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Surgeon-delivered laparoscopic transversus abdominis plane blocks are non-inferior to anesthesia-delivered ultrasound-guided transversus abdominis plane blocks: a blinded, randomized non-inferiority trial

Daniel J. Wong[1] · Thomas Curran[1] · Vitaliy Y. Poylin[1] · Thomas E. Cataldo[1,2]

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Abstract

Background The transversus abdominis plane (TAP) block is an important non-narcotic adjunct for post-operative pain control in abdominal surgery. Surgeons can use laparoscopic guidance for TAP block placement (LTAP), however, direct comparisons to conventional ultrasound-guided TAP (UTAPs) have been lacking. The aim of this study is to determine if surgeon placed LTAPs were non-inferior to anesthesia placed UTAPs for post-operative pain control in laparoscopic colorectal surgery.

Methods This was a prospective, randomized, patient and observer blinded parallel-arm non-inferiority trial conducted at a single tertiary academic center between 2016 and 2018 on adult patients undergoing laparoscopic colorectal surgery. Narcotic consumption and pain scores were compared for LTAP vs. UTAP for 48 h post-operatively.

Results 60 patients completed the trial (31 UTAP, 29 LTAP) of which 25 patients were female (15 UTAP, 10 LTAP) and the mean ages (SD) were 60.0 (13.6) and 61.5 (14.3) in the UTAP and LTAP groups, respectively. There was no significant difference in post-operative narcotic consumption between UTAP and LTAP at the time of PACU discharge (median [IQR] milligrams of morphine, 1.8 [0–4.5] UTAP vs. 0 [0–8.7] LTAP $P = .32$), 6 h post-operatively (5.4 [1.8–17.1] UTAP vs. 3.6 [0–12.6] LTAP $P = .28$), at 12 h post-operatively (9.0 [3.6–29.4] UTAP vs. 7.2 [0.9–22.5] LTAP $P = .51$), at 24 h post-operatively (9.0 [3.6–29.4] UTAP vs. 7.2 [0.9–22.5] LTAP $P = .63$), and 48 h post-operatively (39.9 [7.5–70.2] UTAP vs. 22.2 [7.5–63.8] LTAP P = .41). Patient-reported pain scores as well as pre-, intra-, and post-operative course were similar between groups. Non-inferiority criteria were met at all post-op time points up to and including 24 h but not at 48 h.

Conclusions Surgeon-delivered LTAPs are safe, effective, and non-inferior to anesthesia-administered UTAPs in the immediate post-operative period.

Trial registry The trial was registered at clinicaltrials.gov Identifier NCT03577912.

Keywords Transversus abdominis plane (TAP) block · Laparoscopy · Post-operative pain control · Enhanced recovery after surgery

Enhanced recovery after surgery (ERAS) programs improve post-operative outcomes and reduces cost in colorectal surgery [1–3]. A multimodal, opiate sparing pain regimen is a central component of ERAS protocols [4]. Benefits of reducing opiates include decreased post-operative nausea, vomiting, and sedation as well as reducing time to return of bowel function and expediting patient recovery [5]. A reduction in opiate consumption post-operatively is particularly relevant in light of the ongoing opiate epidemic.

The transversus abdominis plane (TAP) block, whereby local anesthetic is injected between the internal oblique and transversus abdominis fascia to facilitate blockade of somatic afferents nerves, is an effective, non-narcotic adjunct

✉ Thomas E. Cataldo
Tcatald1@bidmc.harvard.edu

[1] Division of Colon & Rectum Surgery, Beth Israel Lahey Health Medical Center, Harvard Medical School, Boston, MA 02215, USA

[2] Beth Israel Lahey Health Medical Center, 330 Brookline Avenue, Gryzmish Building 6th Floor, Boston, MA 02215, USA

incorporated into many ERAS protocols. Numerous studies have shown that the TAP block is effective in reducing post-operative pain, opiate requirement, time to return of bowel function, and length of stay (LOS) [6–9]. The efficacy of the TAP block has been established across a number of other surgical disciplines as well including general, gynecologic, and urologic surgery [6, 10–12]. Correct positioning of the needle in the TAP plane is essential to the safety and efficacy of the procedure. The high rate of peritoneal needle placement during TAP blocks when solely anatomic landmarks and tactile sensation were employed for delivery led to ultrasound guidance becoming standard [13]. Currently, in many institutions, anesthesiologists administer the TAP block under ultrasound guidance (UTAP) immediately prior to or following the operation. This requires an additional provider, time, and potentially an avoidable professional fee.

