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ORIGINAL ARTICLE

Randomized double-blind trial of short- versus long-acting analgesia at the sacrospinous ligament

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Abstract

Introduction and hypothesis Pain control is a key component of postoperative care; our objective was to evaluate if use of long-acting local anesthesia at the sacrospinous ligament leads to decreased postoperative pain versus short-acting local anesthesia in patients undergoing sacrospinous ligament fixation.

Methods Women ≥ 18 years old undergoing sacrospinous ligament fixation to treat pelvic organ prolapse were eligible to participate in this randomized trial. Enrolled patients were randomized 1:1 to one of two study arms: (1) lidocaine arm (LA) or (2) liposomal bupivacaine arm (LBA). Patients in the LA received 30 ml 0.5% lidocaine with 1:200,000 epinephrine local injection at the sacrospinous ligament. Patients in the LBA received 20 ml 1.3% bupivacaine liposomal mixed with 10 ml 0.5% bupivacaine at the sacrospinous ligament. All patients received 50 ml 0.5% lidocaine with 1:200,000 epinephrine for anterior and/or posterior colporrhaphy. The primary outcome of this study was postoperative buttock pain.

Results Of the 37 patients enrolled, 33 completed study procedures. Mean age (± SD) was 62.3 years (± 11.6) in the LA and 66.8 years (± 14.4) in the LBA ($p = 0.32$). All participants underwent sacrospinous ligament fixation; the rate of concomitant procedures did not differ between study arms. Visual analog scale scores for buttock-specific pain were compared between arms at 1, 3, 6, 12, 24, 36, 48, 72, 96, and 120 h postoperatively, and no differences were found.

Conclusions Use of long-acting local analgesia at the sacrospinous ligament at the time of sacrospinous ligament fixation does not provide any benefit over short-acting local analgesia.

Keywords Pain, postoperative · Anesthesia, local · Pelvic organ prolapse · Bupivacaine, lidocaine, gynecologic surgical procedures

Introduction

In 1997, Kehlet introduced the use of multimodal interventions to accelerate postoperative recovery [1]. Multimodal pathways, also known as "enhanced recovery pathways," have been evaluated in the gynecology literature [2, 3]. Kalogera et al. demonstrated adequate pain control with decreased opioid use and reduced length of hospital stay in patients undergoing gynecologic surgery for benign and malignant indications [2]. More recently, Chapman et al. evaluated enhanced recovery in minimally invasive surgery for gynecologic malignancy and showed earlier time to hospital discharge, adequate pain control with decreased use of narcotics, and lower cost [3].

A key component in the postoperative multimodal pathway is "effective, dynamic pain relief with multimodal pain therapy" [1]. Other components in the postoperative period are influenced by effective pain control, including nausea/ileus, disturbances in sleep, catabolism/muscle loss, and immobilization [1]. In addition to providing patient comfort, effective pain control can have a positive impact on these other key factors. Combined use of local anesthetics, systemic non-steroidal anti-inflammatory drugs, and opioids are suggested to achieve optimal control of postoperative pain [1, 4].

Implementing non-narcotic solutions to pain control is an important issue, especially given the current opioid addiction epidemic [5]. Intraoperative use of injected local anesthesia is

This study was registered at ClinicalTrials.gov (NCT02890199).

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an important non-narcotic component of postoperative pain control in gynecologic surgery. Research shows that use of local anesthesia at the time of vaginal hysterectomy, posterior colporrhaphy, and trans-obturator midurethral sling placement decreases postoperative pain [6–8]. However, studies have shown that the duration of this effect is limited to 4 h for posterior repair [7], 6 h for trans-obturator sling [8], and 8 h after vaginal hysterectomy [6]. These studies used short-acting anesthetics with duration of action ranging 1.5–15 h. Longer-acting local anesthesia with duration of action up to 96 h is available and has been studied. In patients undergoing hemorroidectomy, one such longer-acting anesthetic, liposomal bupivacaine, decreased postoperative pain, opioid use, and opioid-related adverse events [9, 10]. Liposomal bupivacaine has been studied for use in posterior colporrhaphy and showed no differences in pain scores with injection at the surgical site at the conclusion of the procedure [11]. However, liposomal bupivacaine use has not yet been evaluated in sacrospinous ligament fixation. Our primary objective was to evaluate if use of long-acting local anesthesia at the sacrospinous ligament leads to decreased postoperative pain versus short-acting local anesthesia in patients undergoing sacrospinous ligament fixation (SSLF).

