Published in final edited form as:

Gynecol Oncol. 2015 September ; 138(3): 609–613. doi:10.1016/j.ygyno.2015.06.008.

Ultrasound guided subcostal transversus abdominis plane (TAP) infiltration with liposomal bupivacaine for patients undergoing robotic assisted hysterectomy: A prospective randomized controlled study

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Abstract

Introduction—Optimal pain control after major surgery contributes to a patient's recovery and satisfaction. The use of liposomal bupivacaine in subcostal transversus abdominis plane (TAP) blocks for postoperative pain control after robot assisted abdominal surgery has yet to be studied.

Methods—We conducted a prospective randomized controlled observer-blinded study comparing bilateral subcostal TAP blocks with bupivacaine to bilateral subcostal TAP blocks with liposomal bupivacaine. These were performed prior to the patient undergoing robot assisted hysterectomy. The patients' pain scores, opioid use, side effects, and satisfaction were followed for 72 h after injection.

Results—Total opioid use in the first 72 h after injection was significantly decreased in the group that received liposomal bupivacaine compared to bupivacaine. Patients in the liposomal bupivacaine group had significantly lower maximal pain scores at all time periods studied as well as decreased incidence of nausea/vomiting. There was a trend toward decreased length of stay in the liposomal bupivacaine group.

Conclusion—Subcostal TAP blocks with liposomal bupivacaine decreased the total opioid requirement for the first 72 h after robot assisted hysterectomy when compared to subcostal TAP blocks with bupivacaine.

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Conflict of interest statement

Jacob Hutchins is on the speaker's bureau, is a consultant, and has received grant funding from Pacira Pharmaceuticals. None of the other authors have anything to disclose.

Keywords

Robotic; Hysterectomy; Transversus abdominis plane; Liposomal bupivacaine; Post-operative pain; Acute pain

1. Introduction

Successful management of post surgical pain can have an impact on a patient's quality of life [1]. Studies have shown that effective management of pain during the acute phase can have an influence on whether or not chronic pain develops [2]. Opioids are routinely used to treat post surgical pain, but are associated with significant side-effects and have the potential risk for long-term abuse [3].

Robotic assisted hysterectomies have been shown to have similar postoperative pain as laparoscopic assisted hysterectomies [4]. When compared to open hysterectomy, robotic assisted hysterectomy have multiple advantages including lower associated blood loss, decreased length of stay, and fewer post-operative wound infections [5,6]. Despite these advantages and the significant increased usage of robotic procedures, minimal data exist on the postoperative pain management plan for patients undergoing robotic assisted hysterectomies. Previous studies have shown that a classic transversus abdominis plane (TAP) block (T10-L1 dermatomes) provides improved postoperative pain control in both open and laparoscopic hysterectomy patients [7,8]. Furthermore, meta analyses examining TAP blocks with bupivacaine for lower abdominal incisions report lower pain scores and reduced morphine consumption over 48 h when compared to opioid PCA [9]. We previously reported in a retrospective study that subcostal TAPs with liposomal bupivacaine decreased postoperative pain [10] but there has yet to be a prospective study evaluating the effect of TAP blocks with liposomal bupivacaine on postoperative pain control in robotic assisted hysterectomies.

Liposomal bupivacaine (EXPAREL®; Pacira Pharmaceuticals, Inc.; Parsippany, NJ, USA) is a multivesicular liposomal formulation of 1.3% bupivacaine, which provides up to 72 h of postoperative pain control in wound and TAP infiltration techniques [11,12]. It is a liposome technology where the reorganization of the triglycerides in the external lipid layer leads to release of the bupivacaine from within the vesicle. This leads to further reorganization of the vesicles and continued release of bupivacaine over several days.

We conducted a single institution randomized controlled trial (RCT) comparing a subcostal TAP block with standard bupivacaine against a TAP block with 1.3% liposomal bupivacaine. The primary objective of this study was to determine if a TAP with liposomal bupivacaine decreased total opioid use in the first 72 h following a robotic assisted hysterectomy compared to a TAP with bupivacaine HCl. The secondary objectives were to determine the effect of TAP with liposomal bupivacaine on minimal and maximal numerical rating score (NRS) pain scores, the presence of nausea/vomiting, patient's length of stay, and patient satisfaction.

