular QL block in addition to our standard TAP block rather than in place of it. Therapeutic overlap likely exists between the two regional anesthetics, and it is possible a more significant effect of the transmuscular QL block would be seen if this were administered independently. However, in addition to experiencing incisional pain, some patients clearly describe flank pain as well, which would not be covered by the incisional TAP block.

These limitations notwithstanding, this randomized control study demonstrates that transmuscular QL block may be safely administered to patients undergoing laparoscopic donor nephrectomy without adding significant time overall in the operating room. Furthermore, these findings provide useful data when counseling potential kidney donors regarding postoperative pain management expectations. While we did not identify an additional subjective patient benefit to pain reduction compared to our standard ERAS protocol, we did observe lower opioid consumption in the immediate postoperative period in patients who received the block. QL block may be considered a tool for providing alternative analgesia in patients who may not tolerate or who may want to avoid standard pain medications.

ACKNOWLEDGMENTS
The authors are grateful to the UCLA pharmacy for approving the off label use of liposomal bupivacaine for this study. They would also like to acknowledge study coordinators Dana Levin, Kristin Williams, Jasymn Akaninwor, Sarah Connor, Jenny Lester, and Deanna Orozco for their efforts in patient accrual and data collection follow up.

CONFLICT OF INTEREST
The authors of this manuscript have no conflicts of interest to disclose as described by Clinical Transplantation.

DATA AVAILABILITY STATEMENT
The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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How to cite this article: Gritsch HA, Osbun N, Grogan T, et al. Randomized controlled trial of a quadratus lumborum block with liposomal bupivacaine for post-operative analgesia in laparoscopic donor nephrectomy. Clin Transplant. 2021:e14403. https://doi.org/10.1111/ctr.14403