

PSOAS COMPARTMENT BLOCK VERSUS PERIARTICULAR LOCAL ANESTHETIC INFILTRATION FOR PAIN MANAGEMENT FOR TOTAL HIP ARTHROPLASTY: A PROSPECTIVE, RANDOMIZED STUDY

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1.0 BACKGROUND AND SIGNIFICANCE

Total hip arthroplasty can be associated with significant pain in the immediate postoperative period. In order to mitigate pain and subsequently facilitate patient mobilization and recovery, surgeons can use various methods of analgesia. Two current techniques are a more novel, psoas compartment block, which is gaining popularity for use in total hip arthroplasty with an anterior approach, and a periarticular local anesthetic injection. For a psoas compartment block, anesthetic is introduced directly into the iliopsoas and spreads to the lumbar plexus. For a periarticular local anesthetic infiltration, an anesthetic “cocktail” is injected at multiple spots to the surrounding tissue at the surgical site. To date, it is unclear which of these methods provides the best pain relief during the immediate postoperative recovery period.

It is theorized that the surgeon-delivered psoas compartment block can provide better and more complete pain relief than the “cocktail” injection since it is a consistent technique, and the injection specifically targets nerves that provide the operative area with sensation. Comparatively, the “cocktail” injection can be performed relatively consistently from one case to the next, but there is less knowledge of where the injectate will go and how effectively it will anesthetize the nerves – especially in the subcutaneous tissues.

The proposed study is a prospective, randomized clinical trial comparing patient-reported pain following total hip arthroplasty with a psoas compartment block versus a periarticular local anesthetic infiltration.

2.0 OBJECTIVE

- The primary objective of this study is to examine whether there is a difference in the level of resting pain following total hip arthroplasty with use of a psoas compartment block versus a periarticular local anesthetic infiltration.
- The secondary objective is to examine whether there is a difference in the amount of in-hospital opioid drug use postoperatively

3.0 HYPOTHESIS

- Our hypothesis is that the psoas compartment block will provide better pain relief (as measured by resting pain score) than the periarticular local anesthetic infiltration postoperatively at one or more of six specified post-operative times
- Additionally, we hypothesize less need for in-hospital opioids with a psoas compartment block within 24 and 24 to 48 hours postoperatively

4.0 RESEARCH DESIGN AND METHODOLOGY

We will perform a single-center, prospective, randomized clinical trial with a total of 100 patients. One orthopaedic adult reconstruction surgeon at Beaumont Hospital Royal Oak (JJV) will perform all surgeries. After the patient has consented they will be randomized to one of the following two groups:

- 1.) Psoas compartment block (n=50)
- 2.) Periarticular local anesthetic infiltration (n=50),

The patient will be blinded to the study group.

4.1 Inclusion Criteria

- Patients undergoing unilateral primary total hip arthroplasty by Dr. James Verner at Beaumont Hospital Royal Oak
- Have a diagnosis of primary osteoarthritis (i.e. degenerative joint disease)
- Surgical approach is anterior

4.2 Exclusion Criteria

- Minors (age less than 18 years)
- Pregnant (surgically sterile, post-menopausal, or negative blood test)
- Previous ipsilateral hip surgery
- Lumbar instrumentation
- Acute trauma
- Rheumatoid arthritis
- Avascular necrosis
- Hip dysplasia
- Known sensitivity, allergy, or contraindication to anesthetics being used in the study
- Narcotic sensitivity
- History of over 6 months of opioid dependency prior to surgery (excluding tramadol)
- Peripheral neuropathy
- Mental/cognitive impairment that would interfere with the patient's self-assessments of function, pain, or quality of life

4.3 Enrollment and Consent

Patients scheduled to undergo total hip arthroplasty with Dr. Verner will be screened preoperatively for eligibility. Patients will be identified by operative schedules. Patients that meet all criteria will be contacted by personnel on the delegation of authority as a

consent provider at least one week in advance of their procedure. After initial contact, if the patient is interested, the research coordinator will offer to email or mail a copy of the consent for the patient to review before consent. The patient will be consented prior to any study procedure or assessments take place. At the time of consent, the patient will have sufficient time to read the consent form and discuss any questions they may have with the consent provider. Patients will be allowed to drop out of the study at any time before their procedure.

