Outcomes after Hypotensive Neuraxial Anesthesia in Total Hip Arthroplasty

FUNDER: Department of Anesthesiology

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TABLE OF CONTENTS

PROTOCOL SYNOPSIS

Protocol Title:	Outcomes after Hypotensive Neuraxial Anesthesia in Total Hip Arthroplasty
Protocol Number:	2018-2235
Protocol Date:	
Sponsor:	Department of Anesthesiology
Principal Investigator:	Jiabin Liu, MD, PhD
Objective:	The proposed project will be the largest study on deliberate hypotensive neuraxial anesthesia and adverse outcome in THA. It will provide essential feedback and guidance to our clinical practice, indicating whether we need to modify our intraoperative management for better patient outcomes and less adverse complications, or conversely may allow us to argue that deliberate hypotensive neuraxial anesthesia is not associated with adverse events. This will be the first significant database study to examine the clinical outcomes of patients undergoing THA with a deliberative hypotensive neuraxial anesthetic technique.
Study Design:	Retrospective study
Enrollment:	10,000
Subject Criteria:	All primary THA patient data with sufficiently complete intraoperative vital signs will be included in the study.
Data Collection:	Sources: Medical record Variables: • MRN • Age • BMI • ASA status • Ethnicity • Gender/sex • zip code • insurance • type of surgery • primary anesthetic type • anesthetic procedures • anesthesia provider name • anesthesia provider helpers (CRNA, Resident, Fellow) • surgeon • duration of surgery • duration of anesthesia

	• Problem list of comorbidities (OSA, COPD, asthma, HTN, HLD, CAD, CHG, arrhythmia, pulmonary hypertension, DM (type 1 or 2), coagulopathy, hx of dvt/PE, anxiety, depression, bipolar disorder, schizophrenia, IBS) • Number of allergies • Pre-op medications: betablockers, asa, anticoagulant, NSAID, Opioid, steroids, ACE inhibitor, calcium antagonists and diuretics, blood pressure (pre-op and all intra-op), intra-op medication: TXA IV or topical, ketamine, blood transfusion, albumin, IV fluids, epinephrine, ephedrine, phenylephrine, bydralazine, labetalol, • Laboratory results: hemoglobin, BUN, creatinine (pre-op and first post-op) • Post-operative medications for the first 24 hours: IV fluids, albumin, blood transfusion, epinephrine, ephedrine, phenylephrine, opioids • Complications: MI, CVA, death, ARF, pneumonia, arrhythmia, DVT, PE
Statistical Analysis:	• Two-step logistic regression modeling to determine odds ratios • Confidence intervals: 95%

2.0 INTRODUCTION

There have been long debates in regards to the appropriate blood pressure management during joint replacement. Traditionally at HSS, many anesthesiologists routinely manage the blood pressure in the 40-60 mmHg MAP range to minimizing perioperative bleeding and optimize surgical outcome. Such deliberate hypotension anesthesia does not seem to cause increased risk of major complications in several studies, including studies from our institution (Paul et al, Can J Anesth 2007; Bombardieri et al, Anesth Analg, 2016; Weinstein et al. RAPM, 2018).

However, concerns still remain due to evidence from other major studies, which indicated increased complication risks with intraoperative hypotension (Salmasi et al, Anesthesiology, 2017; Sessler et al, Anesthesiology, 2018). Previous studies at HSS are mostly limited by the small number of patients, and therefore could not draw more convincing conclusion. With the implementation of EPIC electronic medical record system at HSS in 2016, it is feasible to access thousands of patients' intra-operative data nowadays. Hereby, we propose this project to study whether there is associated between deliberate hypotension and increased adverse outcomes among primary THA patients. In addition, we will explore whether controlled hypotension continues to be an effective technique for reducing intra-operative blood loss with modern surgical techniques and in the setting of widespread use of tranexamic acid.

3.0 OBJECTIVE(S) OF CLINICAL STUDY

The goal of this study is to determine if hypotensive neuraxial anesthesia is associated with worse outcomes in Primary Total Hip Arthroplasty (THA).There is a substantial body of literature supporting the safety and utility of the practice of deliberate neuraxial hypotension for reduction of blood loss during THA. However, substantial controversy remains regarding the safety of deliberate and controlled intraoperative hypotension with epinephrine mediated cardiac output augmentation as compared to inadvertent and/or uncontrolled intraoperative hypotension. Moreover, it is unclear if advances in surgical practice combined with the widespread use of TXA have diminished the clinical utility of deliberate hypotension as a means of minimizing blood loss. Therefore, this study is looking at the extent and duration of hypotension under neuraxial anesthesia in primary THA surgery.

