



# Effects of a multimodal analgesic pathway with transversus abdominis plane block for lumbar spine fusion: a prospective feasibility trial

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## Abstract

**Purpose** Lumbar spine fusion with anterior (ALIF) or lateral (LLIF) approach is a moderately painful procedure associated with significant length of hospital stay (LoS) and opioid requirements. We developed an opioid-sparing analgesic pathway of care for ALIF and LLIF, featuring transversus abdominis plane (TAP) block. In this study, we assessed the feasibility of performing the TAP block as an analgesic adjunct for ALIF or LLIF.

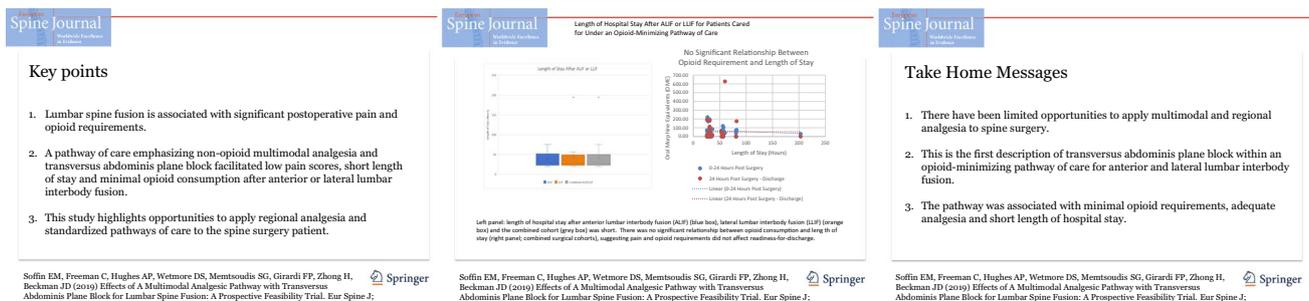
**Methods** This is a prospective feasibility study of 32 patients. All patients received pre-incisional TAP block, regularly scheduled non-opioid analgesics (gabapentin, acetaminophen, ketorolac), and oral tramadol, as needed. The primary feasibility outcomes were rates of recruitment, adherence and adverse events associated with the TAP block. Secondary outcomes included assessment of TAP block efficacy and duration, numeric rating scale (NRS) pain scores, LoS and opioid consumption.

**Results** Thirty-three patients were approached for the study, and all were enrolled. One patient did not have surgery. All patients received the intervention. There were no block-related adverse events. PACU NRS scores were significantly lower ( $1.9 \pm 3.0$ ) than at postoperative day 1 (POD1;  $3.3 \pm 2.5$ ). The TAP block was effective in 31/32 patients, with 1 failed block. Median LoS was 26.8 h (IQR 22.8–49.5 h). Median opioid consumption was 57.5 oral morphine equivalents (IQR 30–74.38). One patient required opioid iv patient-controlled analgesia.

**Conclusions** Applying TAP block to spine surgery is a novel pain management strategy. This study demonstrates high patient acceptance and the general safety of the technique. Although lacking a control arm, these results also provide preliminary data supporting efficacy.

## Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.



**Electronic supplementary material** The online version of this article (<https://doi.org/10.1007/s00586-019-06081-3>) contains supplementary material, which is available to authorized users.

Extended author information available on the last page of the article

**Keywords** Multimodal analgesia · Transversus abdominis plane block · Anterior lumbar interbody fusion · Lateral lumbar interbody fusion · Opioid epidemic · Spine surgery

## Introduction

Lumbar interbody fusion with anterior (ALIF) or lateral (LLIF) approach is a moderately painful procedure associated with significant postoperative opioid requirements and hospital length of stay (LoS) [1, 2]. Both pain and opioid-related side effects are major factors limiting recovery and rehabilitation after spine fusion, leading to calls for novel strategies for improving analgesia while minimizing opioid consumption in this population [3].

Minimizing opioid exposure while providing adequate analgesia has proven challenging after spine surgery: Traditional pain management strategies frequently rely on opioid monotherapy, and there have been limited opportunities for multimodal analgesia (MMA) and local anesthetic-based regional techniques. More recently, pathways of care for spine surgery which emphasize opioid-sparing MMA have been described [4–7]. To date, none include regional analgesia or field blocks as an element of care.

