# Comparison of Lidocaine versus Bupivacaine Spinal Anesthesia in Total Hip Arthroplasty: A Randomized, Double-Blind, Prospective Study

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Emory University Department of Orthopaedic Surgery
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Investigators:
[redacted]

[redacted]

## ABSTRACT

Spinal anesthesia is commonly used in total hip arthroplasty (THA). This will be the first randomized, double-blind, prospective study to compare lidocaine to bupivacaine spinal anesthesia in THA patients. The objective of this study is to compare the two spinal anesthesia treatments with the primary outcome of transient neurological symptoms (TNS). The study will be conducted on healthy adult volunteers who are indicated for THA and agree to have spinal anesthesia. All patients will be randomized by a computer program and will receive either lidocaine or bupivacaine spinal anesthesia prior to their THA. Prospectively collected data will be obtained from the patient charts. In addition to TNS, other outcomes include urinary retention, hypotension, ambulation and length of hospital stay. We predict there will be no difference between lidocaine and bupivacaine spinal anesthesia in THA patients with respect to TNS and other outcome measures.

## INTRODUCTION/BACKGROUND

A. Specific Aims

Most surgeons would agree total hip arthroplasty (THA) is one of the most successful surgical interventions. However, when it comes to the type of anesthesia to improve THA outcomes, surgeons do not agree. General anesthesia has been shown to be associated with increases in adverse events, increased operating room times and increased length of stay [Basques,Helwani]. Therefore, more surgeons are turning to spinal anesthesia for better pain control, decreased need for narcotics resulting in less nausea, sooner recovery of bowel function, and faster participation in physical therapy. All of these factors can lead to a sooner discharge from the hospital, which would lead to significant cost savings.

Transient neurological symptoms (TNS) are a concern of using spinal anesthesia and have been shown to occur up to 16-40% of the time with lidocaine [Ligouri, Capelleri, Hodgson, Keld]. There is no known cause of TNS. Symptoms have been described as pain, dysesthesia, or both that occur in the legs or buttocks and urinary retention after recovery from spinal anesthesia. Intensity of pain varies but can be quite severe. Symptoms can appear in a few hours, for up to 24 hours after surgery [Pollock].

The risk of developing TNS after spinal anesthesia with lidocaine has been shown to be higher when compared to other anesthetics [Zaric]. Lidocaine is the most widely used anesthetic due to its rapid onset, intense nerve blockade, and short duration of action. The use of spinal anesthesia with lidocaine has been shown in knee arthroscopy, general surgery, and obstetric literature [Valanne, Cappelleri, Ben-David B, Casati, Philip].

However, it is unknown whether there are differences between patients who undergo spinal anesthesia with lidocaine versus bupivacaine in THA. This knowledge is important because it has been shown that bupivacaine spinal anesthesia is more effective than lidocaine with minimal adverse effects [Gozdemir]. A large randomized, prospective study is needed to prove the difference between the two types of anesthesia.

The primary goal of this study is to evaluate the incidence of TNS between lidocaine and bupivacaine spinal anesthesia in THA patients. This will be done through examination of the patient records prospectively and telephone questionnaire after randomization to lidocaine or bupivacaine spinal anesthesia in THA patients.

Specific Aim 1: To determine the incidence of TNS after spinal anesthesia with lidocaine versus bupivacaine in THA patients.
Hypothesis: There will be no difference in TNS after surgery between lidocaine and bupivacaine spinal anesthesia in THA patients.

Specific Aim 2: To compare urinary retention after spinal anesthesia with lidocaine versus bupivacaine in THA patients.
Hypothesis: There will be no difference in urinary retention after surgery between lidocaine and bupivacaine spinal anesthesia in THA patients.

Specific Aim 3: To compare timing of ambulation after spinal anesthesia with lidocaine versus bupivacaine in THA patients.

Hypothesis: There will be no difference in timing of ambulation after surgery between lidocaine and bupivacaine spinal anesthesia in THA patients.