Recently, there have been several reports of localizing the TAP injection using laparoscopic guidance [14–17]. Laparoscopically guided TAP blocks (LTAPs) have the potential to decrease resource utilization including time, provider, and cost. The comparative efficacy of surgeon-delivered LTAPs versus anesthesia-delivered UTAPs has only twice been studied in colorectal surgery, employing different delivery techniques and in populations with unclear generalizability to the average colorectal surgery practice [15, 18].

Therefore, we aimed to address this gap in the current understanding of the relative efficacy of LTAP and UTAP through a prospective trial. We hypothesized that surgeon-delivered LTAPs would be non-inferior to anesthesia-delivered UTAPs in terms of post-operative pain control. To test this, we conducted a prospective, randomized, patient and observer blinded non-inferiority trial using post-operative opiate consumption as our primary outcome.

Materials and methods

The study design was a prospective, randomized, observer, and patient-blinded non-inferiority trial with two parallel arms. Approval was obtained from the institutional review board of the Beth Israel Deaconess Medical Center before patient enrollment (2014P-000347). This trial was registered at clinicaltrials.gov NCT03577912.

Participants

Adult (> 18 years old) patients undergoing colorectal resection in the Division of Colorectal Surgery from March 2016 and April 2018 were eligible. Initially open and laparoscopic patients were eligible for enrollment; however, the rate of intended open cases was too low, thus only laparoscopic segmental colectomies without pre-operative intended stoma were recruited. Those patients with allergy to bupivacaine, pre-operative chronic narcotic usage, or chronic pain syndrome were excluded from enrollment. Patients whose anatomy was thought to preclude effective placement of the TAP block, such as those with prior complex abdominal wall reconstruction, were excluded. Prior abdominal surgery in itself was not an exclusion criterion. Post-enrollment, those patients who required an unplanned return to the operating room thus incurring additional incisional pain were also excluded.

Randomization and treatment allocation

Patients were randomized on the day of surgery. The randomization was performed at the beginning of the study by computer algorithm from a non-affiliated statistician with a goal 1:1 patient allocation. Pre-sealed, opaque envelopes were held by independent research staff and delivered to the OR on the day of surgery and opened after induction of anesthesia.

Blinding

The surgeons, regional block team, and operating room staff were not blinded to the treatment. Patients as well as independent research staff who collected pain scores and post-operative nursing teams were all blinded to the treatment received. There were no differences in patient bandages.

Interventions

Two staff surgeons (T.C. and V.P.) performed laparoscopic colorectal surgery using standard port placement with midline specimen extraction. TAP blocks were administered either by the surgeon with laparoscopic guidance or by the anesthesia regional block team under ultrasound guidance. In both groups, the TAP block consisted of 0.25% bupivacaine with 1:100,000 epinephrine with a volume of 1 cc/kg up to 60 cc which was divided equally and injected bilaterally.

Surgeon LTAPs were performed under direct visualization with the laparoscope just prior to closure of the fascia. With the abdomen insufflated, the operating surgeon palpated the lateral border of the rectus to ensure adequate lateral placement and then a 19-gage needle was inserted percutaneously just inferior to the costal margin and as lateral as possible within the draped surgical field. Using the laparoscope to ensure that the peritoneum is not penetrated, the needle is advanced through the internal and external obliques (Fig. 1A) and a small amount of anesthetic is injected into the TAP plane. The spreading of the bulge along the TAP plane is confirmed visually prior to the injection of the whole amount of anesthetic (Fig. 1B). The same process was repeated on the contralateral side. After

