Knee Surgery, Sports Traumatology, Arthroscopy (2018) 26:2536–2541
https://doi.org/10.1007/s00167-018-4874-x

HIP

Fascia iliaca blockade with the addition of liposomal bupivacaine vs. plain bupivacaine for perioperative pain management following hip arthroscopy

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Received: 22 October 2017 / Accepted: 12 February 2018 / Published online: 16 February 2018

Abstract

Purpose A newer formulation of bupivacaine, encapsulated within carrier molecules, has garnered attention for its role in providing extended post-operative analgesia. The purpose was to evaluate the addition of liposomal bupivacaine to fascia iliaca blockade during hip arthroscopy.

Methods Retrospective cohort study of patients undergoing hip arthroscopy with a pre-operative fascia iliaca blockade with either liposomal bupivacaine (Group 1; 266mg + 20 cc 0.5% plain bupivacaine) or bupivacaine (Group 2; 40 cc 0.25% plain bupivacaine). All patients received standardized pre-operative oral pain medications. The primary outcome was the defense veteran pain rating scale (DVPRS). Secondary outcomes included duration of hospital admission, PACU opioid use, PACU pain scores, and duration of nerve blockade.

Results Thirty-eight males and 30 females, mean age of 33 years (range 14–56). There was no difference in pre-operative DVPRS between the groups (n.s.). There was no difference in post-operative DVPRS pain scores at POD0 (3.7 vs. 3.9, n.s.), POD1 (4.2 vs. 3.8, n.s.), POD2 (4.2 vs. 3.7, n.s.), POD3 (3.9 vs. 3.7, n.s.) or POD14 (2.2 vs. 2.4, n.s.). Group 1 trended towards longer mean total hospital admission time (872 vs. 822 min, n.s.), and greater mean morphine equivalents administered in the PACU (33 vs. 29 mg, n.s.). 68% of patients in group 1 reported continued anterior thigh numbness at POD3, compared to 34% in group 2 ($p = 0.008$).

Conclusions Despite the advertised benefits of prolonged post-operative analgesia using liposomal bupivacaine, there were no significant differences in post-operative pain scores or PACU opioid consumption. Our results support that acceptable pain scores are successfully achieved at all time periods with the use of multimodal analgesia including fascia iliaca blockade despite the type of pain medication administered.

Level of evidence III.

Keywords Hip arthroscopy · Bupivacaine · Liposomal bupivacaine · Fascia iliaca

Introduction

Hip arthroscopy is a rapidly increasing procedure performed by Orthopaedic surgeons [4, 16]. In a healthcare environment where reimbursement is increasingly linked to patient satisfaction, better pain control options are constantly being improved. Furthermore, with the increase in scrutiny placed on narcotic prescribing, alongside America's opioid epidemic, multimodal pain control with the use of regional anaesthesia has been shown to be a helpful adjunct in pain relief following hip arthroscopy [13]. However, commonly used local anaesthetics, such as bupivacaine have a relatively short duration of action [1], and unfortunately, may not extend into the time frame where patients still have

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significant postsurgical pain. Liposomal bupivacaine was developed with the goal of prolonging the duration of action by encapsulating bupivacaine within a phospholipid bilayer resulting in a steady, reliable, prolonged drug release up to 72 h post injection [23]. The liposomal formulation as a delivery method for bupivacaine has been shown to be safe in multiple prospective randomized trials for local surgical site wound infiltration [11, 23, 25]. However, the effectiveness in the orthopaedic literature continues to be controversial [2, 8, 14, 17, 18, 20, 24].

The purpose of this study was to determine if liposomal bupivacaine is effective in decreasing pain scores and reducing narcotic requirements following hip arthroscopy when used in addition to a suprainguinal fascia iliaca blockade with traditional bupivacaine alone. Our hypothesis is that decreases in post-operative pain scores will not be statistically significant with the addition of liposomal bupivacaine at any post-operative time period. This is the first report to directly compare the effectiveness of these two medications with respect to post-operative pain scores when used in this manner for this surgical population.