Materials and methods

This was a randomized, double-blinded trial of locally injected pain medications at the time of SSLF for pelvic organ prolapse. This study was approved by the Hartford Healthcare Institutional Review Board (Hartford, Connecticut) and was registered at ClinicalTrials.gov (NCT02890199). This project was funded by a research grant from the American Association of Gynecologic Laparoscopists. Consecutive patients were recruited at Hartford Hospital's Division of Female Pelvic Medicine and Reconstructive Surgery from November 2016 to June 2017, inclusive. This study was designed and reported using Consolidated Standards of Reporting Trials (CONSORT) guidelines [12].

Women ≥ 18 years of age who were scheduled for SSLF to treat pelvic organ prolapse were eligible to participate. Patients were eligible to participate if the planned surgical procedure was to be completed entirely by a vaginal approach. Patients undergoing concomitant hysterectomy or incontinence procedures also were allowed to participate. If the planned surgery included any laparoscopic or abdominal procedures, patients were excluded. Other exclusion criteria were a history of narcotic abuse or chronic narcotic use within 6 months of the surgical procedure; history of chronic pelvic pain, allergy, or intolerance to study medications; and kidney or liver disease. Physicians and research nurses approached study candidates and obtained informed consent. The allocation sequence was generated by simple randomization using a computer. Once informed consent had been obtained and prior to the surgical procedure, patients were randomized 1:1 to one of two study arms: (1) lidocaine arm or (2) liposomal bupivacaine arm. Patients in the lidocaine arm received 30 ml 0.5% lidocaine with 1:200,000 epinephrine local injection at the sacrospinous ligament. Patients in the liposomal bupivacaine group received 20 ml 1.3% bupivacaine liposomal mixed with 10 ml 0.5% bupivacaine at the sacrospinous ligament. Patients in both study arms received 50 ml 0.5% lidocaine with 1:200,000 epinephrine for the anterior and/or posterior colporrhapy. If a patient underwent placement of a midurethral sling, 0.9% injectable saline was used for retropubic hydrodissection. Other than pain medication injected at the sacrospinous ligament, all other pain control procedures were the same for both study arms (Box 1). The pain control procedures utilized represent a multimodal protocol established based on a prior study conducted in our department [13].

Box 1 Multimodal pain regimen

Preoperative
- Celecoxib: 200 mg orally, once
- Gabapentin: 300 mg orally, once

Intraoperative
- Locally injected pain medications per study group assignment
- Ketorolac 15 mg intravenous at the conclusion of the surgical procedure

Postoperative, in hospital
- Scheduled acetaminophen: 500 mg orally every 6 h
- Scheduled non-steroidal anti-inflammatory:
  - Ketorolac 15 mg intravenous every 6 h for 4 doses (discontinued when tolerating oral intake)
  - Ibuprofen 600 mg orally every 6 h (start 6 h after last dose of ketorolac)
- Oral opioids:
  - Oxycodone
    - 5 mg orally every 4 h as needed for moderate pain (pain 4–6/10)
    - 10 mg orally every 4 h as needed for severe pain (pain 7–10/10)
  - If oxycodone not tolerated, oral hydromorphone:
    - 2 mg orally every 4 h as needed for moderate pain (pain 4–6/10)
    - 4 mg orally every 4 h as needed for severe pain (pain 7–10/10)
- Breakthrough pain (pain greater than 7/10 more than 1 h after receiving oxycodone): hydromorphone 0.4 mg intravenous once, may repeat once after 20 min if first dose is ineffective

Postoperative, post-discharge
- Scheduled acetaminophen: 500 mg orally every 6 h for 3 days, then as needed for pain, #50
- Scheduled ibuprofen: 600 mg orally every 6 h for 3 days, then as needed for pain, #50
- Oral opioids:
  - Oxycodone 5 mg, #24
    - 1 tablet every 6 h as needed for mild pain not controlled by motrin and acetaminophen