The transversus abdominis plane (TAP) block is an established method for providing opioid-sparing analgesia to the anterior–lateral abdominal wall after colorectal, gynecology, bariatric and urologic surgery [8]. In contrast, the TAP block has not been described in spine fusion with anterior or lateral approaches. Given the limited evidence to support TAP block and opioid-minimizing strategies for spine surgery, this trial was conducted to establish the feasibility and general safety of the technique in a spine surgery cohort. An allied aim of this study was to generate data to facilitate future comparative research. Specifically, we assessed effects of the pathway on postoperative recovery and requirement for opioid-containing intravenous patient-controlled analgesia (iv-PCA). We hypothesized that a pathway of care with comprehensive MMA and TAP block would be (1) feasible to introduce to the care of ALIF/LLIF patients and (2) associated with opioid-sparing effects without negatively affecting pain states after ALIF and LLIF.

## Methods

### Study design

This is a prospective observational study of a clinical pathway of care for ALIF and LLIF. The study was designed to assess the feasibility and general safety of pathway implementation and associations with pain and opioid-related outcomes. Any patient between ages 18 and 80 presenting

one- or two-level primary standalone ALIF or LLIF was considered for enrollment. Exclusion criteria included hepatic or renal disease, chronic pain conditions, long-term gabapentin or pregabalin use (regular use for longer than 3 months), opioid tolerance, revision surgery and concomitant posterior surgery. Thirty-three patients were enrolled between November 2017 and December 2018. Thirty-two patients underwent surgery (17 ALIF and 15 LLIF) and were included in the final analyses (Fig. 1).

The primary feasibility outcomes were rate of recruitment (the ratio of the number of patients giving informed consent to the number of eligible patients approached to participate), adherence (the number of enrolled patients receiving pre-incisional TAP block) and adverse events (local anesthetic toxicity, hematoma, bleeding, intraperitoneal injection/bowel injury, lower extremity weakness or sensory changes ipsilateral to TAP block). Secondary outcomes included the number of patients requiring postoperative opioid iv-PCA, assessment of TAP block efficacy and duration, numeric rating scale (NRS) of pain at the surgical incision and at the back, length of hospital stay (LoS) and opioid consumption and opioid-related side effects.

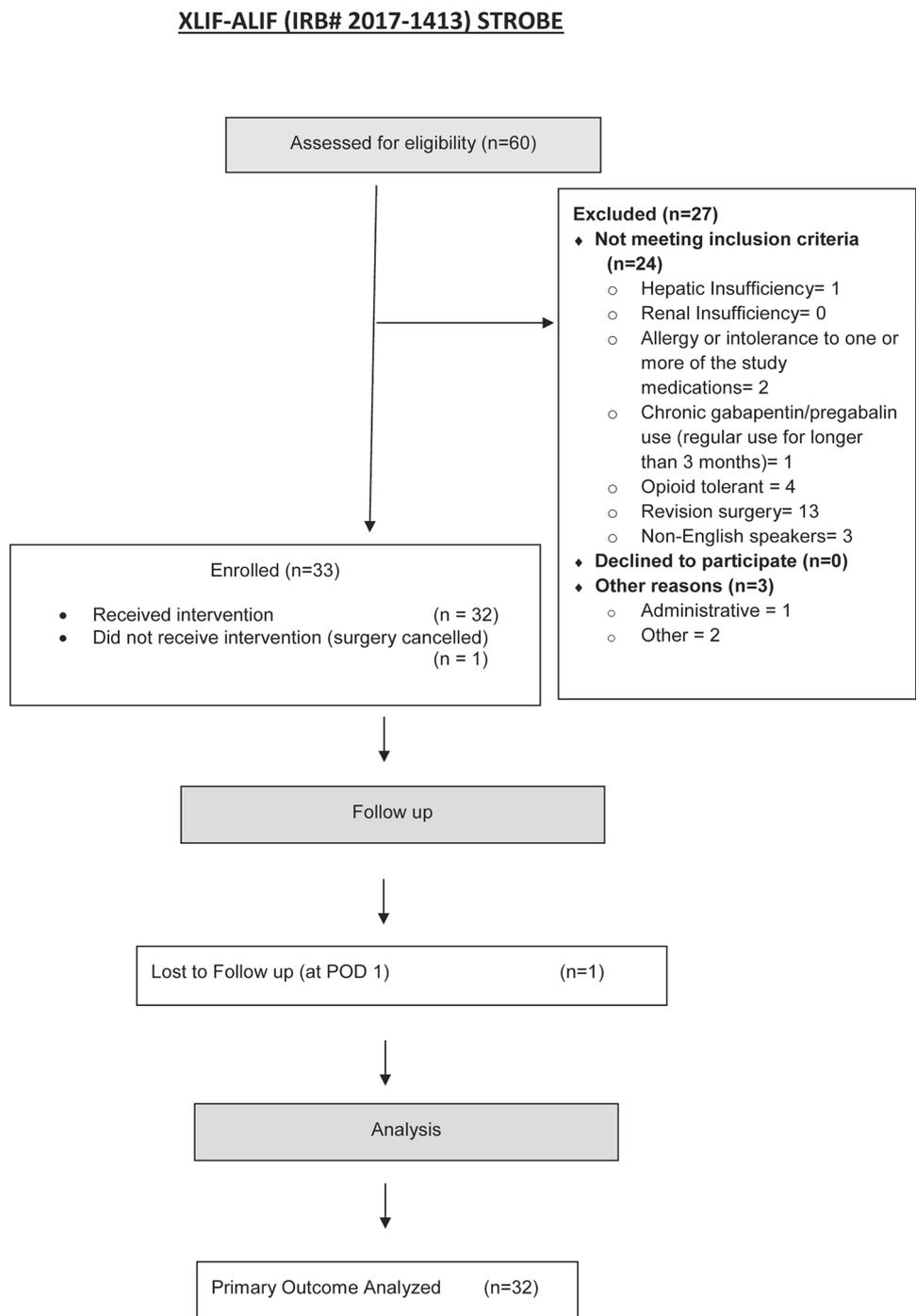
### Clinical pathway and surgical and anesthetic details