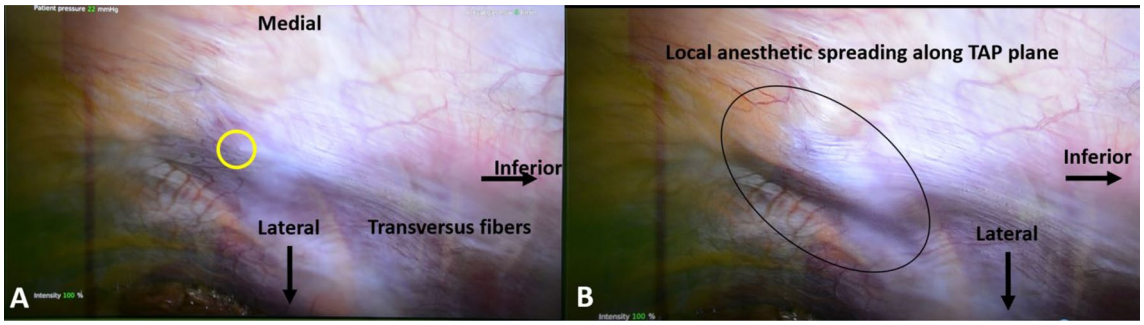

Fig. 1 Surgeon-delivered laparoscopically guided TAP block. **A** Laparoscopic view of abdominal wall with circle highlighting initial bulge of injection within the TAP plane. Laparoscope is used to ensure peritoneum is not entered with needle. **B** Laparoscopic view of anesthetic spreading along TAP plane following injection

bilateral injection, the operation was completed in standard form including maturation of an ostomy, if necessary.

Anesthesia UTAPs were administered by the regional block team under ultrasound guidance (body habitus dictated linear high-frequency 12 MHz or curvilinear abdominal 6 MHz probe use) using a 22-g needle and standard lateral approach immediately following removal of the surgical drapes but prior to patient emergence from general anesthesia.

Post-operative care

All patients received non-narcotic analgesics including acetaminophen and ketorolac as well as anti-emetic medication as part of a standardized ERAS protocol. Patients received an opiate patient-controlled analgesia (PCA) pump in the post-anesthesia care unit (PACU). Rescue boluses of narcotic were administered at discretion of PACU staff. Once tolerating a regular diet, patients were transitioned to an oral narcotic with ongoing utilization of non-narcotic analgesics.

Data collection

Patient, operative, and post-operative characteristics were collected from the patients' medical records by independent nursing staff and recorded using a standardized data collection tool. A blinded member of the research staff assessed subjective pain scores on a scale from 0 to 10 in the PACU, 6, 12, 24, and 48 h post-operatively. Post-operative nausea or vomiting (PONV) was also recorded.

Outcomes measured

The primary outcome was cumulative post-operative opiate requirement. Opiate requirement was tracked from admission to PACU, at 6, 12, 24, and 48 h post-operatively and standardized across pain regimens using milligrams of oral morphine equivalents. Secondary outcomes included subjective pain scores both at rest and with activity as assessed by blinded clinical research staff. Post-operative complications were graded using the modified Clavien–Dindo classification for surgical complications [19].

Sample size calculation and statistical analysis

This study was designed as a non-inferiority trial [20]. Historical data on the opiate sparing effect of a TAP block demonstrated a mean 58 mg decrease in oral morphine usage over 24 h in the TAP block group [21]. A non-inferiority margin of 15 mg of morphine was selected. Using 80% power and a two-sided significance level of 0.05, power calculations necessitated 27 patients per arm of the trial. As the primary outcome is achieved within 48 h of surgery with a very low mortality rate, it was not expected that any patient would be lost to follow-up. However, given that data collection may be imperfect, we increased the sample size by approximately 10% to account for this with a goal of 30 patients per arm.

Categorical data were analyzed with Fisher's exact or χ^2 tests. Continuous variables were tested with unpaired two-tailed t tests if normally distributed or using the Mann–Whitney U test if not normally distributed. Significance was considered as $P < 0.05$ unless otherwise stated. Non-inferiority was established when the 95% confidence interval of the differences of means fell within the pre-specified non-inferior margin. All analyses were performed using GraphPad Prism (version 7.03, La Jolla, CA).