- 2 tablets every 6 h as needed for severe pain, not controlled by motrin and acetaminophen
- If oxycodone is not tolerated, dilaudid 2 mg, #12
  - 1 tablet orally every 6 h as needed for mild pain not controlled by motrin and acetaminophen
  - 2 tablets every 6 h as needed for severe pain, not controlled by motrin and acetaminophen

All participants and postoperative data collectors were blinded to treatment group assignment. Due to differing appearances of the medications, it was not possible to blind surgeons. The computer-generated allocation list was kept under lock by the primary investigator who was not blinded (KP). At the time of randomization, each participant was given a study identifier. On the date of the surgical procedure, the primary investigator determined the study group assignment based on the allocation list and study identifier. Study group assignment was revealed to surgeons at the time of the surgical procedure via direct communication between the primary investigator and the attending surgeon for the procedure. Four fellowship-trained Female Pelvic Medicine and Reconstructive Surgery surgeons performed all surgical procedures. Enrollment continued until the target number resulting from an a priori power analysis was attained. No interim analysis was planned.

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Hartford Hospital [14]. At the time of study enrollment, baseline characteristics were collected, and the Charlson Comorbidity Index score was calculated [15]. Baseline characteristics included: age, body mass index (BMI), history of pelvic surgery, pelvic organ prolapse quantification (POP-Q) [16] examination, and baseline pain assessment (modified Surgical Pain Scale, mSPS) [17]. At the time of the surgical procedure, the vagina was opened, dissection into the right pararectal space was performed, and the sacrospinous ligament was directly visualized. Once dissection was complete, local anesthetic was injected under direct visualization per study group assignment. Once injection was complete, two zero polydioxanone sutures were placed through the ligament using an open-access Capio™ device. Intraoperative data were collected at the conclusion of the procedure: procedure performed, procedure duration, estimated blood loss, complications, adverse events/medication reactions, whether vaginal packing was used, and type of stirrups used for patient positioning.

Postoperative data were collected by blinded study staff. A visual analog pain scale (VAS) [18] was completed for all subjects at 1, 3, 6, 12, 24, 36, 48, 72, 96, and 120 h postoperatively. Two VAS scores were collected at each time point: (1) general postoperative pain and (2) buttock pain with laterality, if present. The frequency of scale administration was chosen to evaluate pain trends and to assess if, and when, the greatest change in pain occurred between arms. The mSPS was collected at 3, 7, 14, and 28 days postoperatively. Date of first postoperative bowel movement was recorded. Total narcotic and antiemetic usage during hospitalization was collected. Post-hospital discharge narcotic usage was evaluated at 4 and 7 days post-hospital discharge. As participants could have used either oxycodone or hydromorphone for pain control, milligrams used were converted to morphine milligram equivalents (MME) for statistical analysis. All subjects underwent a backfilled trial of void (TOV) on the day of hospital discharge. Results were recorded as pass/fail. Satisfaction with pain control during the hospital stay was assessed with two 5-point Likert questions. Hospital length of stay was recorded and was defined as duration of time from the end of the surgical procedure to time of hospital discharge. During the 30-day postoperative period, number of patient phone calls to the office and reason for the call were recorded. It also was noted if a patient required refill of narcotic medication, readmission, or reoperation.

The primary outcome of this study was postoperative buttock pain. Secondary outcomes included global postoperative pain, postoperative opioid use, return to baseline pain status, postoperative time to first bowel movement, postoperative antiemetic use, results of postoperative trial of void, and patient satisfaction with in-hospital pain control.