Specific Aim 4: To compare incidence of hypotension after spinal anesthesia with lidocaine versus bupivacaine in THA patients.
Hypothesis: There will be no difference in incidence of hypotension between lidocaine and bupivacaine spinal anesthesia in THA patients.

Specific Aim 5: To compare length of hospital stay after spinal anesthesia with lidocaine versus bupivacaine in THA patients.
Hypothesis: There will be no difference in length of hospital stay between lidocaine and bupivacaine spinal anesthesia in THA patients.

**RESEARCH DESIGN**

This is a single-center, prospective, randomized, double-blind study to evaluate the effectiveness of spinal anesthesia with lidocaine versus bupivacaine in subjects undergoing total hip arthroplasty. A total of 93 subjects per group will be enrolled in this study. All subjects will be blinded to treatment. Subjects screened at the [redacted] who meet the inclusion criteria, will be offered participation on the study.

Adult patients, age 18-90 years old who satisfy the inclusion criteria and do not meet the exclusion criteria will be enrolled. The enrollment period for this study is one year. Demographics obtained will be age, sex, height, weight, laterality and body-mass index (BMI).

*Randomization:* Patients will be randomized in a blocked fashion to receive either lidocaine or bupivicaine. Randomization will occur after informed consent has been obtained from the patients and after the surgeon has completed the preoperative screening examination. To minimize potential patient bias, each patient will be counseled that both anesthesia techniques are used in standard clinical practice. Patients will be blinded to their randomization until all study visits have been completed. The randomization module in REDCap, a secure, web based application for building and managing online surveys and databases, will be used to randomize the patients. A 1:1 block randomization model will be created by the clinical research coordinator. Each block will contain a random sequence of numbers in groups of twenty (i.e. 1 = lidocaine, 2 = bupivicaine). This sequence will be used to allocate patients to treatment groups. The investigators will be blinded to the allocation sequence.

## SOURCE OF RESEARCH MATERIAL

| Source of Research Material | Standard of Care? (Y/N) |
|---|---|
| Demographics [i. e., age, sex, height, weight, laterality and body-mass index (BMI)] | Y |
| Case Report Form (CRF) | N |
| History and physical exam | Y |
| Spinal Anesthesia Medication | Y |
| Preoperative Time | Y |
| Intraoperative Time | Y |
| Postoperative Time | Y |
| Time of PACU discharge | Y |
| Time of ambulation | Y |
| Vital Signs | Y |
| Urinary retention (intermittent catheter or foley catheterization) | Y |
| Date of admission | Y |
| Date of discharge | Y |
| TNS | Y |

The following data for the study will be obtained from the subject's inpatient medical chart:

- Demographics [i. e., age, sex, height, weight and body-mass index (BMI)].
- TNS: during hospital stay and questionnaire after discharge
- Urinary retention: use of intermittent catheter or foley catheter
- Hypotension: defined as systolic blood pressure <90mmHg
- Operating Room Times: preoperative, intraoperative, postoperative
- Length of Stay: calendar days in the hospital
- Ambulation: Timing of ambulation during hospital stay

All data will be entered on a case report form (CRF), which will not have any identifiable patient information on it, only the patient's study number and initials will appear.

**Inclusion and Exclusion Criteria**

*Inclusion criteria:* Subjects meeting all of the following may continue in the study:

- Subject must be at least 18 years of age and no older than 90 years of age; of either sex
- Radiographic evidence of symptomatic osteoarthritis in one or bilateral hips. Osteoarthritis will be defined as pain with weight-bearing at the hip articulation together with radiographic findings as described below.
- Indicated for total hip arthroplasty
- Agreement to undergo spinal anesthesia for surgery

*Exclusion criteria:* Subjects meeting any of the following will be withdrawn from the study