Results

Study population

80 patients were consented during the enrollment period between April 2016 and April 2018 and 64 underwent randomization (Fig. 2). The primary reason for lack of

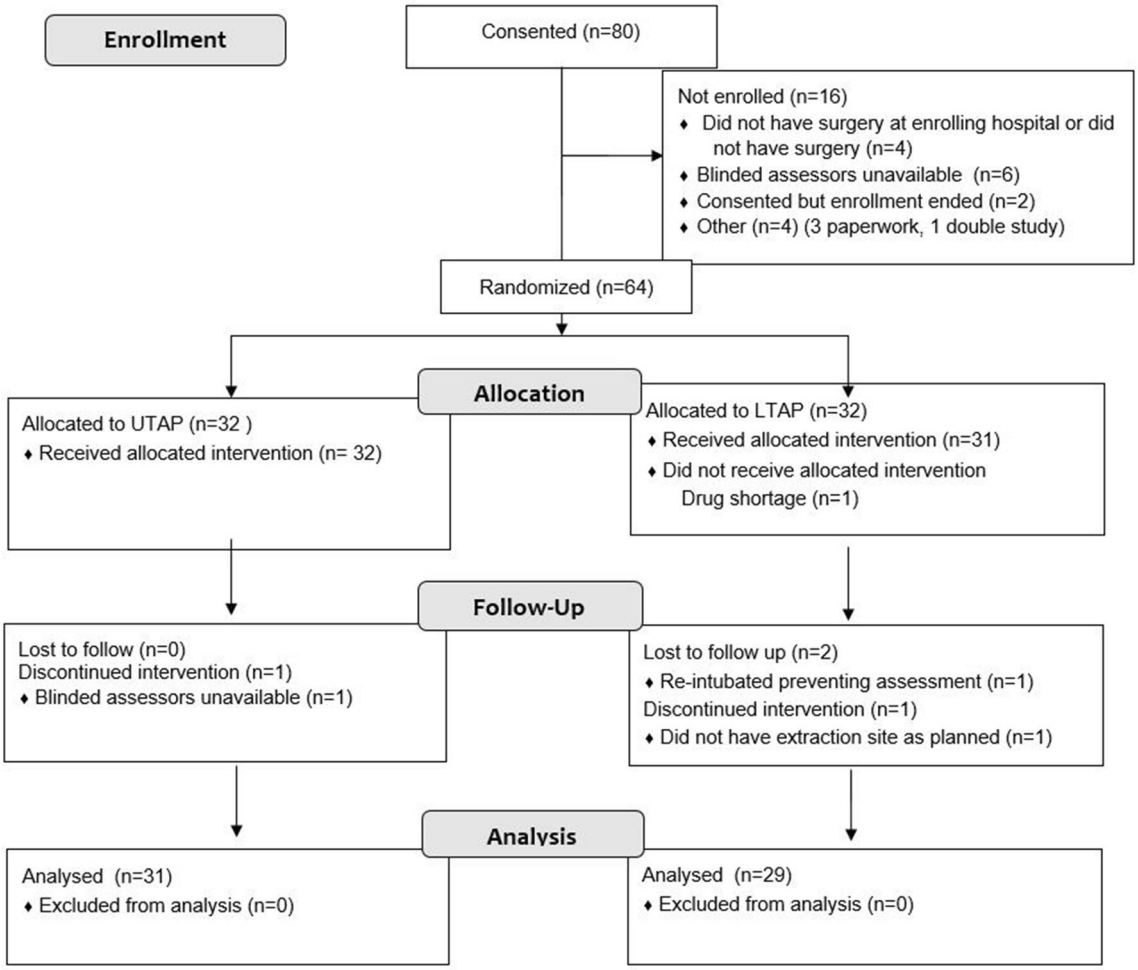

Fig. 2 CONSORT flow diagram of patients in trial. *UTAP* ultrasound-guided transversus abdominis block, *LTAP* laparoscopic-guided transversus abdominis block

randomization among those consented ($N = 16$) was the inability to schedule the research personnel to perform independent blinded assessments. Of the 64 patients randomized on the day of surgery, 4 patients were excluded from the final analysis. One patient did not have the anticipated procedure and did not require a midline abdominal incision. One patient was re-intubated and unavailable for pain assessment. One patient could not have their blinded assessment completed due to a scheduling conflict, and one patient could not receive standardized TAP block due to drug shortage.