4.4 Randomization

The 100 patients in the study will be randomized in a 1:1 ratio to have their procedure performed either with a psoas compartment block or with local anesthetic infiltrate. Randomization assignments will be contained in sequentially numbered, opaque, sealed envelopes, which will be prepared by a statistician in the Research Institute using blocked randomization from The SAS System for Windows version 9.3. After the patient is consented, the consentor will assign the patient to a group following the treatment listed in the envelope and inform the surgeon. Logs will be maintained by consenting personnel to ensure the list is being followed and each patient's group is documented.

4.5 Study Procedures/Intervention

4.5.1 Psoas Compartment Block Administration

Following exposure, the rectus femoris muscles are elevated with a two-prong retractor, thus exposing the iliopsoas muscle. An 18G spinal needle is inserted to a depth of 0.5-1.0 cm under the fascia at the level of the musculotendinous junction or more proximally, and 0.3% ropivacaine in 50 mL are administered into the psoas compartment. The local anesthetic travels proximally and anesthetizes a portion of the lumbar plexus specifically targeting the obturator, femoral, and lateral femoral cutaneous nerves to provide local pain control.

4.5.2 Local Anesthetic Infiltration Administration

A combination of medications including 30 mL 0.5% ropivacaine, 0.15 mg epinephrine, 4 mg morphine, and 30 mg toradol (hereby referred to as "cocktail") will be diluted with 19 mL of 0.9% NaCl and will be injected into the tissues surrounding the hip joint in a systematic fashion ensuring uniform delivery to all tissues incised and instrumented. This cocktail is infiltrated into the periarticular tissues including muscle, joint capsule, and subcutaneous tissues at the surgeon's discretion. We will use the following technique, which will be standardized amongst all patients: joint capsule, rectus femoris direct and reflected head, tensor fascia lata, and subcutaneous tissues circumferentially every 25 mm.

4.5.3 Postoperative Pain Management Protocol

All patients will follow Dr. Verner's standard of care pain management protocol. There may be slight differences in the amount of pain medication given to the patients' intra- and postoperatively at the anesthesiologist's and/or nurse anesthetist's discretion.

4.6 Data Collection

- Primary outcome variable: VAS Pain scores measured at times in Appendix I: Table I
- Secondary outcome variable: Total amount of opioid usage in-hospital (and with 24 hours and 24-48 hours postoperatively)

Demographic and Operative Variables

- Sex
- Age
- Race
- BMI
- ASA score
- Comorbidities, as recorded by anesthesiology
- Date of Surgery
- Time of Surgery
- Laterality (left/right)
- Operative Time (skin incision to skin close, mins)
- Estimated Blood Loss (mL)
- Intraoperative Complications (fracture, bleeding events, etc.)

Outcomes Variables

- Narcotic Use (expressed in oral morphine equivalent units)
- Non-narcotic pain medication usage
- Major Postoperative Complications (DVT, Falls, Infection, etc.) through first postoperative visit
- Units of blood transfused
- Complications related to block/anesthetic
- VAS Resting Pain Scores
- VAS Ambulating Pain Scores
- Time of First Physical Therapy Session
- Length of Hospital Stay (Days)
- Readiness for discharge (days), requiring the following:
 - A pain score of <4 (numeric rating scale) without non-oral narcotics

- Normal eating
- Minimal nausea
- Urination without a catheter
- A dry surgical wound
- No acute medical problems
- The ability to independently transfer and walk 100 feet
- Stable vitals

Pain will be measured on a numeric Likert scale, rating the pain from 0 (none) to 10 (maximal). Scores will be collected at 3 hours postoperatively, in the morning and afternoon on postoperative day one and two and at the post-operative clinic visit. The patient will record their pain on a data collection form that is given to them at each time point. Pain will be recorded for when the patient is at rest and when the patient is ambulating. On postoperative day one and postoperative day two the patient will be asked to fill out the Quality of Recovery Score [Myles] and Opioid-Related Symptom Distress Scale [Apfelbaum, Yadeau] (Appendix I: Table I).