The clinical pathway is presented in Table 1. The pathway included 12 standardized pre-, intra- and postoperative care elements. All patients received general anesthesia (GA) with endotracheal intubation and an arterial line. An ultrasound-guided TAP block was performed ipsilateral to the planned surgical incision after induction of GA, prior to patient positioning for surgery. The probe was placed at the mid-clavicular line, midway between the anterior superior iliac spine and subcostal margin to obtain a transverse view of the abdominal layers [external oblique (EO), internal oblique (IO), transversus abdominis (TA)] and the peritoneal cavity. A 22-gauge × 3.5-inch Whitacre needle was advanced in-plane toward the aponeurosis between the IO and TA muscles, and 20–30 mL 0.5% bupivacaine with 2 mg preservative-free dexamethasone was injected. The expected duration of analgesia was 24 h.

### Surgical details

Patients were positioned in the lateral decubitus (LLIF) or the *DaVinci* supine position (ALIF). At our institution, a mini-open or muscle-preserving approach is utilized to

**Fig. 1** STROBE diagram showing flow of patients through the protocol. *POD* postoperative day



access the operative space [2]. A 4-cm incision was made with blunt dissection through the external and internal oblique muscles and transversalis fascia. The muscles were sequentially split in a minimal fashion, along the direction of their respective fibers. The retroperitoneal space was then entered and developed under direct palpation. Blunt dissection was carried out down to the disk space.

After fluoroscopic confirmation of the appropriate level, a minimally invasive retractor was docked and dilated at the segment. Through the dilating retractor, a standard discectomy, endplate preparation, trialing and implant insertion were performed under fluoroscopic control. Standard closure included absorbable closure of the TA, IO, EO and the dermal layer.

**Table 1** A clinical pathway for anterior lumbar interbody fusion and lateral lumbar interbody fusion*Preoperative*

1. Patient education and expectation setting: emphasizes expected LoS, anticipated pain and the role of opioids in pain management
2. Preemptive analgesia: oral acetaminophen (1000 mg), gabapentin (300 mg)
3. PONV risk assessment and prophylactic scopolamine patch (1.5 mg transdermal) for high-risk patients

*Intraoperative*

4. General anesthesia with endotracheal intubation and arterial line
5. Ultrasound-guided single-injection TAP block (20–30 mL 0.5% bupivacaine with 2 mg preservative-free dexamethasone)
6. Standardized mini-open surgical approach
7. Multimodal anesthetic and analgesic agents: ketamine (0.1–0.5 mg min<sup>-1</sup>), propofol (50–150 µg kg h<sup>-1</sup>) inhaled anesthetic (up to 0.3 MAC), lidocaine (1–2 mg kg h<sup>-1</sup>) limited opioids (hydromorphone up to 1 mg and/or fentanyl, up to 4 mcg kg<sup>-1</sup>) ketorolac (30 mg; 15 mg if weight < 60 kg or age > 70)
8. PONV prophylaxis: dexamethasone (4–8 mg), ondansetron (4 mg)

*Postoperative*

9. Continued scheduled acetaminophen, gabapentin, ketorolac
10. Oral opioids required, guided by NRS scores: NRS 5–7 = tramadol 50 mg × 2 doses, PRN; NRS > 7 = oxycodone 5–15 mg
11. Intravenous opioids as required, after all other MMA agents exhausted and NRS ≥ 8
12. PONV treated as needed

*TAP* transversus abdominis plane, *PONV* postoperative nausea and vomiting, *MMA* multimodal analgesia