As there were no studies of liposomal bupivacaine in vaginal repair of pelvic organ prolapse at the start of this trial, power analysis was based on prior studies comparing short-acting local analgesia with injectable saline. These studies showed a difference of 40–60% decreased pain with use of local analgesia [6, 7, 9]. Therefore, this study was powered to detect a 45% difference between arms in pain scores at any observation. An 11-point VAS scale was used to assess the primary outcome with 0 representing no pain and 10 representing maximum pain. Based on VAS, power calculation indicated that a sample size of 26 (13 per arm) would afford 82% power to detect a difference of 45% (e.g., 8.0 vs. 3.6 or 7.0 vs. 3.2) between the null hypothesis that the mean of both arms was 7.0 and the alternative hypothesis that the mean of the experimental arm was 50% less, with estimated standard deviations of half of each mean. These assumptions used a two-sided, two-sample *t* test with a significance level (alpha) of 0.05. To account for attrition/loss to follow-up as high as 10%, a sample of 30 women (15 per arm) was planned.

Continuous descriptive data (e.g., VAS pain scores) were reported as mean and standard deviation (±SD) or median with interquartile range (IQR), depending on distribution. Categorical data were reported as frequencies, using percentages. Pain scores at each time point and overall narcotic and antiemetic use were compared between arms. Mean pain levels at each time point were plotted as a line graph to visualize the time that the arms begin to or cease to differ. Pain scores were compared using Student's *t* test or Mann-Whitney

U, depending on distribution. Narcotic and antiemetic use was compared using Student's *t* test or Mann-Whitney U, depending on data distribution. Pain levels and narcotic usage were also compared as dichotomized variables using Fisher's exact test. Trial of void results were compared between arms using Fisher's exact test. The postoperative day of first bowel movement was evaluated using a Student's *t* test. All single-point time analyses were conducted with an a priori alpha level of 0.05; results yielding $p < 0.05$ were deemed statistically significant. All descriptive and inferential analyses were conducted with SPSS v. 21 (IBM, Armonk, NY, 2013).

Results

Seventy patients were screened for eligibility; 37 consented to participation and 33 completed study procedures (Fig. 1). Demographic and procedure characteristics are listed in Table 1. All participants underwent SSLF with anterior and/or posterior repair. The study arms did not differ in demographic characteristics or in rates of concomitant hysterectomy or placement of retropubic midurethral sling. There were no intraoperative adverse events in the lidocaine group. One patient in the liposomal bupivacaine group experienced an intraoperative adverse event, ureteral kinking, which required removal and replacement of the SSLF sutures.

Postoperative pain was compared between arms. Buttock-specific and global pain were compared between arms at 1, 3, 6, 12, 24, 36, 48, 72, 96, and 120 h postoperatively. No differences were found between the arms for buttock-specific pain (Fig. 2). Global postoperative pain differed between the arms at 36 h with median (IQR) pain score 4.0 (1.5–4.5) in the lidocaine arm and 0 (0–3) in the liposomal bupivacaine arm ($p = 0.04$). Otherwise, there were no differences between the arms in global postoperative pain (Fig. 3). Proportion of patients reporting a VAS score of zero buttock-specific pain did not differ between arms at any time point. Proportion of patients reporting a VAS score of zero for global postoperative pain differed at 36 h with 3 patients (17.6%) in the lidocaine arm reporting zero pain versus 9 (60.0%) in the liposomal bupivacaine group ($p = 0.02$). Otherwise, the proportion of patients reporting a VAS pain score of zero did not differ between arms.

Postoperative opioid use was assessed during hospitalization and at 4 and 7 days post-discharge. During hospitalization, at 4 days post-discharge, and at 7 days post-discharge,