This proposed project will be the largest study on deliberative hypotensive neuraxial anesthesia and adverse outcome in total hip arthroplasty. It will provide essential feedback and guidance to our clinical practice, indicating whether we need to modify our intra-operative management for better patient outcomes and less adverse complications, or conversely may allow us to argue that deliberate hypotensive neuraxial anesthesia is not associated with adverse events.

We will be accessing and reviewing EPIC data of patients who have undergone Primary Total Hip Arthroplasty at HSS from January 2016- December 3, 2018

4.0 STUDY HYPOTHESES

This is retrospective study hypothesize that:

A. There is no association between level and duration of hypotension with (i) myocardial infarction (MI), (ii) cerebrovascular accident (CVA), (iii) death in primary total hip arthroplasty patients.
B. With the use of IV tranexamic acid is administered, the use of deliberate neuraxial anesthesia induced hypotension does not result in a further clinically relevant reduction in calculated blood loss after total hip arthroplasty.

5.0 STUDY DESIGN

5.1 Endpoints

5.1.1 Primary Endpoint

The primary outcomes are the incidences of:

i. myocardial infarction (MI)
ii. cerebrovascular accident (CVA)
iii. death
iv. calculated perioperative intraoperative blood loss.

All primary outcomes are events during the inpatients stay.

5.1.2 Secondary Endpoints

The secondary outcomes are incidences of:

i. acute renal failure (ARF)
ii. Pneumonia
iii. Arrhythmia
iv. deep venous thrombosis (DVT)
v. pulmonary embolism (PE)
vi. blood transfusion

5.2 Study Sites

This study will take place at the main campus of the Hospital for Special Surgery (HSS).

6.0 STUDY POPULATION

6.1 Number of Subjects

10,000

6.2 Inclusion Criteria

All primary THA patient data with sufficiently complete intraoperative vital signs will be included in the study.

6.3 Exclusion Criteria

Subjects will be excluded from the study if:

- Revision THA
- Incomplete intraoperative vital signs
- Anterior THA

7.0 PROCEDURES

The independent variables of interest include extent of intraoperative hypotension (MAP <45, 50, 55, 60 mmHg) and duration of hypotension (5 mins interval). Intraoperative blood loss will be calculated based on pre-operative and post-operative laboratory hemoglobin levels.

The outcome variables include MI, CVA, death, intraoperative blood loss, ARF, pneumonia, arrhythmia, DVT, PE, and number of packed red blood cell (pRBC) transfusions.

7.1 Data Collection

The following data will be collected:

Pre-operative/Baseline

- MRN
- Age
- Height
- Weight
- BMI
- ASA classification
- Ethnicity
- Gender
- Baseline status: METS, substance hx, smoking hx, SOB
- Comorbidity: OSA, COPD, asthma, HTN, CAD, CHF, Arrhythmia, pulmonary hypertension, seizure, TIA/CVA, renal dx, DM (type I or type II), coagulopathy, hx of dvt/PE
- Pre-op medications: beta-block, asa, anti-coagulant, nsaid, steroids
- Blood pressure: pre-op BP, and all intra-op

Intra-Operative

- Blood pressure: pre-op BP and all intra-op
- Intra-op medications: TXA IV or topical, ketamine, blood transfusion, albumin, IV fluids, epinephrine, ephedrine, phenylephrine, hydralazine, labetalol

Post-Operative

- Laboratory results: hemoglobin, BUN, creatinine

- Post-operative medications: (first 24 hours) IV fluids, albumin, blood transfusion, epinephrine, ephedrine, phenylephrine
- Complications: MI, CVA, death, ARF, pneumonia, arrhythmia, DVT, PE

8.0 STATISTICAL ANALYSIS

1. Proposed analysis (e.g., student's t-test, ANOVA, chi-square, regression, etc.): Two-step logistic regression modeling to determine odds ratios
2. Confidence intervals: 95%
3. Total sample size required: 10,000

9.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report.