## Data collection

Patients were assessed three times: preoperatively (in the holding area), postoperatively (in the post-anesthesia care unit, PACU) and at 24 h after surgery (postoperative day 1, POD1). Patients rated their worst pain on an NRS scale where 0 = no pain and 10 was the worst imaginable pain. Back pain and pain at the surgical incision site were assessed separately. TAP block efficacy was assessed twice: in the PACU and at POD1. Efficacy was assessed by sensory function testing using a monofilament and patient-reported NRS of sensation, where 0 = complete numbness/no sensation and 10 = full sensation. The T7-L1 dermatomes were tested on both the operative (TAP block) and non-operative (no block) sides. Opioid-related side effects were assessed by scores on the Opioid-Related Symptom Distress Scale (ORSDS) [9].

## Statistical methods

### Sample size

We studied an intervention in a population without published or institutional data. Sample sizes of 12–15 patients per group have been recommended for pilot and feasibility studies [10].

### Statistical analyses

Groups (ALIF and LLIF) were compared for balance on baseline variables by calculating standardized differences, calculated as the difference in means divided by the square root of the mean sample variance. Differences of 20% or less

indicated adequate balance. All analyses were performed on an intention-to-treat basis. Continuous variables are presented as mean (M) and standard deviation (SD), and categorical outcomes are presented as counts and percentages. Normality of distribution was determined by Shapiro–Wilk testing where significance of > 0.05 indicated normally distributed data. Skewed data are presented as median (MED) and interquartile range (IQR) and compared with Mann–Whitney U test. Changes in NRS scores over time were analyzed using generalized estimated equations (GEE) with an unstructured correlation structure and identity link. Comparison of TAP block efficacy between ALIF and LLIF was made via unpaired *t* test. LoS was compared using Hodges–Lehman scale parameter estimates. A Pearson product–moment correlation coefficient was computed to assess the relationship between opioid consumption and LoS.

### Missing data

The primary outcome was analyzed for all patients who underwent surgery. One patient was lost to follow-up for assessments at POD1. Data for this patient were excluded from analysis of secondary outcomes at POD1.

## Results

### Demographics

Patient demographics and procedural details are presented in Table 2. Standardized differences were consistent with

**Table 2** Patient and surgical characteristics

	Treatment group		Standardized difference
	LLIF ( <i>n</i> = 16)	ALIF ( <i>n</i> = 17)	
Age (years), mean ± SD	58.8 ± 10.3	47.4 ± 11.2	− 1.0635
BMI (kg m <sup>−2</sup> ), mean ± SD	28.8 ± 3.9	27.6 ± 4	0.1737
Female, count (%)	6 (38)	5 (29)	− 0.1721
Race, count (%)			0.395
White	12 (75)	13 (77)	
Black or African American	1 (6)	1 (6)	
Asian	0 (0)	1 (6)	
Declined/unknown	3 (19)	2 (12)	
Ethnicity, count (%)			− 0.6258
Hispanic or Latino	6 (38)	2 (12)	
ASA class, count (%)			
I	4 (25)	4 (24)	0.1187
II	12 (75)	13 (76)	
Length of surgery (min), mean ± SD*	56.9 ± 19.6	111.5 ± 27.9	2.9089
No. of levels fused, count (%)*			0.7368
I	10 (63)	16 (94)	
II	5 (31)	1 (6)	

*BMI* body mass index, *ASA* American Society of Anesthesiology

\*One patient enrolled in the LLIF group did not have surgery. Length of surgery and the number of levels fused are reported for *n* = 15 patients who underwent LLIF

acceptable balance among the groups in patient age, ASA class, BMI, gender and race. The mean duration of surgery for ALIF was longer than LLIF.

### Primary and secondary outcomes

A total of 60 patients were screened for eligibility. Of these, 27 were excluded for failing to meet inclusion criteria (*n* = 24), administrative (*n* = 1; anticipated surgery end time outside duty hours for research assistant to collect PACU outcome data), or other reasons (*n* = 2; patients participating in other competing research studies). No patients declined to participate in the study, resulting in a recruitment rate of 100%. All patients who underwent the planned procedure received the intervention, resulting in an adherence rate of 100%. No major adverse events were noted.

One patient required hydromorphone iv-PCA after one-level LLIF. TAP efficacy was assessed for 32 patients in PACU and for 31 patients at POD1. The block was successfully performed in 31/32 patients in PACU with one failed block (patient-reported full sensation in all dermatomes tested) (Fig. 2). Fifteen patients (47%) reported full or almost full resolution of the TAP block by POD1.