- Patient refusal to undergo spinal anesthesia
- Patients with a known history of lumbar or sacral spinal fusion.
- Patients with a known history of prostate, urological, or kidney surgery.
- Patients who need monitoring of urine output during surgery (including patients with confirmed renal disease, renal failure, chronic renal insufficiency, or an indwelling catheter at the time of surgery).
- Current infection at site of injection
- Women of child-bearing potential who are on Medicare (child-bearing potential will be determined prior to surgery per Anesthesia standard of care)
- Hypovolemia
- Indeterminate neurologic disease
- Allergy or hypersensitivity to the study medications
- Currently taking any anti-coagulation medications or coagulopathic
- Increased intracranial pressure
- Subject is unable to make his/her own decision regarding the informed consent
- Subject is unable to read/understand English

**Subject Screening Procedures**. History and physical examination, hip radiographs, indication for total hip arthroplasty.

**Description of the Recruitment and Consent Process**

Potential study participants will be identified in the Emory Orthopaedic and Spine Center outpatient clinic by the study team (Principal Investigator (PI), Co-Investigator (Co-I), or research coordinator). The patient's history and physical examinations and hip radiographs will be evaluated to determine if the inclusion/exclusion criteria are met. Subjects will have the study procedures, risks and benefits explained to them by a study team member (PI, Co-I, and/or research coordinator). The patient will be given the opportunity to read the informed consent and given time to ask questions prior to consenting for the study. Once the subject has read the consent form and had time to ask questions, they should be asked to explain their understanding of the requirements of the study. Subjects should be asked to voluntarily sign the consent form. The subject must be able to self-consent to be eligible. The following procedures will be conducted and documented for all subjects:

- Informed Consent/HIPAA Authorization form (ICF/HIPAA form)
- Evaluation of compliance with inclusion and exclusion criteria
- Known Medication allergies

Subjects who sign the ICF/HIPAA Form and who agree to the study procedures may be enrolled in the study. Following subject enrollment, if it is determined by the investigators that he/she does not meet inclusion/exclusion criteria, or a medical situation arises that causes the subject to be unable to continue in the study, the patient will be

withdrawn from the study and considered enrolled, but "withdrawn by primary investigator." Subjects may choose to withdraw at any time.

There is no plan to compensate enrolled subjects for their participation in the study.

**Drugs, Dietary Supplements, Biologics, or Devices.**

Patients in the intervention arms will receive one dose of either lidocaine or bupivacaine spinal, per Anesthesia standard of care for spinal anesthesia. The equipment is included in a tray that includes a 24 gauge pencil point spinal needle with introducer, and 22 gauge Quinke needle that are both 3.5 inches long. The approach will be either midline or paramedian with the patient sitting or lateral per Anesthesiologist preference and based on the patient.

Medications:

1. Bupivacaine: 0.75% hyperbaric in dextrose. Dose is primarily dependent on patient height 7.5-9mg </= 5 feet tall to 15mg >/= 6 feet tall.
2. Lidocaine: 2% isobaric. Dose is primarily height dependent 40mg for </= to 5 feet tall to 100mg >/= 6 feet tall.
3. Any additive medications to assist with pain control will be at the discretion of the Anesthesiologist and will be recorded for comparison. Additive medication will be per standard anesthesia protocol

The administration of either treatment will occur in a double-blinded fashion. Neither the patient receiving the medication nor the surgeon or investigators collecting study outcome data will be aware of whether or not the patient received lidocaine or bupivacaine. Due to patient safety concerns, the Anesthesiologist will not be blinded. Both treatment groups will receive a standard postoperative total hip arthroplasty pathway.