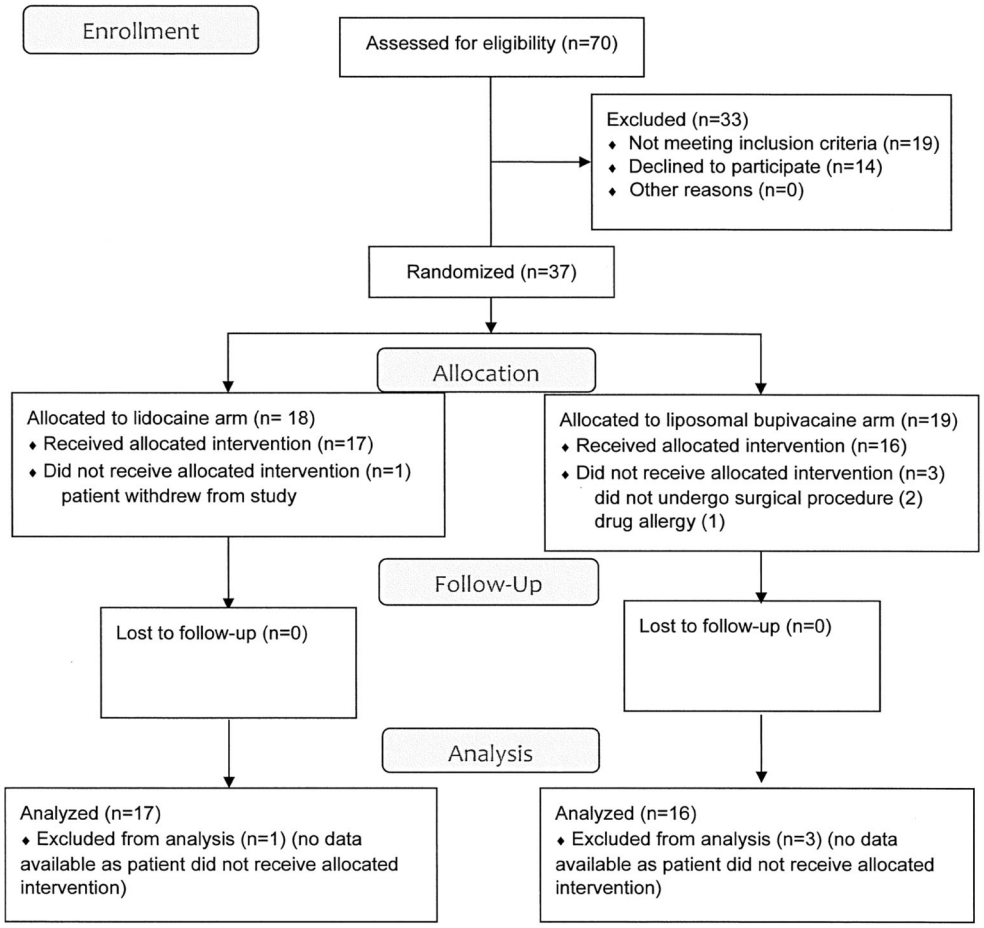

Fig. 1 Participant enrollment

Table 1 Study population demographics, medical history, and procedure characteristics

Variable	Lidocaine arm ($n = 17$)	Liposomal bupivacaine arm ($n = 16$)	p value
Age (years)	62.3 ± 11.6	66.8 ± 14.4	0.32*
BMI (kg/m^2)	28.9 ± 5.4	28.1 ± 5.1	0.67*
Charlson Comorbidity Index Score			0.78‡
0	1 (5.9)	2 (12.5)	
1	3 (17.6)	2 (12.5)	
2	6 (35.3)	3 (18.7)	
3	4 (23.5)	5 (31.3)	
4	3 (17.6)	4 (25.0)	
History of pelvic surgery	10 (58.8)	11 (68.8)	0.72+
History of hysterectomy	7 (41.2)	7 (43.8)	1.0+
Prolapse stage			0.35‡
I	0	1 (6.3)	
II	10 (58.8)	5 (31.3)	
III	6 (35.3)	9 (56.3)	
IV	1 (5.9)	1 (6.3)	
mSPS			
Question 1	0 (0–1.5)	0 (0–2)	0.92§
Question 2	1 (0–2.5)	0.5 (0–3.75)	0.90§
Question 3	3 (0–4) ($n = 11$)	1 (0–4.25) ($n = 14$)	0.68§
Question 4	0 (0–3)	0 (0–4.75)	0.63§
Concomitant vaginal hysterectomy	6 (35.3)	3 (18.8)	0.43+
Concomitant retropubic midurethral sling	5 (29.4)	9 (56.3)	0.16+
Surgery duration (min)	117.4 (61.8)	122.5 ± 53.2	0.77*
Estimated blood loss (ml)	133.8 ± 61.8	137.5 ± 105.7	0.90*
Stirrups used			1.0+
Candy cane	7 (41.2)	7 (43.8)	
Yellofin™	10 (58.8)	9 (56.3)	
Vaginal pack placed	14 (82.4)	11 (68.8)	0.43+

BMI, body mass index

Question 1: What was the average amount of pain you had when you were at rest?