2. Methods

2.1. Study population

Following approval by the University of Minnesota Institutional Review Board, all consecutive robotic hysterectomy patients were screened for enrollment between October 2013 and October 2014. This study was registered at clinicaltrials.gov (NCT02289079). The inclusion criteria were women age greater than or equal to 18, undergoing elective robotic assisted hysterectomy. Exclusion criteria included those converted to an open surgery, emergency surgery, non-English speaking patients, weight less than 60 kg, history of chronic pain, or opioid use for greater than three weeks prior to surgery.

2.2. Study design

We conducted a RCT at the University of Minnesota Medical Center to compare a subcostal transversus abdominis plane (TAP) block with standard bupivacaine against a TAP block with 1.3% liposomal bupivacaine. Eligible patients who provided consent were randomized 1:1 to either receive bilateral subcostal TAP blocks with 1.3% liposomal bupivacaine or with 0.25% bupivacaine HCl. The randomization was performed using a random number generator on the day of surgery. All surgical, nursing, and research personnel were blinded to the treatment assignment except for the anesthesiologist performing the patients' TAP block.

We planned to enroll and randomize 60 women with the goal of obtaining complete data on at least 48 (24 per group), assuming a 20% loss to follow-up. With a sample size of 48, we could achieve 80% power to detect a difference of 30% decreased total opioids at an alpha level of 0.05.

2.3. Study procedures

TAP blocks were performed in the preoperative holding area by one of four anesthesiologists on the regional anesthesia service. Once consented, patients were sedated using 1–2 mg of intravenous midazolam and/or 50–100 mcg of Fentanyl. Patients were attached to standard monitors and a safety time out was performed. The site was prepared with chlorhexidine gluconate and isopropyl alcohol prep stick (CareFusion, Leawood, Kansas USA). Using ultrasound, a 22-gauge 30° beveled needle was guided below the transversus abdominis fascia as previously described by Hebbard [13]. Once the needle pierced the transversus abdominis plane fascia a total volume of 30 mL was injected. For the liposomal bupivacaine group the 30 mL consisted 10 mL of 1.3% liposomal bupivacaine and 20 mL of normal saline. For the bupivacaine group the 30 mL consisted of 30 mL of 0.25% bupivacaine HCl with 1:200,000 of epinephrine. This process was repeated on the contralateral side. Within 30–60 min after injection the patients were taken to the operating room and underwent general anesthesia for the intended procedure. General anesthesia consisted of maintenance with isoflurane or desflurane, a neuromuscular blocker, and fentanyl and/or hydromorphone as per certified registered nurse anesthetist (CRNA) or anesthesiology resident discretion. The incisions consisted of five supraumbilical port sites.

Once in phase I of the Post Anesthesia Care Unit (PACU), patients were assessed for pain and treated with either hydromorphone or fentanyl at the nurse's discretion. Pain intensity was assessed and recorded by the PACU nurse. Patients were then transitioned to phase II after meeting discharge criteria from phase I. Phase I discharge criteria include an Aldrete score greater than 8 and pain controlled without IV opioids [14]. Once in phase II patients were assessed for tolerable pain control and either admitted for observation or discharged home. This was at the blinded surgeon's discretion and based on standard of care at out hospital. Robotic assisted hysterectomy patients are to be sent home the day of surgery once the following discharge criteria are met: adequate pain control, nausea/vomiting controlled, and able to void without difficulty.