Materials and methods

Prior to initiation of this study, both plain bupivacaine and liposomal bupivacaine were being used at our institution on a routine basis for suprainguinal fascia iliaca blockade to improve perioperative pain control following hip arthroscopy. After obtaining institutional board review approval, this study was developed as a retrospective cohort study of consecutive patients undergoing hip arthroscopy between the dates of August 2015 through February 2016. Any patient undergoing hip arthroscopy over this time period who consented to having an ultrasound-guided suprainguinal fascia iliaca blockade performed was included [7, 10, 15]. Patient demographics were obtained from our electronical medial record (EMR) to include age, gender, weight, obesity status, history of lumbar disease, history of prior hip surgery, pre-operative defense veteran pain rating scale (DVPRS) scores, smoking status and history of obstructive sleep apnea (OSA). Patients received one of two medications based on the personal preference of the attending anaesthesia provider administering the blockade. All blocks were performed pre-operatively in the regional anaesthesia block area under the direct supervision of a fellowship trained pain management physician and were performed under ultrasound guidance. One group received a blockade consisting of 40 cc of 0.25% plain bupivacaine (100 mg). The second group received a blockade consisting of 20 cc (266 mg) of liposomal bupivacaine mixed with 20 cc of 0.5% plain bupivacaine (100 mg) for a total volume of 40 cc. This allowed for the same dosage (100 mg) of plain bupivacaine administered to each group, as nerve block duration is dose-dependent, not volume-dependent. The maximum recommended dose of liposomal bupivacaine is 266 mg and given that the fascia iliaca blockade is highly dependent on the spread of local anaesthesia within a large compartment we chose to optimize the probability of benefit using the maximum dose. Pre-operative administration of 200 mg celecoxib, 975 mg acetaminophen, 300 mg gabapentin, and 10 mg extended-release oxycodone is uniform at our institution for all patients undergoing hip arthroscopy, regardless of undergoing a pre-operative regional anaesthesia blockade or regardless of the type regional medication administered. Post-operatively, all patients were prescribed immediate release oxycodone, extended-release oxycodone, acetaminophen, celecoxib, and aspirin as part of a standard order set. All pre- and post-operative medications were prescribed unless specific patient allergies precluded this.

The primary outcomes examined were post-operative pain scores, using the validated DVPRS, at 1 day, 2 days, 3 days, and 2 weeks post-operatively, obtained via routine post-operative phone surveys by the anaesthesia nurses [6, 19, 21]. Secondary outcomes included: duration of hospital admission, post-anaesthesia care unit (PACU) opioid consumption, PACU Numerical Rating Pain Scores (NRS), presence of nerve blockade at 48 h measured by subjective lack of anterior thigh sensation, and any complications. Prior to initiation of this study, IRB approval was obtained from the Walter Reed National Military Medical Center review board #500195.

Statistical analysis

All statistical analysis was performed using SPSS software (IBM Armonk, NY). Differences in means between the study and control groups were calculated among multiple variables utilizing an Analysis of Variance model (ANOVA). Categorical differences between the two groups were calculated using a chi-squared test. An a priori power analysis assuming a minimal clinically significant difference in pain of two points on the DVPRS scale was performed with the standard deviation in pain scores in each group assumed to be 2.5. Controlling the probability of a Type I error at alpha = 0.0125 {the Type I error is adjusted for four comparison points (post-operative days 1, 2, 3, and 14) using a Bonferroni correction [e.g. the experiment-wise alpha of 0.05 is divided by the number of comparisons (4)] to give a comparison-wise alpha level = 0.0125}. Based on these assumptions the number of patients needed per group to achieve a power of 80% was 37. An alpha of 0.0125 was used for the primary outcome of post-operative DVPRS scores, and an alpha of 0.05 was used for secondary outcomes not influenced by multiplicity.