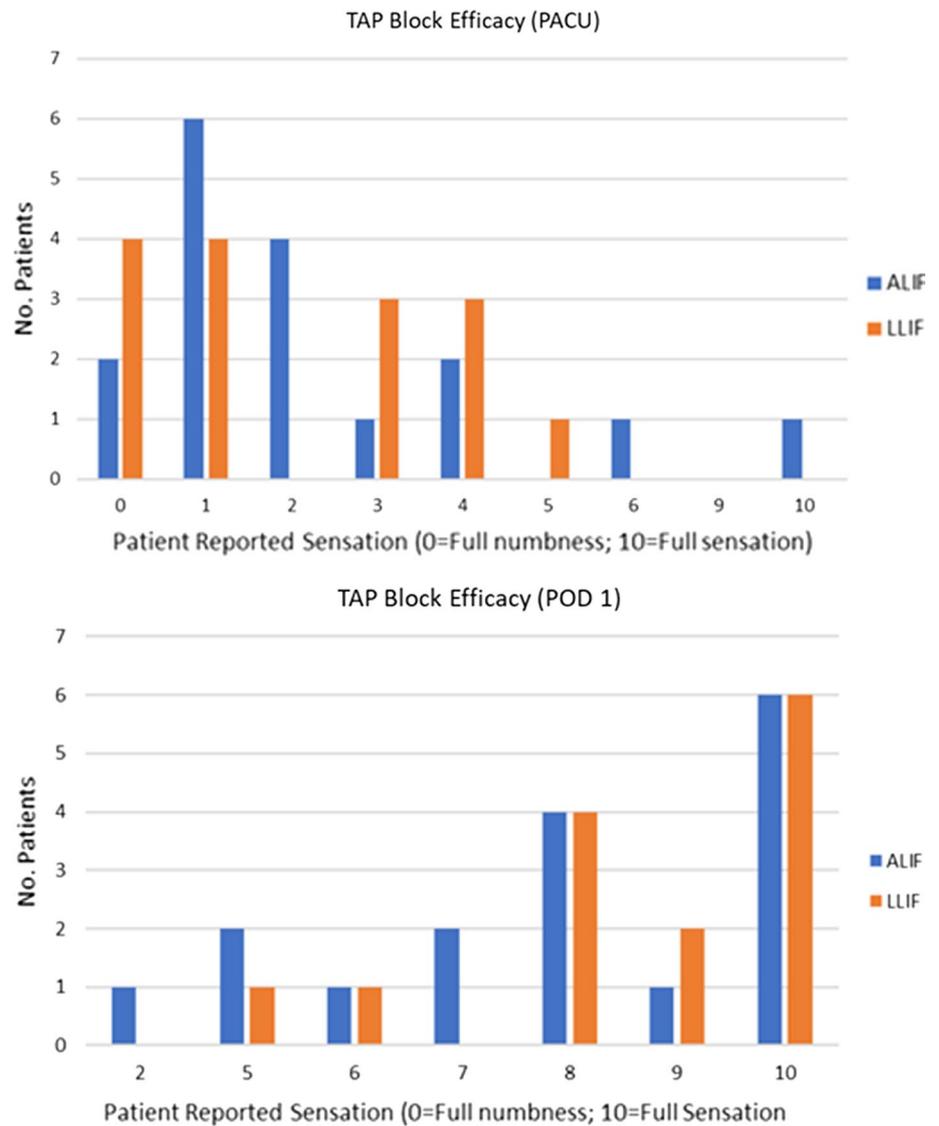
Mean NRS pain scores at the surgical incision site were significantly lower in the PACU compared to POD1 for the combined cohort (Table 3, Fig. 3). Subgroup analyses

confirmed this finding for both surgical subtypes (Table 3, Fig. 3). In contrast, mean NRS scores for back pain were significantly higher in PACU compared to POD1 for the combined cohort as well as on subgroup analyses (Table 3, Fig. 3).

Median opioid consumption in the first 24 h was 57.50 (30–74.38) oral morphine equivalents (OME) for the full cohort and no significant difference in opioid consumption between patients undergoing ALIF and LLIF (Table 3). Median opioid consumption from POD1–discharge was low for the full cohort (10 OME; 0–53.1) with no significant differences between the surgical subtypes found on subgroup analyses (Table 3). Three patients (9.7%) took no opioids during the first 24 h, 15 patients (48.4%) took no opioids after the first 24 h, and 2 patients did not take any postoperative opioids. The median ORSDS score was 0.3 (0.1–0.5) with no significant difference in ORSDS scores between the two procedure types.

Median LoS was 26.8 h (22.8–49.5 h) for the combined cohort, and there was no significant difference in LoS between the two surgical subtypes (Fig. 4). Ten patients were discharged within 24 h of surgery (5 ALIF and 5 LLIF). There was no significant relationship between opioid consumption and LoS at POD1 ( $r^2 = 0.0147$ ) or from POD1–discharge ( $r^2 = 0$ ) (Fig. 4).