**Study Procedures/Research Interventions**

Potential study subjects will be identified in the Emory Orthopaedics and Spine Center clinic by history and physical and hip radiographs. A protocol approved investigator or research coordinator will approach the potential subject and briefly explain the study. Following the subject's agreement to participate in the study and attainment of proper consent, the subject's baseline Case Report Form (CRF) will be completed. The Inclusion/Exclusion Criteria outlined in this protocol should be reviewed for determination of subject eligibility and continuance in the study. For female subjects, a negative pregnancy test will be obtained to continue in the study. Only when eligibility has been determined, will the subject be allowed to participate in the planned study procedures. Final eligibility will be determined by the PI or Co-I.

| Assessment | Study Day/Period | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Screening | Op Day | POD #1 | POD #2 | POD #3 | POD #4 | 1 week post-op | 2 week post-op |
| History/Physical Exam | x | | | | | | | |
| Hip Radiographs | x | | | | | | | |
| Pregnancy test (females-if needed) | x | | | | | | | |
| Informed Consent Discussion | x | | | | | | | |
| Demographics [i. e., age, sex, height, weight, laterality and body-mass index (BMI)] | x | | | | | | | |
| Randomization | | x | | | | | | |
| Study drug | | x | | | | | | |
| Admission Date | | x | | | | | | |
| Preop Time | | x | | | | | | |
| Intraop Time | | x | | | | | | |
| Postop Time | | x | | | | | | |
| Vitals | | x | x | x | x | x | | |
| Ambulation | | x | x | x | x | x | | |
| Anesthesia Duration | | | | | | | | |
| Urinary retention | | x | x | x | x | x | | |
| TNS: weakness, numbness, parasthesias, etc. | | x | x | x | x | x | x | x |
| Discharge date | | x | x | x | x | x | | |

*TNS Evaluation*

The duration of the anesthesia, defined as the time until the subject had normal sensation and was able to lift both extremities, will be recorded. The subject will be contacted on the first and third postoperative days by the study team, who are blinded to the anesthetic used and only informed of the subjects' data and telephone number. Following a prepared questionnaire [APPENDIX B], the study team member will ask about symptoms of TNS and pain not associated with the operation area. The subject will be asked to specify the location of the symptoms and grade the complaints after a verbal analogue scale from 0 to 10, with zero as no discomfort and ten as unbearable discomfort. The subject will be asked about the time to full mobilization and time of first voiding.

Another follow-up call will be made within 7 and 14 days post-operatively. If any subject continues to have symptoms, further follow-up evaluation will proceed on a case-by-case basis until the problem resolved, the subject is unable or unwilling to be contacted again, or the primary physician requests no further follow-up calls by the study team. The remaining data points will be prospectively obtained from the inpatient chart and recorded on the CRF.

**Data Collection**

A subject key listing name, medical record number (MRN), age, sex, study number and treatment received will be kept in electronic format, as well as in the research binder stored in a secure locked file cabinet.

Radiographs will be obtained at the initial clinic visit per standard of care. Demographic data, including height, weight, BMI, sex, laterality and age, at the initial clinic visit will be recorded on the CRF. During the subject's inpatient hospitalization, study treatment, vital signs, TNS, ambulation, urinary retention and length of stay will be recorded on the CRF. All data collected on the CRF will be kept in REDCap as well as in the research binder. The CRF will not have any identifiable subject information, only the study number and subject's initials.

Data from the paper CRFs will be entered into an electronic database in REDCap by a study team member. The database will be made available to all investigators electronically. Data analysis will be performed by the investigators which will also be performed on a password enabled computer. There will be no patient identifiers in the data provided to the investigators, only the subject number.

**Primary (i.e., primary outcome variables) and secondary endpoints**

*Primary:* TNS

*Secondary:* Need for supplemental anesthesia (ie- conversion to general anesthesia), urinary retention, urinary incontinence, hypotension, ambulation, length of stay

Confounders: Height, weight, BMI, gender, age, laterality

**Sample size and power considerations**: The primary outcome for the THA intent-to-treat trial will be TNS [APPENDIX B]. Previous studies suggest the incidence of TNS after spinal anesthesia in patients treated with bupivacaine as <5% and 16-40% in patients treated with lidocaine. For example, TNS incidence among 150 women that underwent gynecologic or obstetric procedures and received 0.5% bupivacaine was less than 1% on postoperative day 3 (1 of 150 with TNS; Hampl *et al*). TNS incidence was approximately 3% (1/30; 95% confidence interval: 0.6% to 16.7%) in patients undergoing inguinal hernia, appendectomy, varicose vein or minor orthopedic operations (Gozdemir *et al*).