Results

Over the study period, 68 study patients were identified through the EMR, with 34 patients in the liposomal bupivacaine + plain bupivacaine group and 34 patients in the plain bupivacaine only group. The male to female ratio was 38:30 with a mean age of 33.6 years (range 14–56 years). The mean BMI was 27.2 kg/m^2 (17.48–41.78 kg/m^2). No patient had a history of lumbar disease and a total eight patients (11.8%) had previous hip surgery, five patients in the study group and three patients in the control group (n.s.). There was no difference in age, gender, BMI, number of previous hip surgeries, obesity, OSA, number of smokers, or pre-operative DVPRS scores between groups. However, there was a difference in mean surgical time between groups, with the liposomal bupivacaine + plain bupivacaine group having a mean surgical time 0.42 h longer than the control group (3.07 vs. 2.65 h; $p = 0.004$). Similarly, the liposomal group also had longer mean traction time compared to the plain bupivacaine group (102 vs. 86 min; $p = 0.03$) (Table 1).

Telephone survey results were complete and available for all 68 patients at all post-operative time periods. There were no differences in DVPRS pain scores at any time point. In fact, during the three most critical days following surgery where liposomal bupivacaine has been marketed to be most effective, patients who received the liposomal formation trended towards having higher pain scores than the control group. There was no difference in mean total PACU opioid consumption between the study and the control group. Further, there was no statistical difference between the two groups in the overall mean PACU pain scores, mean PACU pain scores on arrival, maximum PACU pain scores, and mean pain scores at PACU discharge. More so, there was not a significant difference between the two groups in regards to time spent in the PACU or total hospital admission time. (Table 2).

The successful implementation of the blockade was judged by subjective sensation loss in the thigh prior to

Table 1 Patient demographics

	LB + PB ($n = 34$) (95% CI)	PB ($n = 34$) (95% CI)	p value
Age (years)	32.4 (28.8–36.0)	34.7 (31.3–38.2)	n.s
M:F	15:19	23:11	n.s
BMI (kg/m^2)	26.9 (25.4–28.3)	27.6 (25.9–29.3)	n.s
Previous hip surgery	14.7% ($n = 5$)	8.8% ($n = 3$)	n.s
OSA	2.9% ($n = 1$)	14.7% ($n = 5$)	n.s
Smoker	79.4% ($n = 7$)	79.4% ($n = 7$)	n.s
Pre-op DVPRS	3.35 (2.53–4.18)	3.65 (2.94–4.35)	n.s
Mean surgery time (h)	3.07	2.65	0.004
Mean traction time (min)	101.6	87.6	0.03

LB liposomal bupivacaine, *PB* plain bupivacaine, *DVPRS* defense veteran pain rating scale

Table 2 Post-operative outcomes

	LB + PB ($n = 34$) (95% CI)	PB ($n = 34$) (95% CI)	p value
DVPRS pre-op	3.35 (2.53–4.18)	3.65 (2.94–4.35)	n.s
DVPRS POD 1	4.17 (3.37–4.96)	3.80 (3.10–4.50)	n.s
DVPRS POD 2	4.21 (3.48–4.94)	3.73 (3.19–4.28)	n.s
DVPRS POD 3	3.93 (3.09–4.77)	3.69 (2.88–4.51)	n.s
DVPRS POD 14	2.19 (1.62–2.76)	2.37 (1.71–3.03)	n.s
PACU opioid consumption[a]	29.46 (17–41.18)	32.53 (21.77–43.29)	n.s
PACU pain score (arrival)	3.18 (2.05–4.30)	3.68 (2.68–4.68)	n.s
PACU pain score (mean)	3.68 (3.14–4.21)	3.85 (3.14–4.57)	n.s
PACU pain score (max)	5.59 (4.80–6.38)	5.47 (4.60–6.34)	n.s
PACU pain score (discharge)	2.41 (1.83–3.00)	2.88 (2.20–3.56)	n.s
Time spent in PACU (min)	108.6 (94.6–122.7)	110.6 (94.9–126.3)	n.s
Total hospital admission time (min)	872 (675.7–1068.9)	822 (613.5–1031.9)	n.s

LB liposomal bupivacaine, *PB* plain bupivacaine, *DVPRS* defense veteran pain rating scale, *POD* post-operative day

[a]Morphine equivalents

being discharged home, which was documented in 93.9% of the study group compared to 84.8% of the control group (n.s.). In regards to anterior thigh sensation at 48 h, 79.4% of the study group lacked sensation, compared to 58.8% of the control group ($p = 0.017$). At 3 days post-operatively, 67.7% of the study group lacked sensation compared to 34.4% of the controls ($p = 0.008$). There were no complications in either group.