Patient characteristics

There were no significant differences between groups in age, sex, body mass index (BMI), rate of prior abdominal surgery, diabetes, or pre-operative narcotic usage (Table 1). Nor were there any significant differences in indication for colectomy.

Operative and post-operative course

No significant differences in operative details were observed between groups (Table 2). Case time, as defined by "room in" to "room out" times, was similar as was estimated blood loss (EBL). There were no conversions to open surgery. There were no significant differences in rate of stoma creation or anatomic location of resection. Similarly, there were no significant differences in post-operative course including frequency of PONV, time to oral narcotic consumption (indicating tolerance of a regular diet), or time to discharge (Table 2). No adverse events such as hematoma or inadvertent bowel or solid organ puncture related to the TAP block occurred. There were 3 and 5 Clavien–Dindo grade I–II complications and 2 and 1 Grade III–V complication in the UTAP and LTAP groups, respectively, which were not significantly different.

Table 1 Demographic and pre-operative clinical characteristics

Characteristic	Ultrasound TAP ($N = 31$)	Laparoscopic TAP ($N = 29$)	*P* value
Age, years; mean ± SD	60.0 ± 13.6	61.5 ± 14.3	.68[a]
Female sex; *N* (%)	15 (48.4)	10 (34.5)	.31[b]
BMI; mean ± SD	28.1 ± 5.9	30.6 ± 5.8	.11[a]
Pre-op narcotic usage; *N* (%)	0 (0)	2 (6.8)	.23[b]
Baseline Pain; median (IQR)	0 (0-0)	0 (0-1.5)	.70[c]
Diabetes; *N* (%)	3 (9.7)	5 (17.2)	.47[b]
Prior abdominal surgery; *N* (%)	11 (35.5)	18 (62.1)	.07[b]
Surgery indication; *N* (%)			.39[d]
Cancer	12 (38.7)	16 (55.1)	
Benign	16 (51.6)	10 (34.4)	
IBD	3 (9.6)	3 (10.3)	

BMI body mass index, *Pre-op* pre-operative, *IBD* inflammatory bowel disease

[a]Statistical analysis performed using unpaired *t* test

[b]Statistical analysis performed with Fisher's exact test

[c]Statistical analysis performed using Mann–Whitney *U* test

[d]Statistical analysis performed with χ^2 all *P* values reported as 2-sided

Table 2 Operative details and post-operative hospital course of patients who completed study

Characteristic	Ultrasound TAP ($n = 31$)	Laparoscopic TAP ($n = 29$)	*P* value
Estimated blood loss (ml) median (IQR)	50 (25–100)	30 (20–62.5)	.39[a]
Case time, min.; median (IQR)	157 (120–199)	153 (124.5–198)	.72 [a]
Conversion to open no. (%)	0 (0)	0 (0)	> .99
Stoma creation no. (%)	0 (0)	2 (6.9)	.23
Colectomy type no. (%)			.64[b]
Right	16 (51.6)	14 (48.3)	
Left	4 (12.9)	2 (6.9)	
Sigmoid	11 (35.5)	13 (44.8)	
PONV no. (%)			
PACU	8 (25.8)	3 (10.3)	.18[c]
12 h post-op	5 (16.1)	5 (17.2)	> .99 [c]
24 h post-op	4 (12.9)	3 (10.3)	>.99 [c]
48 h post-op	3 (12.5)	1 (4.4)	.61 [c]
Time (h) to oral pain medication median (IQR)	25.9 (22.9–33.1)	27.5 (24.3–42.5)	.23 [a]
Time (h) to discharge median (IQR)	50.8 (46.4–73.0)	50.4 (46.1–70.0)	.74 [a]

min minutes, *PONV* post-operative nausea or vomiting), *PACU* post-anesthesia care unit, *post-op* post-operative, *h* hours

