Pain Outcomes Following Hip Arthroscopy: A prospective randomized control study comparing fascia iliaca blockade with marcaine vs extracapsular local field infiltration with liposomal bupivacaine

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PROTOCOL SUMMARY

Purpose and Knowledge to be Gained	• The purpose the research is to help determine optimal means of post operative analgesia following hip arthroscopic procedures. • Post operative pain is a significant contributor to patient satisfaction and the side effects of narcotic pain medication are well described. The ideal intervention for achieving appropriate analgesia following hip arthroscopy has not yet been defined. Determining means of achieving acceptable post operative pain relief while minimizing narcotic usage will help yield maximal patient outcomes.
Research Procedures	• The primary research procedures entailed in this study include fascia iliaca nerve blockade with Marcaine and local field infiltration with liposomal bupivicane (Exparel).
Subject Population	• The patients in this study will include those who have both a clinical and radiographic diagnosis of femoracetabular impingement (FAI), have failed non operative treatment, and are indicated for hip arthroscopy with labral repair and femoroplasty/acetabuloplasty.
Duration	• The study includes the surgical procedure and the first post operative follow up visit. • The total study duration is approximately 1.5 weeks for each patient. The study will be carried out until the patients first post operative visit which typically occurs 7-10 days after the procedure. We are to include approximately 40 patients in total for this study over a period of 4 months.

GENERAL INFORMATION

CSMC Co-Investigators	*Zach Mcvicker MD, Adam Cady PA-C*
Sponsor/Funder	Kerlan-Jobe Institute
Collaborating Institutions Involved in the Research	*NA*

1.0 BACKGROUND, RATIONALE

The number of hip arthroscopies performed in the US has risen dramatically in recent years with expanding indications, advances in surgical techniques, and better understanding of hip pathology. With this rise, there is a growing interest in improving postoperative pain control as pain following arthroscopic hip procedures can be considerable, with up to 90% of patients reporting severe pain in the immediate post operative period in some series[1].

Peripheral nerve blockade has been used for a multitude of orthopedic procedures as an adjunct to oral or IV pain medication administration. While femoral nerve blockade has been successfully used in total knee and hip arthroplasty[2], the results of femoral nerve block following hip arthroscopy have been mixed. A decrease in opioid usage has been demonstrated in some studies[2], but falls secondary to muscle weakness in blocked patients remains a worrisome complication[3]. Fascia iliaca blockade has been proposed as a means to achieve analgesia without frank motor deficit[4,5]; however recent studies have shown quadriceps weakness still occurs with fascia iliaca blocks[6]. At our institution, we have anecdotally corroborated this result with several patients undergoing hip arthroscopy with fascia iliaca blockade having fallen in the early postoperative period.

Liposomal bupivacaine is a novel medication formulation encapsulating bupivacaine in a phospholipid bilayer inducing a protracted steady state release resulting in a prolonged duration of medication action. Local wound infiltration with liposomal bupivacaine has been successfully utilized for postoperative analgesia in a number of different orthopedic procedures[7,8].

We plan to compare the efficacy of extracapsular liposomal bupivacaine field infiltration for postoperative analgesia in hip arthroscopy patients in comparison to the fascia iliaca blockade.

2.0 STUDY OBJECTIVES

The purpose of this study is to compare two utilized methods of analgesia for hip arthroscopy. Patients will be randomized into two groups: fascia iliaca blockade and local field infiltration with liposomal bupivacaine. Pain numeric rating scale (NRS) scores, narcotic usage, and any self reported falls in the immediate post operative period will be compared between groups.

3.0 STUDY POPULATION

3.1 SELECTION OF THE STUDY POPULATION

Patients will be selected for the study from the principal investigator's practice (Michael Banffy MD). Patients seen in the outpatient office at the Kerlan Jobe Institute with a clinical and radiographic diagnosis of FAI that are indicated for hip arthroscopy and subsequently undergo surgery will be eligible for participation.

3.2 INCLUSION CRITERIA

Inclusion criteria for this study will be adult patients (>18 years old) with diagnosed FAI that are indicated for hip arthroscopic labral repair and femoroplasty/acetabuloplasty.

3.3 EXCLUSION CRITERIA

Exclusion criteria include patients undergoing revision procedures, bilateral procedures, those with advanced osteoarthritis (<2mm joint space on plain radiographs), frank dysplasia (anterior and/or lateral center edge angles <20 degrees

and/or Tonnis angle >15 degrees), or diagnoses other than FAI (Legg Calve Perthes, femoral head avascular necrosis, septic arthritis, or post traumatic deformity).