A sample size of 93 patients per treatment group achieves 90% statistical power to detect a difference between the two treatment group proportions of 0.15 (Table 1). The proportion of patients in the bupivacaine group that report TNS over the 2-week study period is assumed to be 0.20 under the null hypothesis and 0.05 under the alternative hypothesis. The proportion of patients in the lidocaine group (control arm) that report TNS over the 2-week study period is assumed to be 0.20. The test statistic used is the two-sided Z test with pooled variance (significance level = 0.05).

An intent-to-treat design will be followed and all subjects will continue to be followed with all scheduled outcome evaluations until the end of the study, death of the subject or subject refusal. Subjects may be withdrawn from their randomly assigned treatment for considerations of subject safety. No interim analyses are planned.

Table 1. Sample Size and Power Considerations for the Lidocaine versus Bupivacaine Spinal Anesthesia THA trial (primary outcome: Transient Neurologic Symptoms, TNS)

| Bupivacaine, $p_1$ | Lidocaine, $p_2$ | Difference ($p_2$-$p_1$) | # Participants per Group | Statistical Power |
|---|---|---|---|---|
| | | | | |
| 0.05 | 0.30 | .25 | 42 | 90% |
| 0.05 | 0.25 | .15 | 61 | 90% |
| **0.05** | **0.20** | **.15** | **93** | **90%** |
| 0.05 | 0.15 | .10 | 188 | 90% |
| 0.05 | 0.10 | .08 | 582 | 90% |
| 0.10 | 0.30 | .20 | 78 | 90% |

$p_1$=proportion of patients reporting TNS during the 2-week study period in the Bupivacaine group and $p_2$=proportion of patients reporting TNS during the 2-week study period in the Lidocaine group.

**Statistical analysis**

The primary analyses of the data will be performed according to subjects' original treatment assignment (i.e., intention-to-treat analyses) and all data from all subjects randomized will be included in the final analysis. TNS rates will be estimated and compared using 2 approaches. First, the overall TNS rates (as a simple fraction for each treatment group) will be compared between treatment groups using a $\chi^2$ test. Confidence intervals (95%) will be calculated for TNS rates within each study cohort and for the observed treatment difference in TNS rates. Second, TNS rates by treatment group and time on study (at discharge, 1-week post-op and 2-weeks post-op) will be estimated and compared by performing a generalized estimating equations (GEE) analysis using SAS Proc Genmod with an exchangeable correlation structure for the repeated measures within the participant (binomial-logit model). The statistical model provides estimates of the percentages of patients with TNS by treatment arm and time on study. The model-based estimates are unbiased with unbalanced and missing data, so long as the missing data are non-informative (missing completely at random). Results will be summarized with TNS rates and 95% confidence intervals. A P value $\leq$0.05 will be considered statistically significant for the main effects (treatment and time on study) and interaction factor (treatment arm by time on study) from the repeated measures analysis.

A potential problem in any of the above analyses is missing data. Missing data cause the usual statistical analysis of complete or all available data to be subject to bias. Since the required follow-up for this clinical trial is only 2-weeks we expect no lost to follow-up for the primary endpoint, TNS. Every effort will be made to minimize missing data on outcomes and covariates. There are no universally applicable methods for handling missing data. If missing data becomes an issue then we will conduct sensitivity analyses to encompass different scenarios of assumptions and discuss consistency or discrepancy among them.

**Data and Safety Monitoring and Reporting**

Oversight of the progress and safety of the trial will be provided by the primary investigator. Adverse events are not anticipated, but any occurring will be documented and reported according to Emory Institutional Review Board (IRB) policies and procedures.