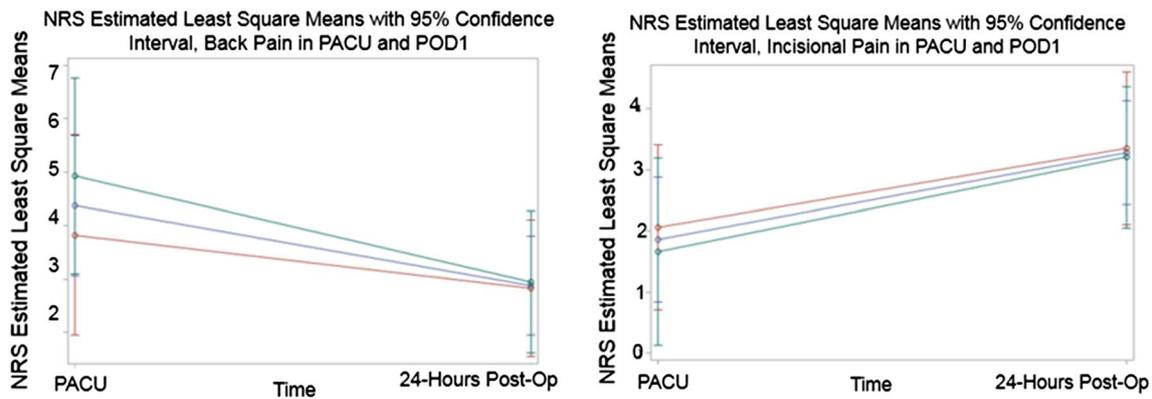
**Fig. 2** TAP block efficacy and duration, assessed in the post-anesthesia care unit (PACU; top panel) and at postoperative day 1 (POD1; bottom panel)



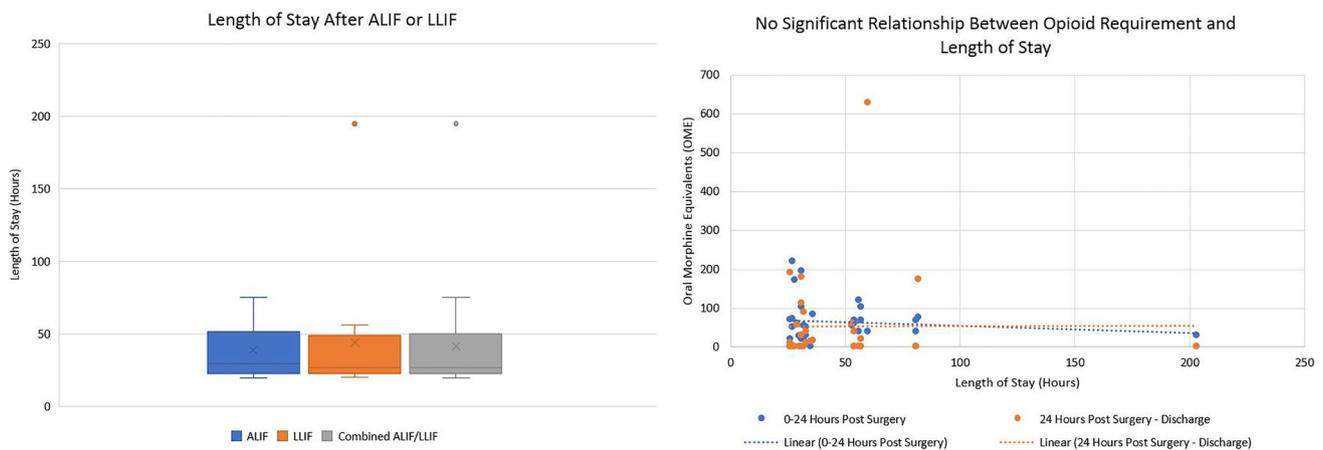
**Table 3** Pain scores and opioid use

Outcome	LLIF <i>n</i>	ALIF <i>n</i>	Combined <i>n</i>	<i>p</i> value*
NRS back pain, mean ± SD				
PACU	15 4.9 ± 3.8	17 4.3 ± 3.9	32 4.3 ± 3.9	0.03
Post-op 24 h	14 3 ± 2.7	17 2.8 ± 2.8	31 2.9 ± 2.7	
NRS incisional pain, mean ± SD				
PACU	15 1.7 ± 3.1	17 2.1 ± 2.9	32 1.9 ± 3	0.04
Post-op 24 h	14 3.2 ± 2.3	17 3.4 ± 2.7	31 3.2 ± 2.5	
Opioid consumption (OME) (MED, IQR)				
PACU to 24 h post-surgery	15 50 (27.5, 67.5)	17 60 (35, 73.5)	32 57.5 (30, 74.38)	ns
24 h post-surgery-to-discharge	14 0 (0, 60)	17 16 (0, 48.75)	31 10 (0, 53.13)	ns