All pain medications will be prescribed per standard of care. Pain medication usage in-hospital will be recorded from Epic. All opioid consumption will be converted to oral morphine equivalents in milligrams. All demographic and operative variables will also be collected for each patient from electronic medical records.

Readiness for discharge will be assessed in both the morning and evening of each postoperative day.

4.7 Statistical Analyses

A table of descriptive summaries on demographic and operative variables by treatment group will be prepared (means and standard deviations if normally distributed, median and range if not normally distributed, counts and percentages for categorical variables); inference procedures which are consistent with the chosen variable summaries will be used to compare treatment groups.

Before analyzing continuous variables, data sets will be assessed for normality using a Shapiro-Wilk Test and equal variance using the Levene-test. For normal data an independent Student's t-test will be used to compare means, and a Mann-Whitney Rank Sum Test will be used for data that is not normally distributed. The two treatment groups will be compared on categorical variables using the Chi-Square test or a Fisher Exact test for low frequency occurrences.

VAS Pain scores (resting, ambulating) will be compared between groups at each time point using a Mann-Whitney Rank Sum test. A Bonferroni correction will be used to

account for repeated measures and control for a Type I error. A p -value below $.05/6 = .0083$ at each individual postoperative time point will be considered statistically significant. Opioid usage will be compared for total in-hospital as well as broken down by use a 24 hours and use from 24-48 hours using the Mann-Whitney Rank Sum test. A p -value below $.05/3 = .017$ at each individual postoperative time point will be considered statistically significant. Composite scores and subscores of the Quality of Recovery-40 and Opioid-related Symptom Distress Scale, as well as the time to readiness for discharge, will be compared between groups with the t -test or Mann-Whitney Rank Sum test as appropriate.

For all other tests which do not include Bonferroni adjustment, a two-sided p -value < 0.05 will be considered statistically significant. Missing data will be treated as such; there will be no imputation. An exploratory subgroup analysis will also be performed, excluding patients with longer than 3 day stay or patients that required additional surgical intervention. Confidence intervals for the difference in means/medians/odds ratios between the two groups will also be calculated where appropriate. Graduate-trained engineers will analyze data with SPSS statistical software (SPSS Version 20.0, IBM, Inc).

4.7.1 Sample Size

The sample size determination of 50 per group was based on a review of the literature and feasibility. Dr. Coffey has provided justification for a lack of sample size analysis (see Appendix I).

5.0 RISKS AND BENEFITS

5.1 Potential Benefits to Subjects

Participants enrolled in the study may have better pain relief if they are randomized to the psoas compartment block group. However, this has not been proven and patients may receive no direct benefit from inclusion in this study. Knowledge gained in this study may provide benefit to future patients undergoing total hip arthroplasty with an anterior approach if benefits of one technique can be identified.

5.2 Potential Risks to Subjects

The risks of participating in this study include the same risks normally associated with hip surgery whether the patient is in the study or not. The risks directly related to the techniques being studied are as follows:

Standard of Care Risks

Less Frequent (occurring from 1% to 10% of the time):

- Low blood pressure
- Nausea
- Vomiting
- Low heart rate
- Anxiety
- Numbness of skin
- Pain
- Itching
- Fever
- Dizziness
- Chills
- Reduced sensation of your hip area (where the surgery will take place)
- Block failure (this is when the block does not work, thus causing pain after surgery)

Rare (occurring less than 1% of the time):

- Runny nose
- Allergic reaction
- Temporary or permanent nerve damage
- Infection
- Perioperative injury secondary to numbness or weakness, such as falling if trying to walk before the block wears off

With any procedure, unusual, unexpected or previously unreported side effects may occur. Risks will be assessed throughout the course of the study.