2.4. Measures

The primary outcome of the study was total opioid use 0–72 h post-operatively, calculated as intravenous morphine equivalents using a standard conversion [15]. Secondary outcomes included self-reported pain intensity, pain medication use, length of hospital stay, nausea/vomiting, and patient satisfaction with pain control. Pain intensity was reported on an eleven point (0–10) NRS and both maximal and minimal pain were assessed at 0–24, 24–48, 48–72 h post-operatively by a blinded medical student or resident. If the patient was at home, they were called by a blinded medical student who asked a scripted list of questions to the patients to assess pain and medications used. Use of pain medications (opioids, Acetaminophen, Ibuprofen) taken during each of the first three 24 hour periods following surgery were self-reported. Patients were instructed to use acetaminophen and ibuprofen if their pain was moderate and to use opioids if their pain was severe. All opioids were converted to intravenous morphine equivalents. Patient's self-report of satisfaction with pain control was assessed using a survey given by a blinded research assistant via a telephone call at 72 h post injection. Length of surgery, estimated blood loss, intraoperative opioids, total time in phase I, total opioids in Phase I, length of hospital stay, patient-reported nausea and/or vomiting and demographics were abstracted from the patient's electronic medical record. Demographics collected included age, weight and American Society of Anesthesiologists (ASA) physical status classification system status.

2.5. Statistical methods

Baseline and operative characteristics were summarized and compared by randomization group using Chi-squared and Fisher's Exact tests as appropriate for categorical variables and T-tests and Wilcoxon Rank Sum tests as appropriate for continuous variables. Pain medication use and pain intensity scores were not normally distributed and therefore comparisons between randomization groups were conducted using Wilcoxon rank-sum non-parametric tests. The proportion of patients who reported nausea and/or vomiting during follow-up and patient-reported satisfaction with pain control was compared by randomization group using a Chi-squared test. The length of the post-surgery hospital stay (number of hours) was compared by randomization group using Poisson regression, adjusting for over-dispersion. p-Values for the numerous secondary outcomes were not adjusted for multiple comparisons. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC) and p-values of <0.05 were considered statistically significant.

3. Results

One hundred and ten patients were screened with 50 being excluded (Fig. 1). A total of sixty were consented and randomized. Two patient's procedures were converted to open within 30 min of procedure start, removed from the study, and therefore were excluded from data analysis per protocol. There were 58 patients analyzed; 28 randomized to the liposomal bupivacaine group and 30 to the bupivacaine group. One patient in the liposomal bupivacaine group was lost to follow up after their first post-operative day but was included in all analyses for which data were available.

The average age of patients was 56.8 ± 10.0 years and all were ASA classes I–III (Table 1). There were no significant differences in ASA class, age, length of surgery, estimated blood loss, and whether or not lymph nodes were removed. There was also no significant difference between the two groups in the amount of intraoperative opioids required. Final pathology for the bupivacaine group showed 21 patients with malignant and 9 with benign. For the liposomal bupivacaine group 20 were malignant and 8 were benign.

We found a greater than 50% reduction in total opioid use during the 72 hour post-operative period in those randomized to the liposomal bupivacaine group compared to those randomized to the bupivacaine group (median: 24.9 vs 51.7 mg Morphine equivalents; $p = 0.002$, Table 2). These results were primarily driven by differences between the randomized groups during the 0–24 and 24–48 hour postoperative periods described in detail below.

While in phase I of PACU, patients randomized to liposomal bupivacaine reported a statistically significant reduction in reported maximum ($p = 0.002$) and minimum ($p = 0.010$) NRS pain scores compared to those randomized to standard bupivacaine (Table 2). There was no difference between the two groups in opioid use or total time spent in the phase I.

Maximum and minimum NRS pain scores reported during the first 24 h postoperatively were statistically significantly lower for the liposomal bupivacaine group compared to the bupivacaine group ($p = 0.006$ and $p = 0.003$, respectively). Those randomized to the liposomal bupivacaine TAP blocks also used significantly fewer opioids during this time period than those randomized to standard bupivacaine ($p = 0.023$). Between 24 and 48 h, the maximum NRS pain scores remained statistically significantly lower in the liposomal bupivacaine TAP group ($p = 0.044$), though there was not a difference in minimal pain scores. There remained a statistically significant decrease in opioids for those receiving liposomal bupivacaine during this time period ($p = 0.015$). From 48 to 72 h postoperatively, there remained a significant decrease in maximal pain scores ($p = 0.047$) however the minimal pain score and opioid use were not statistically different during this time period. There were no statistically significant differences between the two groups in acetaminophen or ibuprofen use at any time point.