Question 2: How much pain did you have during your normal activities?

Question 3: How much pain did you have when you were exercising, doing strenuous work, or lifting objects you used to be able to lift comfortably?

Question 4: How unpleasant or disturbing was the worst pain that you had today?

Data are mean ± standard deviation, n (%), or median (IQR)

*t test

+ Fisher exact test

‡ χ^2

§ Mann-Whitney U

there were no differences in MME used between study arms: 15.0 (7.5–29.5) MME in the control arm versus 11.5 (0–47.2) MME in the liposomal bupivacaine arm during hospitalization ($p = 0.84$), 15.0 (0–59.0) MME in the control arm versus 11.5 (0–59.0) MME in the liposomal bupivacaine arm at 4 days post-discharge ($p = 0.83$), and 15.0 (4.6–81.5) MME in the control arm versus 15.0 (0–112.0) MME in the liposomal bupivacaine arm at 7 days post-discharge ($p = 0.89$). Proportion of patients who used no narcotics was also compared between arms during hospitalization, at 4 days post-discharge, and at 7 days post-discharge, and no differences were found.

Return to baseline pain status was assessed by comparing baseline mSPS responses to those at 3, 7, 14, and 28 days postoperatively. Question 3 was eliminated from this comparison as most patients reported that they had not performed the activities referenced in Question 3. At 3, 7, 14, and 28 days postoperatively, there was no difference in change from

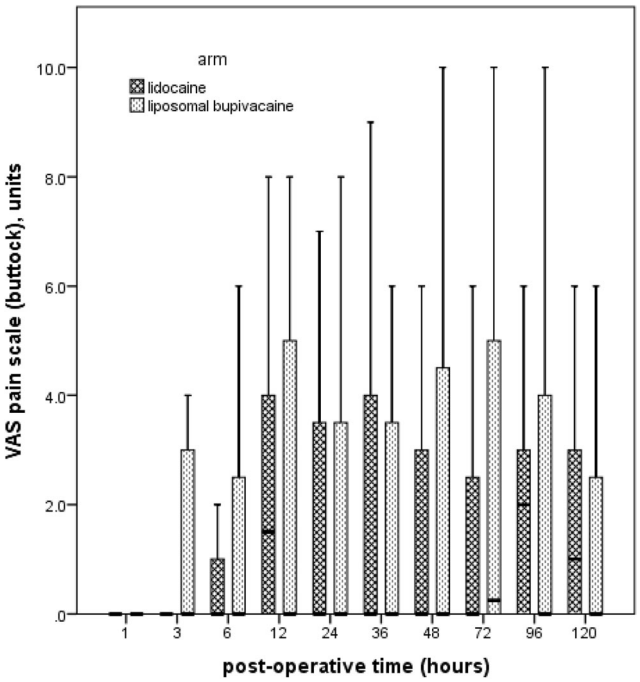

Fig. 2 Mean visual analog scale (VAS) pain scores for buttock pain, median and IQR

baseline pain scores between the study arms for any of the mSPS questions (Table 2). Time to first postoperative bowel movement did not differ between arms, with a mean of 2.9 (±1.1) days in the lidocaine arm and 3.2 (±1.2) days in the liposomal bupivacaine arm ($p = 0.47$).

There were no differences between the arms in mean antiemetic dose, duration of hospital stay, postoperative perineal/groin numbness, phone calls to the office, or narcotic prescription refills (all $p > 0.05$).

TOV results were compared between arms. Patients in the lidocaine arm passed the TOV at a significantly higher rate than those in the liposomal bupivacaine arm [15 (88.2%) and 8 (15%), respectively; $p = 0.02$].

Patient satisfaction with in-hospital pain control also was assessed. Patients were asked, "During your hospital stay, how often was your pain well controlled?" Responses did not differ between arms ($p = 0.65$). Patients were asked, "During your hospital stay, how often did hospital staff do everything they could to help you with your pain?" Responses did not differ between arms ($p = 1.0$).