There is also a rare risk of breach of confidentiality. Every effort will be made to maintain patient privacy, however this cannot be guaranteed.

6.0 DATA SAFETY MONITORING AND ADVERSE EVENTS

6.1 Plan for Monitoring and Safety Review

An internal safety monitoring committee will be assembled. Members of group will include a scientific reviewer, two clinicians, and a biostatistician for an independent review of adverse event data provided by the investigator. Members invited to participate in the group are independent of the study. The scientific reviewer is Tristan Maerz, PhD. The clinicians are Randy Fayne, MD, and attending anesthesiologist, and Kelly Pseres, NP who works at MOI with adult reconstruction patients. The group will meet twice throughout the course of the study to monitor safety, recruitment, subject eligibility, adherence to treatment plan, documentation of dropouts and adverse events. The first meeting will be after 30 patients have completed the study. The second meeting will be after 75 patients

have completed the study. Enrollment will continue while these meetings are being planned and taking place. Members will receive a composite of the collected data including complications and adverse events broken down by study group from the study investigators to review before the meeting. One member will be responsible for taking minutes at the meeting. Reports from all meetings will be presented to the study investigators who will be responsible for reporting the data to the HIC.

6.2 Risk Monitoring and Adverse Event Reporting

An adverse event (AE) is any noxious, unintended, or untoward medical occurrence that may appear or worsen in a subject during the course of a study. A serious adverse event (SAE) is any AE which:

- Results in death
- Is life-threatening (i.e., in the opinion of the investigator the subject is at immediate risk of death from the AE)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity (a substantial disruption of the subject's ability to conduct normal life functions)
- A medical event that may jeopardize the subject or require medical or surgical intervention

The severity of adverse events (AEs) will be graded on a scale of 1 to 5 according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events ([The NCI Common Terminology Criteria for Adverse Events, Version 4.0 [NCI CTCAE]). The PI will determine the relationship between the administration of the block and the occurrence of an AE/SAE as unrelated, probably not related, probably related, or definitely related.

The participant will be monitored for risks and AEs in the hospital as standard of care. The PI and surgeon co-investigators will be responsible for tracking the occurrence of AEs while the patient is in-hospital. After discharge through the first follow-up appointment the patient will be monitored for hospital readmissions and asked to notify the PI of the occurrence of any AEs. A final assessment of complications and AEs will be made at a 3 week follow-up visit in the clinic (Michigan Orthopaedic Institute).

AEs of grade 4 or 5 will be reported to the HIC within 7 days. They will also be reported to the chair of the internal safety monitoring committee within 7 days and he will make a recommendation as to whether the study should continue.

7.0 REFERENCES

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8.0 APPENDIX I

Table I. Schedule of Events

Study Procedures	Screening	Surgery	3 hours postop	POD1 9 AM	POD1 5 PM	POD2 9 AM	POD2 5 PM	3 weeks postop
Visit Windows	-21 to 0 days	N/A	± 1 hours	± 2 hours	± 3 hours	± 2 hours	± 3 hours	± 1 week
Review inclusion and exclusion criteria	X							
Informed consent review and signature	X*							
Study Group Determination (Randomization)	X*							
Intervention (psoas block or periarticular injection)		X						
Collect resting pain score	X ^a		X	X	X	X ^b	X ^b	X
Collect pain with ambulation	X ^a			X ^c	X ^c	X ^{b,c}	X ^{b,c}	X ^c
Quality of Recovery-40 assessment				X		X ^b		
Opioid-related symptom distress scale assessment				X		X ^b		
Assess for adverse events			X	X	X	X	X	X

POD = postoperative day

*Consent will happen before any study procedures or assessment are done and randomization will occur at that time

a. Collected as standard of care in the clinic

b. If patient has been discharged before this time point assessments will not be collected

c. If patient is not ambulating they will have the option of selecting 'N/A'