Discussion

With an emphasis on patient satisfaction and scrutiny of opioid use, multimodal pain management regimens are becoming standard of care. A suprainguinal fascia iliaca blockade during hip arthroscopy is routinely offered utilizing plain bupivacaine as an adjuvant to oral pain control. The addition of liposomal bupivacaine to the market with its longer action [23] has sparked many questions into its effectiveness. The most important finding of the current study was that we were able to demonstrate similar post-operative pain scores between the liposomal bupivacaine group and the plain bupivacaine group following a fascia iliaca blockade during hip arthroscopy surgery, and the addition of liposomal bupivacaine offered no additional benefit with regards to PACU opioid consumption.

Many recent studies have surfaced evaluating the effectiveness of liposomal bupivacaine in both local wound infiltration and peripheral nerve blockades. In some of the first studies for which liposomal bupivacaine was initially FDA-approved, Gorfine et al. demonstrated increased efficacy of liposomal bupivacaine over placebo when used at the surgical site of hemorrhoidectomy with lower pain scores, increased time to first narcotic use, less narcotics used and overall higher patient satisfaction with postsurgical analgesia [9]. Similar results were shown in bunionectomy patients following the local adminstration of liposomal bupivacaine [8]. However, this result is expected as local anaesthesia would be expected to perform better than normal saline infiltration. Additionally, Bramlett et al. also showed a dose–response decrease in pain scores in total knee arthroplasty when used for pericapsular injection and wound infiltration with liposomal bupivacaine when compared to plain bupivacaine on post-operative days 1 and 5, in a randomized double-blinded study [5]. However, the only significant difference between the groups was found at a liposomal bupivacaine dose of 532 mg, and pain scores at the FDA-approved dose of 266 mg were not statistically different. Despite this, further studies, including a recent systematic review and meta-analysis dispute the effectiveness when used in periarticular injections during total knee arthroplasty and conclude the increased cost of using the liposomal formulation with similar post-operative functional outcomes and pain scores are not justified [3, 14]. The findings of the current study are in accordance with these studies that also used the FDA-approved dose of 266 mg, and while we may have found different outcomes in pain scores had we used larger doses of liposomal bupivacaine, this is outside our institutions current protocol.

As hip arthroscopy is becoming an increasingly common surgical procedure, multiple peripheral anaesthesia techniques have been utilized to aid in perioperative pain control to include lumbar plexus blockade, paravertebral blockade, femoral nerve blockade and more recently, suprainguinal fascia iliaca blockades. These techniques have repeatedly been shown to be beneficial with regards to improving post-operative pain and opioid consumption, however, each blockade is associated with it its own set of complications and side effect profiles [12, 13, 26]. The fascia iliaca blockade is an attractive adjunct to hip arthroscopy surgery as it does not carry with it the potential post-operative motor deficits seen with the other techniques and reliably targets the nerves responsible for providing sensation to the anterior capsule of the hip joint [12]. In the available literature, there are only two studies evaluating the use of the fascia iliaca blockade during hip arthroscopy [13, 22]. Both studies demonstrated acceptable post-operative pain scores, few complications, along with lower narcotic usage compared to patients who were managed with oral and intravenous analgesics alone. The current study supports the findings in these studies and demonstrates acceptable pain scores following hip arthroscopy with fascia iliaca blockades, which has been established to be a useful adjunct in the post-operative pain management strategy.