Four patients in the liposomal bupivacaine arm experienced adverse events during the postoperative hospital course versus none in the lidocaine arm ($p = 0.04$). Adverse events included: one patient experienced symptomatic anemia and required transfusion of packed red blood cells; one patient developed a rectovaginal hematoma that did not require intervention; one patient was delirious, and one patient had a right sciatic nerve sensory neuropathy that resolved without intervention.

No patients were readmitted in the 30-day postoperative period. One patient in the lidocaine arm underwent reoperation in the 30-day postoperative period; this patient underwent placement of a mid-urethral sling because of stress urinary incontinence.

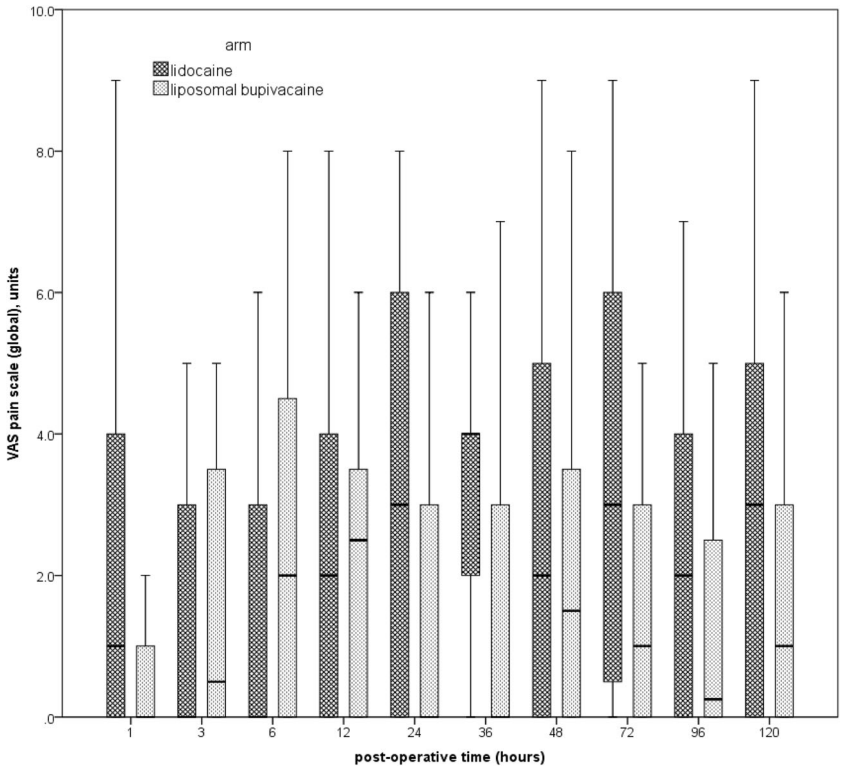

Fig. 3 Mean visual analog scale (VAS) pain scores for global postoperative pain, median and IQR

Table 2 Postoperative modified surgical pain scale

Postoperative time	Lidocaine arm	Liposomal bupivacaine arm	*p* value (Mann-Whitney U)
3 days	*n* = 16	*n* = 16	
Question 1	1 (−0.75–2.75)	0 (−0.75–5.25)	0.98
Question 2	2.5 (0.25–4)	0 (−0.75–5.75)	0.46
Question 4	4 (3–6.75)	1.5 (0–6)	0.21
7 days	*n* = 17	*n* = 15	
Question 1	1 (−1–2)	0 (−1–3)	0.94
Question 2	2 (−2–3)	0 (−1–4)	0.91
Question 4	2 (−1–2.5)	0 (−2–4)	0.85
14 days	n- = 17	n- = 16	
Question 1	0 (−1–1)	0.5 (−0.75–2.75)	0.32
Question 2	0 (−2–2)	0 (−1.5–3.75)	0.63
Question 4	1 (−1–2.5)	0 (−3.25–2.75)	0.63
28 days	*n* = 17	*n* = 16	
Question 1	0 (−1.5–0.5)	0 (−1.5–1.75)	0.63
Question 2	0 (−2.5–1)	0 (−2.75–1.5)	0.63
Question 4	0 (−3–2)	0 (−4.75–1.75)	0.79

Data are median and interquartile range (IQR)

These data represent change from baseline; an improvement from baseline is indicated by negative numbers

Data are listed per time point because of missing responses

Question 1: What was the average amount of pain you had when you were at rest?