[a]Statistical analysis performed using Mann–Whitney *U* test

[b]Statistical analysis performed with χ^2

[c]Fisher's exact test. All *P* values reported as 2 sided

Post-operative narcotic consumption

Post-operative narcotic requirement administration was recorded from admission to the PACU until 48 h following the operation. Intravenous and oral doses were converted to oral morphine equivalents. Cumulative opiate consumption at the time of PACU discharge (median [IQR] milligrams of morphine, 1.8 [0–4.5] UTAP vs. 0 [0–8.7] LTAP $P = .32$), 6 h post-operatively (5.4 [1.8–17.1] UTAP vs. 3.6 [0–12.6] LTAP $P = .28$), at 12 h post-operatively, (9.0 [3.6–29.4] UTAP vs. 7.2 [0.9–22.5] LTAP $P = .51$), at 24 h post-operatively, (9.0 [3.6–29.4] UTAP vs. 7.2 [0.9–22.5] LTAP $P = .63$), and 48 h post-operatively (39.9 [7.5–70.2] UTAP vs. 22.2 [7.5–63.8] LTAP $P = .41$)

(Fig. 3A). There were no significant differences at any time point.

The upper boundary (favoring anesthesia-delivered UTAP) of the 95% confidence interval of the difference of mean opiate consumption between groups was 3.3 in the PACU, 2.6 at 6 h post-op, 7.1 at 12 h post-op, 12.6 at 24 h, and 18.1 at 48 h. Since the pre-determined non-inferiority margin was 15 mg of morphine, surgeon-delivered LTAP met the non-inferiority criteria at all points up to and including 24 h but not at 48 h (Fig. 3B).

Pain scores

Patient-reported pain scores at rest (RPS) and with motion (MPS) were recorded on a scale from 0 to 10 in the PACU and at 6, 12, 24, and 48 h post-operatively (Fig. 4A). Mean resting pain score ± standard deviation (SD) at 48 h was 2.8 ± 2.7 and 1.4 ± 1.6 ($P = 0.048$) for anesthesia-delivered UTAP and surgeon-delivered LTAP, respectively (Fig. 4B). There were no other significant differences at any other time point.