3.4 SUBJECT SCREENING AND ENROLLMENT

Data will be procured for this study in a prospective manner. Immediately following surgery, the post anesthesia care unit staff will record NRS pain scores and document narcotic usage in the immediate post operative period. Upon discharge, enrolled patients will maintain an NRS pain score log and record the amount of narcotics required at home prior to their first post operative visit. No further interrogation of the patients medical record will be required

3.5 SUBJECT RECRUITMENT

Subjects recruited for this study will come solely from the principal investigator's practice. Patients will be approached at their preoperative visit by either Michael Banffy MD or Adam Cady PA-C. No advertising will be used.

4.0 STUDY DESIGN AND METHODS

Hypothesis: Patients treated with local field infiltration of liposomal bupivacaine will report less pain in the immediate post operative period and will utilize less narcotic pain medications than those who undergo a fascia iliaca block. Fewer post operative falls will be seen in patients without fascia iliaca block.

Variable: NRS pain scores will be recorded in the PACU at 15 min and 1 hr post op in the PACU immediately following surgery. Enrolled patients will then record their NRS pain scores at home from POD 0 to 4. Total narcotic utilization and any reported falls will be recorded.

Study Design/Methods: After consenting to participate, subjects will be randomized into one of two groups, using a random number generator. http://stattrek.com/statistics/random-number-generator.aspx. 60 consecutive patients will be enrolled into their appropriate study arm.

Group 1 patients will undergo a standard preoperative fascia iliaca blockade performed by anesthesia per with 0.5% Marcaine according to standard protocol. Group 2 patients will receive no regional anesthesia prior the procedure

Both groups will then be placed under general anesthesia and undergo arthroscopic treatment of FAI. At the conclusion of the procedure, patients in the experimental group will undergo extracapsular local field blockade in the operative hip using a standardized mixture of 20ccs liposomal bupivacaine, 20ccs 1/4percent Marcaine and 80ccs of normal saline. This injection is performed in a standardized fashion through the preexisting arthroscopic portals into the pericapsular tissue according to FDA labeling/guidelines. This confers no increased risk to the patient beyond that of a standard hip therapeutic injection. Patients in the control group will not undergo any injection following the procedure.

Perioperative nursing staff will administer the NRS pain scale surveys at 15 min and 1 hour post procedure in the recovery room. The nurses will provide pain medication and make patient assessments per their standard patient care responsibilities in the post anesthesia care unit and are not administering medication or performing procedures specifically for research purposes.

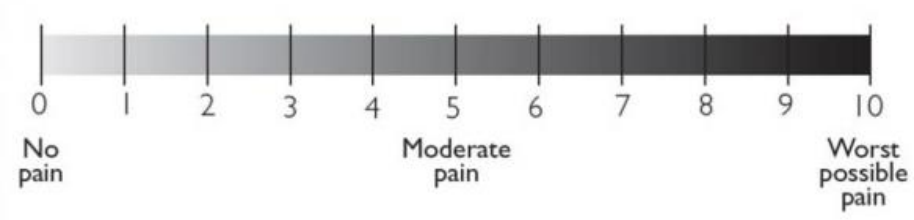
All patients will be discharged home on the same day of the procedure. Patients in both groups will adhere to the same post operative protocol. A hip brace to be worn at all times will be applied to prevent excessive internal/external rotation of the operative extremity. Patients will be made 50% partial weightbearing on the operative extremity and will use crutches for ambulation. A standard prescription of Percocet 5-325 mg will be given to each patient with instructions to take 1 tab every 6 hours as needed for pain. A log of pain levels and amount of pain medication taken from POD 0-4 will be recorded by each patient. Patients will return to the office for the first post op visit in 7-10 days where the pain logs will be collected for analysis and any reported falls at home will be documented

For Studies that Include Surveys

The questionnaire to be used for this study is attached below. Numerical Rating Scale (NRS) Pain scores have previously been established as a validated metric for tracking pain intensity. Patients will be asked to rate their pain at 2 time points each day until POD 4. Additionally, patients will asked to document the number of narcotic pain medication pills taken each day until POD 4. Lastly, any self reported falls will be captured with this questionnaire. Any literacy or language concerns will be addressed at the preoperative visit using the teach back method as well as language interpreter services as needed.

ANALOG PAIN SCALE FOR HOME

Please indicate your pain level FIRST THING in the morning after waking before taking pain medication and at night before sleep BEFORE taking pills by selecting the appropriate number on the scale. Perform this every day after surgery until the 4th day.