Question 2: How much pain did you have during your normal activities?

Question 3 was eliminated from this comparison as most patients reported that they had not performed the activities referenced in Question 3

Question 4: How unpleasant or disturbing was the worst pain that you had today?

Discussion

In this randomized trial of local anesthesia for postoperative pain control following SSLF, we found few differences between the study arms. Patients in the liposomal bupivacaine arm experienced less global postoperative pain than the lidocaine arm at the 36-h post-surgical time point, failed the TOV at a significantly higher rate and had more adverse events during the postoperative hospital course.

The lack of differences in pain scores between arms may be related to several factors. In this project, we used a multimodal pain control regimen that has been shown to provide comparative pain relief with use of fewer narcotics [13]. Perhaps this regimen is effective enough on its own that further improvements via long-acting local analgesia are difficult to attain. Additionally, the SSLF represents only one portion of the procedures performed in these patients, and pain relief at the sacrospinous ligament is only one aspect of a patient's recovery. This study was powered to find a 45% difference in pain scores between arms. Patients in both arms experienced low overall pain scores; therefore, a difference of 45% was not detectable. The 45% difference was chosen based on studies of other local analgesics in pelvic surgery while keeping in mind the relatively high cost (~$300/dose) of liposomal bupivacaine. The authors believe that a large reduction in postoperative pain or narcotic medication use would be needed to justify the use of liposomal bupivacaine. After the start of this trial, a randomized trial comparing local injection of 0.25% bupivacaine to sterile water at the sacrospinous ligament showed decreased use of non-steroidal anti-inflammatory medications in the bupivacaine group but showed no differences in postoperative pain or narcotic use [19]. Based on our findings, long-acting analgesia also provides no additional benefit over short-acting local analgesia for SSLF.

The higher TOV failure rate in the liposomal bupivacaine arm was an unexpected finding. All injections were performed by placing the needle through the sacrospinous ligament and infiltrating the area deep to the ligament; it is possible that the injected medication that reached the parasympathetic innervation of the bladder temporarily impaired detrusor contraction. Use of liposomal bupivacaine has been studied in retropubic midurethral sling placement and showed improved pain and decreased narcotic use compared with placebo, with no differences in TOV results [20].

More adverse events were seen in the liposomal bupivacaine group. Of the four adverse events, two were bleeding-related. It could be hypothesized that this is related to the lack of epinephrine in the liposomal bupivacaine group

and resultant increased bleeding at the SSL. Use of epinephrine damages the liposomes and causes immediate release of the bupivacaine; it was therefore avoided at the SSL. It is unclear if use of epinephrine at the SSL would have prevented these adverse events.

Strengths of this study include its design as a randomized double-blind trial and inclusion of all Female Pelvic Medicine and Reconstructive Surgery surgeons at our institution. Both patients and postoperative data collectors were blinded.

Weaknesses of this study include the lack of a control group and a concern for lack of power to demonstrate the planned difference between arms. However, the fact that differences in pain scores between arms were relatively small, as were differences in secondary outcomes (as explained above), certainly came as a surprise given the values reported in the literature. Had the lower-than-expected differences been used in the power calculations, it would have resulted in far too large of a sample to have been practical, given time and resource considerations. Additionally, surgeons could not be blinded because of differing appearances of the study medications. Although surgeons did not perform any data collection procedures, they did have contact with patients postoperatively and could have introduced bias.

The findings in this trial indicate that long-acting local analgesia at the sacrospinous ligament at the time of SSLF does not provide benefit over short-acting local analgesia and may impair bladder function in the immediate postoperative period.

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Compliance with ethical standards

Conflicts of interest Adam C. Steinberg has received honoraria from Boston Scientific for speaking and educational activities. He also has received honoraria from Johnson and Johnson and Trevena for consultation.

All other authors declare no conflicts of interest.

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