To our knowledge, this is the first report comparing liposomal bupivacaine and plain bupivacaine in peripheral anaesthesia for hip arthroscopy. The data demonstrate that despite having increased duration of action evident by prolonged anterior thigh numbness, liposomal bupivacaine did not significantly reduce post-operative pain scores at any time point despite being nearly six times the cost of plain bupivacaine at our institution. Further, it did not lead to decreased PACU narcotic use or shorter hospital time. There are several possible explanations for why patients experienced longer thigh numbness despite having similar post-operative pain scores. The hip joint/capsule has a complex innervation by both the lumbar and sacral plexuses, and the fascia iliaca block only addresses the lumbar plexus, which provides sensation to the anterior capsule via branches of the femoral and obturator nerves. As a result, patients may still be experiencing subjective 'hip' pain due to the innervation from the sacral plexus despite continuing to experience thigh numbness from the blockade of the lateral femoral cutaneous nerve. Additionally, even though liposomal bupivacaine has been marketed to provide analgesia up to 72 h, it is possible that hip arthroscopy patients may not necessarily need

the adjunct pain relief offered by the fascia iliaca block for that extended time. With the multimodal pain management strategy we utilized, it is possible that patients only need analgesia provided by the block for the initial 18–24 h after surgery, which is covered by the plain bupivacaine block. We believe that there may be a role for liposomal bupivacaine in other aspects of peripheral analgesia as it does show an increase in the duration of action; however, we were unable to show a difference in pain scores when used in the fascia iliaca blockade for hip arthroscopy.

The DVPRS has undergone three validation studies in mixed populations to include surgical populations and has demonstrated excellent psychometric properties when compared to the numerical rating scale; however, we do recognize that the DVPRS scale has not been used in the literature to the extent that other numeric rating scales has been [6, 19, 21]. In a similar fashion to civilian care, the Department of Defense and Veteran's Health Administration is shifting to outcomes that focus on function and are meaningful to patients. While the numerical rating scale is commonly used in clinical trials, it focuses only on the sensory experience of pain and does not consider the impact on patient function and other psychosocial measures. The standard of care at our institution for collecting post-operative pain outcome scores is utilization of the DVPRS. While the NRS may have detected a difference in the sensory experience of pain, we submit that the DVPRS along with its validated psychometric properties provided a better measure of patient function and the actual impact of post-operative pain.

This study does contain limitations. By virtue of design this study has inherent limitations, including selection bias, as it was a retrospective study. Second, the mean traction and surgical times were longer for the study group, potentially negating any potential benefit from the liposomal formulation. However, with only a 14-minute difference in traction time between the groups, we do not feel that this small difference could entirely negate the as-marketed advantage of the liposomal bupivacaine. Last, we reported on 68 patients, and were unable to collect sufficient data on our proposed enrollment of 74 patients per the power analysis, this study does fall below the 80% threshold for power. However, in an effort to reduce the possibility of multiplicity resulting in finding an erroneous statistically significant outcome in pain scores we utilized a conservative correction factor in the power analysis. Only 26 patients per group would be needed to achieve a power of 80% if a traditional alpha of 0.05 was used. Achieving 74 patients to meet 80% power would likely not have changed the primary outcome and this study does not suffer from type-II error as the post-operative DVPRS scores were so highly non-significant, and in fact, the liposomal group trended towards having higher pain scores. To eliminate any selection bias and to evaluate the influence of the liposomal formulation on post-operative oral narcotics usage, further prospective randomized studies should be completed which would certainly prove beneficial in the current state of the opioid epidemic.

Conclusion

Though liposomal bupivacaine in addition to plain bupivacaine for fascia iliaca blockade has a longer duration of action and no increased complications, it is not beneficial in decreasing post-operative pain scores or decreasing PACU narcotic requirement in our series and may not warrant the sixfold higher cost of this medication when used in this manner. Our institution has since abandoned the use of the liposomal formulation for the fascia iliaca blockade in hip arthroscopy patients.

Author contributions RP and DG were responsible for data collection and analysis. RP, KN and DG all participated in manuscript preparation and MM, TA, MK aided in final editing and proofs.

Funding No source of funding.

Compliance with ethical standards

Conflict of interest Neither Richard Purcell, Kyle Nappo, Daniel Griffin, Michael McCabe, Terrence Anderson or Michael Kent have any financial disclosures or conflicts of interest to report.

Ethical approval This study was appoved by our institution's ethical review commitee in conjunction with the institutional review board approval.

Informed consent For this type of study, formal consent was not required.

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