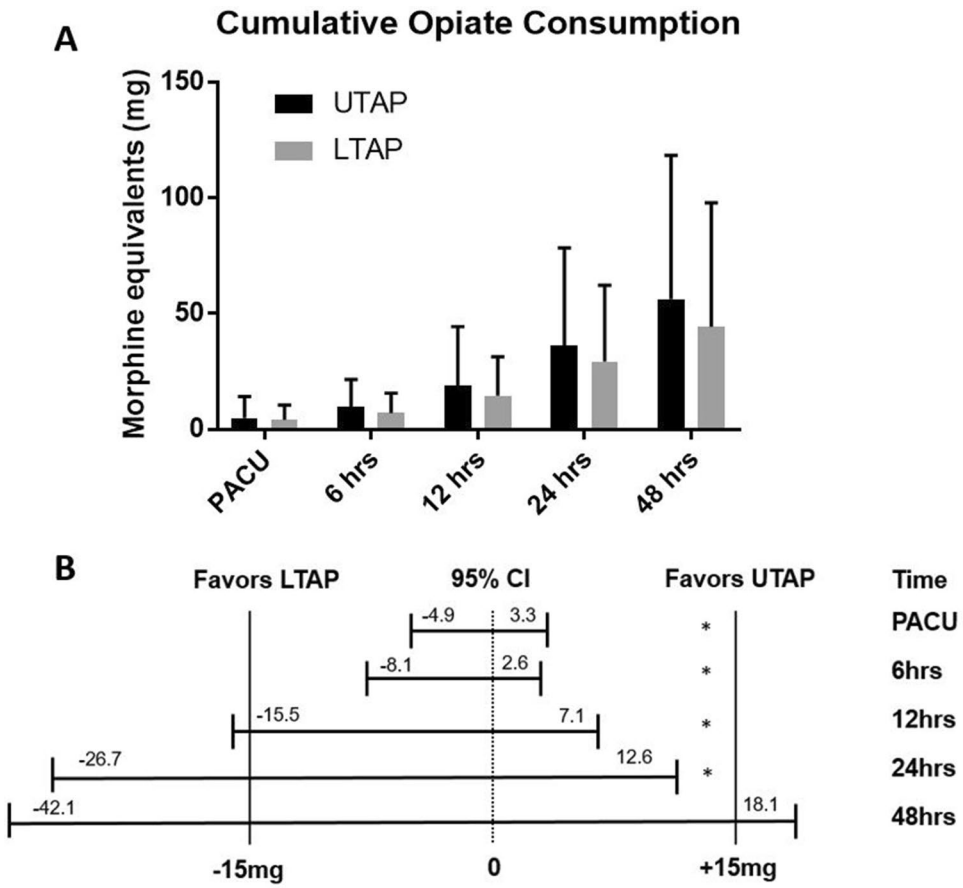

Fig. 3 Post-operative narcotic consumption. **A** No significant differences in opiate requirement between anesthesia-administered ultrasound-guided TAP block (UTAP) and surgeon-administered laparoscopic TAP block (LTAP) Bars represent mean opiate consumption ± SD. **B** Graphic representation of 95% CIs of difference of means of opiate requirements in relation to 15 mg non-inferiority margin. Numbers indicate bounds of 95% CI. *Signifies met non-inferiority criteria at indicated time point. *PACU* post-anesthesia care unit, *mg* milligrams

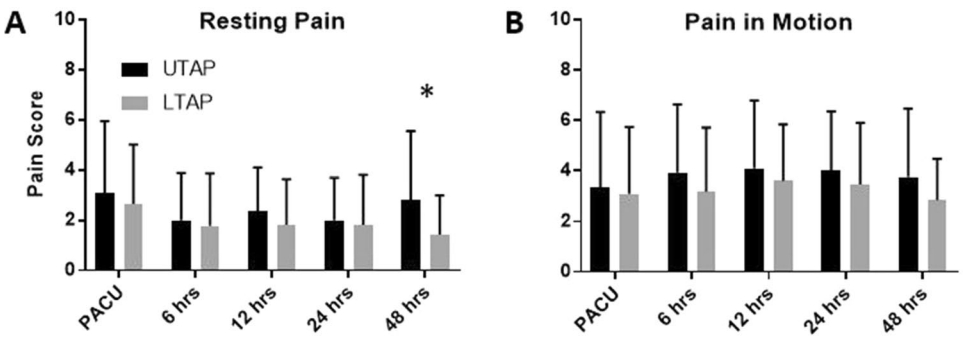

Fig. 4 Post-operative pain scores. No differences in patient-reported pain scores at rest (**A**) or in motion (**B**) between UTAP and LTAP groups. Bars represent mean scores ± SD. *$P < 0.05$. *UTAP* ultrasound-guided transversus abdominis block, *LTAP* laparoscopic-guided transversus abdominis block, *PACU* post-anesthesia care unit

Discussion

In this prospective, randomized, non-inferiority trial comparing LTAP *vs.* UTAP, we found that surgeon-delivered LTAPs were non-inferior to anesthesia-delivered UTAPs in the first 24 h post-operatively with regard to cumulative narcotic requirement in these similar groups. In the 48 h following surgery, there were no significant differences in narcotic requirement or patient-reported pain scores (except at the 48 h resting pain score which favored surgeon-delivered LTAPs). Therefore, we conclude that surgeon-delivered LTAPs are non-inferior to anesthesia-delivered UTAPs in patients undergoing laparoscopic colorectal resections.

Over the past two decades, TAP blocks have been shown to reduce post-operative pain and narcotic requirement in patients undergoing a wide range of surgery requiring abdominal incision [6, 7, 22, 23]. A number of studies have also demonstrated that TAP blocks reduce time to discharge prompting the inclusion of the TAP block into many ERAS protocols [8, 24]. This effect persists in newer studies using liposomal formulations of the local anesthetic [25, 26]. Moreover, the growing body of evidence surrounding TAP block and its inclusion in individual society ERAS guidelines demonstrates that TAP blocks are a reliable and broadly applicable non-narcotic adjunct to post-operative pain management [4, 7].