There was a substantial reduction in nausea between the two groups, with 7 (25.0%) reporting nausea in the liposomal bupivacaine group compared to 17 (56.7%) reporting nausea for the bupivacaine group ($p = 0.014$). In addition, those randomized to the liposomal bupivacaine group trended toward requiring a shorter hospital stay (11.0 ± 9.1 h) than those

in the standard bupivacaine group (17.0 ± 13.9 h; $p = 0.055$). Twenty-six patients required 24-h observation; 11 (39%) in the liposomal bupivacaine group and 15 (50%) in the standard bupivacaine group ($p = 0.412$). One patient in each group had a procedure finish after 1800 thus leading to an overnight observation.

A total of 55 patients reported their satisfaction with pain control; 26 (92.9%) of the liposomal bupivacaine group and 24 (82.8%) of the bupivacaine group reported being highly satisfied with their pain control ($p = 0.423$).

4. Discussion

This is the first RCT evaluating the use of liposomal bupivacaine in a subcostal TAP block for patients undergoing robotic assisted hysterectomies. We found patients randomized to liposomal bupivacaine TAP compared to bupivacaine TAP had improved postoperative analgesia with greater than 50% decrease in total opioid use in the first postoperative 72 h. Furthermore the decrease in maximal pain scores reported from 0 to 24, 24 to 48, and 48 to 72 hour time points, decreased incidence of nausea and vomiting, and a trend toward a decreased length of hospital stay suggest that the use of liposomal bupivacaine offers not only an immediate but also prolonged postoperative analgesic benefit.

The prolonged analgesic benefit shown in this study suggests that liposomal bupivacaine provides extended duration of action when compared to bupivacaine. What is surprising is that there was a significant opioid sparing effect at 0–24 h postoperatively when the two groups were compared. TAP blocks have been described to last anywhere from 6 to 24 h [16]. It's likely that since there was a significant difference at 24 h the bupivacaine TAP blocks in our study lasted less than 24 h. This shorter duration could explain why we saw both an opioid sparing and pain score decrease effect with the liposomal bupivacaine group. The continued difference in maximal pain scores and opioid use during the 24–48 hour time period and maximal pain scores during the 48–72 hour time period illustrates that the decrease in total opioids seen was not just due to a large difference in the first 24 h. Despite the decreased maximal pain and total opioid use, both groups reported high satisfaction rates with their postoperative pain control.

The greater than 50% decrease in total opioids in the first 72 h post-operatively is of great importance. There is continuing focus on minimizing the amount of postoperative opioids. They are a contributing factor to the observation of increased nausea and vomiting in the first 72 h postoperatively. Nausea and vomiting is a common opioid related adverse event (ORAE) as well as urinary retention, oversedation, pruritus, constipation, and respiratory depression [17]. Those patients who have ORAE have been shown to have increased length of stay as well as increased hospital costs [18]. In addition a recent alert from Joint commission conveyed the need for safe use of opioids in the hospital [19].

There are few randomized trials evaluating the use of TAP blocks in robotic procedures. Recently, Hotujec et al. evaluated the effect of a unilateral TAP block with 0.25% bupivacaine and epinephrine compared to a unilateral sham TAP block on postoperative opioid use in patients undergoing robotic hysterectomy [20]. There was no difference between the two interventions in that study however, the mean morphine use in the first 24 h

was 64.9 mg morphine equivalents in the TAP group and 69.3 mg Morphine equivalents in the sham block group. This is significantly larger than the total opioids used in the first 72 h postoperative in either of our TAP groups suggesting that bilateral TAP blocks may offer better pain control than unilateral TAP blocks.

Despite the use of a RCT, there are limitations to our study. The main limitation is that there was no protocol for opioid administration. Opioid administration was performed by PACU nurses, ward nurses, and patients. However, all were blinded to which group the patient was randomized to and this likely represents a real world scenario. We relied on patient recall and counting of medications taken each time period which could result in inaccurate numbers. Additionally the anesthesiologist performing the TAP blocks was not blinded to the study group designations as we were unable to account for the color difference in the two medications. Finally, the study was not powered to explore all of the secondary outcomes; a larger study would be needed to confirm those findings.