Confidentiality will be protected by utilizing a code number as the only identifier for each subject and the master list will be kept in an excel spreadsheet on a password protected, encrypted computer access limited to the primary investigator and study team. All Case Report Forms (CRFs) will be completed and entered in a secure, password protected database within a reasonable time frame. All CRFs will be reviewed and electronically signed by the PI. Completed paper CRFs and other identifiable study documents will be stored securely in a locked filing cabinet in a locked office.

The principal investigator will be responsible for reviewing protocol compliance, data collection and verification. The PI will also review the data after the first 60 participants to note any changes, safety issues, and/or unanticipated problems.

## RISKS/BENEFITS ASSESSMENT

In the event of a serious adverse event or the subject develops a severe adverse reaction, they may be withdrawn by the investigators due to safety concerns. The research coordinator would go to the patient key to identify the patient number and withdraw the patient from the study.

Risks to the patient include exposure of personally identifiable information. Measures to reduce this risk will include a subject key listing the name, last four digits of social security number, subject number (randomly assigned) and treatment received will be kept with the research assistant in the Emory Orthopaedics and Spine Center Clinic in a research folder, locked in a cabinet. Only the research coordinator will have access to this key, none of the investigators will not have access to this information. Physical risks apply to the adverse reactions to the medication as listed. This study involves injection of a spinal anesthesia and may cause TNS, hypotension, urinary retention or infection. There may be additional risks that are unknown at this time. Prior to enrollment, all included subjects will receive counseling regarding the risks of the study.

Subjects may benefit from the study by reducing the use of narcotics leading to better function postoperatively and earlier discharge, reducing costs for the hospital.

## ADVERSE EVENTS, UNANTICIPATED PROBLEMS, AND DEVIATIONS

Adverse events may occur with the use of spinal anesthesia using lidocaine or bupivacaine which include: headache, weakness, numbness, tingling, pain, infection. The risks in this study are the same as any patient undergoing THA with spinal anesthesia.

## WITHDRAWAL FROM STUDY PARTICIPATION

There will be no consequences to the subject for withdrawal from the study. Subjects may still follow-up in the [redacted] r another provider if they wish. The subject will be asked to follow-up in [redacted] or with their Primary Care Physician to ensure no development of adverse events. In the event of a serious adverse event, the subject will be advised to present to the Emergency Department. If the subject develops a severe adverse reaction, they may be withdrawn by the investigators due to safety concerns.

## TIME REQUIRED TO COMPLETE THE RESEARCH (including data analysis)

Enrollment from October 2016 through October 2017. Data analysis will be complete by August 2017.

## STUDY CLOSURE PROCEDURES

The procedures to close the protocol will be to destroy by shredding all personally identifiable information including subject key, CRFs, consent forms, randomization cards and HIPAA forms. Data collected will not have any personally identifiable information, only the subject number, which was randomly assigned. The subject number is only connected to the subject via the subject key, which will be destroyed as described. A Protocol Closure Report will be submitted.

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**APPENDIX A**
Case Report Form from REDCap

**APPENDIX B**

Transient Neurological Symptoms Checklist/Survey:

Did you recuperate completely from your anesthetic?

☐ Yes ☐ No

If no: What are your problems? _____

☐ Fatigue
☐ Dizziness
☐ Nausea/vomiting
☐ Difficulty urinating or defecating
☐ Pain at the site of injection
☐ Pain at site of surgery
☐ Pain at other sites/any unusual sensations?
☐ Yes ☐ No
If yes: What is the problem? _____

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If the patient mentions pain or any symptoms such as dysesthesia or hypesthesia, please indicate location:

☐ Buttocks ☐ Thighs front
☐ Thighs back ☐ Lower limbs
☐ One-sided ☐ Bilateral

Severity of pain: (verbal reporting scale: 1 = no pain; 6 = worst conceivable pain)