Laparoscopically guided TAP blocks have been gaining popularity in recent years and several studies have demonstrated their efficacy; however, direct comparisons between LTAPs and UTAPs are lacking. [14–18] One previous study which examined LTAP *vs.* UTAP in Korean patients undergoing colorectal resections demonstrated that LTAP was non-inferior although the primary outcome was subjective pain scores. Our findings build upon those of Park and colleagues in several important ways [15]. First, these authors employ an intra-abdominal approach to LTAP using a laparoscopic needle rather than a percutaneous technique, which requires specialized equipment for administration. Second, our patients more accurately reflect the United States population with a mean BMI of 29.3 as compared to their cohort with a mean BMI of 24.

A recent study by Zaghiyan et al. examined a protocol similar to our own for LTAPs in comparison to anesthesia-delivered UTAPs and patients receiving no TAP [18]. This study found that LTAPs were superior to UTAPs; however, in this study UTAPs had no benefit over the no TAP group in the primary endpoint of 24 h morphine consumption calling into question the efficacy of the UTAPs delivered in this study. Similar to the study by Park and colleagues, average BMI in the Zaghiyan trial was between 23.6 and 25.6. Nevertheless, the superiority of LTAP over UTAP in their study reinforces the results of this study that LTAP is, at the least, non-inferior to UTAP.

There was no difference in length of stay, operating room time, or other operative or post-operative parameters between UTAP and LTAP. Anecdotally we feel that surgeon-administered LTAPs decrease operating room time as compared to a UTAP when performed before the patient leaves the operating room. However, our study did not seek to compare operative time and the large standard deviation in case time precluded identification of differences in this context. Additionally, while billing practices and compensation rates vary, we suggest that performing surgeon-delivered TAP blocks as part of the surgery avoids potential fees involved with a separate operator and additional required equipment.

A strength of this study was its performance in the context of our ERAS protocol with both narcotic and non-narcotic pain medication used at the patient's discretion. The primary outcome in this study was post-operative opioid requirement as compared to other studies that have focused primarily on patient-reported pain scores [10, 15]. We felt that an emphasis on the objective measure of post-operative opiate requirement was more generalizable, and thus we chose that value as our primary outcome. Opiate requirement differs among patients both in effective dose and agent and this variation is reflected in the wide range of dosage used by patients in this study. While lacking some of the uniformity of other studies, we believe that this "real-world" method further emphasizes the generalizability of these findings in modern colorectal surgery.

This study has several limitations. There was no placebo arm in this trial, which would have strengthened conclusions about the efficacy of LTAP and UTAP; however, given the widespread adoption of TAP block in abdominal surgery, our institutional review board felt that excluding patients from a proven non-narcotic adjunct was not ethical. Another limitation is the employment of opiate patient-controlled analgesia (PCA) in the initial post-operative period instead of an immediate transition to oral pain medication which is the case in many ERAS protocols. There are a range of doses, routes of administration (single vs. multiple injections and continuous infusion), and timing used for TAP blocks. This study specifically compares bupivacaine with epinephrine in one subcostal injection site bilaterally at the end of the operation in an academic teaching hospital. Therefore our findings may not be generalizable to other techniques, formulations of local anesthetic, or healthcare settings [23, 27]. All patients underwent peri-umbilical midline extraction of the specimen in this study and thus generalizability to other extraction sites is limited. Cadaver studies with single subcostal TAP injections have demonstrated broad spread along the abdominal wall encompassing multiple thoracic segmental nerves; however, this technique may not be adequate for Pfannenstiel incisions [27]. Finally, the proportion

of patients who had undergone previous abdominal surgery in the LTAP group was nearly twice that of the UTAP group, which could have resulted in potential confounding with patient opiate consumption and pain scores.

Conclusion

Multimodal adjuncts to post-operative pain management have become the standard of care in colorectal surgery. While there remains debate about which method or medication is best for patients, our results demonstrate that surgeon-delivered LTAP is safe, simple, effective, and non-inferior to anesthesia-delivered UTAP. This method should be considered in all patients undergoing laparoscopic colorectal surgery where an ultrasound-guided TAP block is planned.

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Compliance with ethical standards

Disclosures Dr. Curran reports personal fees from KCI Inc, outside the scope of the submitted work. Dr. Wong, Dr. Poylin, and Dr. Cataldo have no conflicts of interest or financial ties to disclose.

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