*NRS* numeric rating scale, *PACU* post-anesthesia care unit, *OME* oral morphine equivalents



**Fig. 3** Back (left panel) and incisional pain (right panel) scores over the first 24 h after ALIF (red line), LLIF (green line) and for the combined cohort (blue line)



**Fig. 4** Length of hospital stay after ALIF, LLIF and the combined cohort (left panel). There was no significant relationship between opioid consumption and length of stay (right panel; combined surgical cohorts)

### Discussion

This prospective, observational study evaluated the feasibility of an opioid-sparing pathway of care for patients undergoing ALIF/LLIF. We found high recruitment and adherence rates and no major complications, suggesting feasibility of this technique in spine surgery. We associated the pathway with minimal opioid requirements, low pain scores and short LoS. Except for surgical duration, we did not find significant differences in outcomes between the two surgical subtypes, suggesting that the same pathway can be applied to both procedures in future studies.

Given that the TAP block was performed after induction of GA, it was not surprising that we found high patient acceptability. Adherence was also high as expected, likely because TAP block requires minimal time, equipment and expertise to perform [8]. We acknowledge that our

institution benefits from comprehensive regional anesthesia services, all anesthesiologists providing spine surgery care are trained in advanced regional techniques, and our surgical colleagues support the culture of providing regional analgesia. Other practice settings lacking developed services may not find similar high rates of adherence due to practitioner and workflow issues. Finally, there were no complications associated with the TAP block in this study. This is consistent with published accounts of the TAP block as a relatively simple, safe block to perform, with few reported complications [8, 11]. Rare complications include local anesthetic systemic toxicity, bowel injury (perforation and hematoma), transient femoral nerve palsy and liver laceration.

An emerging body of research links pathways of care for spine surgery to improved outcomes [4–7]. All reports emphasize the importance of MMA, but the optimal regimen is unclear, and none include peripheral nerve or field blocks.

The requirement for rapid, ongoing neurologic assessment after spine surgery may preclude regional techniques which have the potential liability of epidural spread of local anesthetic (epidural analgesia or lumbar paravertebral blocks). Alternatives to epidural and paravertebral blocks are rapidly being described and applied to spine surgery, including erector spinae plane [12] and thoracolumbar interfascial plane blocks [13]. Both have demonstrated benefits for pain control and opioid consumption after spine surgery with posterior approaches.

The TAP block may represent the optimal field block for ALIF and LLIF by providing motor-sparing analgesia at the sites of surgical incision and dissection, without the potential liability of epidural or lumbar plexus spread and compromised postoperative examination. The TAP block is relatively simple to perform and is recommended as part of MMA in society and clinical guidelines for patients undergoing abdominal/pelvic surgeries [11]. The main alternative to TAP block is surgeon-administered local infiltration analgesia (LIA). However, we chose TAP block for our pathway given the high level of evidence of superiority of TAP blocks over LIA for analgesia and opioid-sparing benefits after abdominal and pelvic surgery [14].

Pain after spinal fusion can be severe and is frequently associated with high opioid requirements [3]. Given this, our finding that mean NRS scores were low, and only one patient required opioid iv-PCA was surprising. We attribute this finding to the bundled delivery of multimodal anesthetic and analgesic choices, consistent with established principles underlying effective MMA for orthopedic procedures [15]. We included individual analgesic components of care with high levels of evidence for benefit in spine surgery. Two recent SR/MAs concluded gabapentin improved pain scores and decreased opioid consumption and opioid-related side effects after lumbar fusion and decompression [16, 17]. Intraoperative ketamine infusion reduces analgesic consumption and pain intensity after spine surgery and may also minimize PONV [18]. NSAIDs are analgesic and opioid-sparing after lumbar fusion [19]. Recent analyses balancing the analgesic benefits of NSAIDs with potential consequences on bone remodeling and fusion suggest that a short course of a low-dose NSAID is probably safe [20]. We limited intraoperative opioids and prescribed the lowest dose(s) of postoperative opioids to achieve analgesia according to NRS scores; these strategies may protect patients from the development of opioid-induced hyperalgesia and harmful exposure [15, 21].