In summary, our RCT demonstrated that the use of liposomal bupivacaine in subcostal TAP blocks for robotic hysterectomy procedure decreased overall total opioid use when compared to bupivacaine TAP blocks. Larger RCTs with a detailed cost analysis are needed to confirm the benefits in patients undergoing robotic assisted abdominal procedures.

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HIGHLIGHTS

- We compare liposomal bupivacaine TAPs to bupivacaine TAPs.
- Liposomal bupivacaine TAP decrease maximal pain and total opioids.
- Liposomal bupivacaine TAP decrease nausea/vomiting.

Fig. 1.
Flow diagram of enrollment.

Table 1

Patient demographic and surgery characteristics by randomization group.

Variable	Bupivacaine (N = 30)		Liposomal bupivacaine (N = 28)		p-Value
	N	%	N	%	
ASA status					0.632
1 — Normal healthy patient	4	13.3	4	14.3	
2 — Patient with mild systemic disease	13	43.3	15	53.6	
3 — Patient with severe systemic disease	13	43.3	9	32.1	
Lymph nodes removed					0.300
No	18	60.0	13	46.4	
Yes	12	40.0	15	53.6	
Pathology results					
Malignant	21	70	20	71.4	
Benign	9	30	8	28.6	
Variable	N	Mean (SD)	N	Mean (SD)	p-Value
Age (years)	30	56.8 (10.0)	28	60.5 (10.8)	0.174
Weight (kg)	30	98.5 (34.2)	28	89.3 (25.1)	0.243
Variable	N	Median (range)	N	Median (range)	p-Value
Length of surgery (minutes)	30	245.5 (154–430)	28	256.5 (166–364)	0.479
Estimated blood loss (mL)	30	50.0 (20–200)	28	87.5 (20–500)	0.838
Intraoperative narcotics (MS equivalents)	30	35 (10–60)	28	33.8 (5–58)	0.673
Total time in PACU (minutes)	30	119.0 (44–398)	28	128.0 (45–195)	0.686

Table 2

Patient post-operative medication use and self-reported pain scores by randomization group.

Variable	Bupivacaine (N = 30)		Liposomal bupivacaine (N = 28)		p-Value
	N	Median (range)	N	Median (range)	
Primary outcome					
Total opioid use (MS equivalents, 0–72 h)	29	51.7 (0–249.7)	28	24.9 (0–86.7)	0.002
Secondary outcomes					
PACU					
Opioid use (MS equivalents)	30	12.5 (0–35.0)	28	9.0 (0–33.3)	0.206
Max pain score	30	6 (0–10)	28	5 (0–10)	0.002
Min pain score	30	3 (0–6)	28	1.5 (0–6)	0.010
0–24 h (including PACU)					
Opioid use (MS equivalents)	30	25.0 (5–88.3)	28	13.3 (0–50.0)	0.023
Acetaminophen use (mg)	30	650 (0–3575)	28	488 (0–6650)	0.494
Ibuprofen use (mg)	30	300 (0–2400)	28	0 (0–2400)	0.229
Max pain score	29	7.0 (1–10)	28	4.5 (0–10)	0.006
Min pain score	29	3.0 (0–8)	28	1.5 (0–5)	0.003
24–48 h					
Opioid use (MS equivalents)	29	7.5 (0–68.0)	28	2.9 (0–26.7)	0.015
Acetaminophen use (mg)	29	975 (0–2925)	28	163 (0–2600)	0.068
Ibuprofen use (mg)	29	0 (0–2400)	28	150 (0–2400)	0.753
Max pain score	29	5.0 (1–10)	28	4.0 (0–8)	0.044
Min pain score	29	2.0 (0–6)	28	2.0 (0–7)	0.942
48–72 h					
Opioid use (MS equivalents)	29	5.0 (0–40.0)	28	1.7 (0–11.7)	0.297
Acetaminophen use (mg)	29	0 (0–2600)	28	0 (0–2275)	0.383
Ibuprofen use (mg)	29	0 (0–2400)	28	0 (0–3600)	0.796
Max pain score	29	5.0 (0–10)	28	3.0 (0–8)	0.047
Min pain score	29	2.0 (0–5)	28	2.0 (0–5)	0.717

Note: 1 person lost to follow-up in the bupivacaine group following PACU stay.