Day	Pain Score (0-10) 0=no pain 10=worst pain

1 (AM)	
1 (PM)	
2 (AM)	
2 (PM)	
3 (AM)	
3 (PM)	
4 (AM)	
4 (PM)	

NARCOTIC USAGE HOME LOG

Please indicate the total amount of narcotic pain pills taken per day

Day	Total number of pills taken
1	
2	
3	
4	

FALL AT HOME LOG

If you fell down at home after surgery, please indicate how many times this happened. If no falls occurred, indicate N/A (not applicable)

Number of falls	

***Schedule of Procedures**

Procedures	Preop Visit	Surgery	Post-op day 1 to 4	First post operative visit (within 7-10 days after procedure)
Informed consent	R			
Randomization	R			
Fascia Iliaca Blockade with 0.5% Marcaine (Group I only)		S		
Hip arthroscopy under general anesthesia (Group I and II)		S		
Exparel extracapsular local field injection (right after surgical procedure- Group II only)		S		
Hip brace with 50% partial weightbearing on the operative extremity prior to hospital discharge		S	S	S
Percocet 5-325 mg every 6 hours as needed		S	S	S
Numeric pain scale			R	
Narcotic Usage home log (Number of narcotic pain medication taken each day)			R	
Self reported occurrence of falls questionnaire			R	

5.0 DATA COLLECTION AND MANAGEMENT

5.1 DATA PROCUREMENT

- Data procurement will be driven by the patient. NRS pain scores and the amount of narcotic utilization will be documented in the PACU by the PACU staff. Upon discharge from the surgery center, patients will be responsible for filling out the above questionnaire at home and will bring the completed form to their first postoperative visit

5.2 TIME PERIOD OF DATA UNDER REVIEW

- Data will be reviewed from the date of surgery POD 0 and up until POD 4. Data will be collected from the following timepoints: morning and evening NRS pain scales and daily narcotic utilization. Data will be collected prospectively and will be maintained until final data analysis has been completed at which point all documentation related to the study with PHI will be discarded in a HIPAA compliant manner.

5.3 VARIABLES COLLECTED

- The following data points/variables will be collected: Bidaily NRS pain scores, daily narcotic pain medication utilization, and self reported falls.

5.4 SOURCE DOCUMENTS

- Source documents (patient questionnaires) will be collected at the first postoperative visit. At this time point, the patient data will be de identified and placed into an excel sheet on a secure flash drive. The linking information will be maintained on a separate secure flash drive.

5.5 DATA COLLECTION AND STORAGE

- Upon collection of the paper patient survey at the first postoperative visit, information will be transferred to an electronic Excel sheet on a secure password protected flashdrive. The paper survey will be destroyed. Only the study authors will have access to the deidentified patient data and only the primary author will have access to the linking information.

5.6 Confidentiality and Security of Data

- Confidentiality will be maintained according to the CSMC Office of Research Compliance and Quality Improvement Requirements for Safeguarding and Maintaining Confidentiality of Subject Information Collected for Research. See previous section for details.

6.0 DATA AND SAFETY MONITORING

6.1 DATA AND SAFETY MONITORING PLAN

Patients are routinely called by the attending anesthesiologist as well as the attending surgeons office on POD 1 for postoperative evaluation. During this contact, both the anesthesia team and surgeon can assess for any complication or untoward effect of the liposomal bupivacaine injection. Management of any complication will be directed by the anesthesia staff or surgeon. Patients will be seen for their first follow up visit at 7-10 days following surgery. Any protocol deviations will be recorded at this time point. The principal author (Nicholas Ramos MD) will review data records at 4 week time points during data collection to ensure appropriate capture of NRS pain score, narcotic utilization, and patient reported falls.

6.2 QUALITY CONTROL AND QUALITY ASSURANCE

- Patients are routinely contacted on POD 1 by both the attending anesthesiologist as well as the attending surgeon. During this contact, patients will be reminded to fill out their paper questionnaires in the appropriate manner according to study protocol.

7.0 STATISTICAL CONSIDERATIONS

7.1 STUDY OUTCOME MEASURES

- Baseline demographics will be compared between groups using the chi square test for categorical data (sex) and ANOVA for continuous variables (age). Non parametric Kruskal Wallis testing will be used to compare average NRS pain scores and analgesia utilization between groups. The incidence of post operative falls will be compared between groups using the chi square test.

7.2 SAMPLE SIZE CONSIDERATIONS

- Power estimates were determined before patient enrollment to determine the enrollment size. The sample size was estimated with a basis on the numerical rating scale of pain as main variable. Alpha error accepted = 0.05 (type I error probability for a 2-sided independent t test) and a beta error = 0.2 (power = 80%). Effect size was estimated to be 1 (mean difference between groups =2 and SD both groups =2) It was calculated that it would be necessary to enroll 17 patients in each group. We will plan to enroll 40 patients total to account for any patient loss/dropout (20 pts each group)

8.0 REFERENCES

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