Postoperative opioid consumption was variable, and all but two patients required oral opioids. Nonetheless, ORSDS scores were low, and median LoS was short, suggesting that pain and opioid-related side effects were not major factors limiting recovery. Indeed, we did not find a relationship between LoS and total OME consumed during

the postoperative phase of care. Opioid consumption is increasingly identified as an independent risk factor affecting recovery and discharge after spine surgery, where extended admission may be needed to achieve pain control and/or to treat opioid-induced side effects [22]. Analgesic and opioid-sparing effects of our pathway may contribute to the rapid time-to-discharge reported here.

Consistent with this, the median length of stay associated with the pathway (26.8 h) was shorter than is described in studies reporting outcomes after ALIF or LLIF (2 to 5 days) [1, 2]. Longer hospital stays are associated with increased risk of complications after spine surgery [23]. Thus, it is critical to identify factors and interventions associated with shorter LoS after spinal fusion. LoS is multifactorial, and we are unable to determine which factors, or combination of factors, contributed to our shorter LoS. Previous studies in lumbar fusion have associated patient factors (including BMI, age and ASA class) and surgical factors (operative duration, transfusion requirement and multilevel procedures) with extended LoS [23, 24].

## Limitations

A major limitation of this study was the pragmatic design. As a prospective feasibility study, the trial lacked a control group and was not blinded. Additional limitations include generalizability of our results to practice settings lacking developed regional anesthesia/analgesia services or where surgical expertise precludes anterior and lateral approaches to spinal fusion. Finally, our surgical population comprises overall younger, relatively healthy patients, and we excluded patients with chronic pain conditions and opioid dependence. Thus, the results may not be universally applicable to other populations presenting for ALIF or LLIF. In any event, special caution in older patients or those with higher baseline opioid requirements should be exercised when considering the use of multiple pharmacological agents as described here.

## Future work

This study evaluated the feasibility of providing a novel analgesic pathway for ALIF/XLIF. Future research is required to define the components associated with positive outcomes and to determine their relative contributions. The ideal future trial would be a prospective randomized, placebo-controlled trial of TAP block versus placebo or saline/sham block in patients undergoing ALIF or LLIF within a standardized pathway. The global value of the TAP block remains to be evaluated in this context, particularly as relates to the optimal duration of sensory block. If extended-duration TAP block is desired, future research should include the role of TAP catheters, long-acting local anesthetics (such

as liposomal bupivacaine) and/or other adjuvants added to plain bupivacaine to extend the duration of analgesia. Given the higher cost of liposomal bupivacaine compared to plain bupivacaine, studies which evaluate the benefits of and requirements for extended-duration analgesia are needed before routinely incorporating liposomal bupivacaine into pathways of care. We also encourage future randomized controlled trials comparing liposomal bupivacaine to pain bupivacaine plus dexamethasone–TAP blocks, as well as comparisons between TAP and surgeon-administered LIA. Likewise, the TAP block could be compared to other field blocks within spine care pathways and with other strategies for minimizing opioids for spine surgery [25]. Finally, these results suggest that TAP block may be of more value for incisional vs. skeletal pain, and this merits further study.

Although we did not analyze potential cost savings of our pathway, it is possible that significant reductions in length of stay may be achieved via care approaches which emphasize opioid-minimizing analgesia. Allied to this, if pain can be adequately controlled without use of intravenous opioids, ALIF and LLIF procedures may be moved to the outpatient or ambulatory settings in appropriate patients, creating further potential resource savings. These topics represent important subjects for future study.

## Conclusions

This study established the feasibility of studying the TAP block within a standardized pathway of care for patients undergoing ALIF/LLIF. The pathway was associated with modest pain scores and opioid consumption and short LoS. Well designed, adequately powered trials exploring the benefits of TAP block and opioid-minimizing strategies for spine surgery are required before concluding safety and efficacy of these techniques.

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## Compliance with ethical standards

**Conflict of interest** EMS, CF, DSW, HZ and JDB declare no conflicts of interest. APH declares conflicts of interest with the following (not related to this study): 4WEB Medical, NuVasive, Inc., Mallinckrodt Pharmaceuticals and Pfizer, Inc. FPG declares conflicts of interest with the following (not related to this study): Lanx, Nuvasive, Orthodevelopment Crop, Depuy Spine, Small Bone Innovations, Pioneer Surgical Technology, Life Spine, Centinel Spine, Spinal Kinetics, Paradigm Spine, Gerson Lehrman Group, Spineart USA, Pharmawrite, Scient'x USA, HealthpointCapital and MiMedx. SGM is the owner of SGM Consulting, LLC, and FC Monmouth LLC is a former consultant for Teikoku and Sandoz and a patent holder for multicatheter infusion system.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Hospital for Special Surgery Institutional Review Board: HSS IRB 2017-1413) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed consent** Written informed consent was obtained from all individual participants included in the study.

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