

A Prospective Randomized Control Trial Comparing Preoperative Bilateral Superficial Cervical Plexus Block and Local Wound Infiltration Under General Anesthesia In Parathyroidectomy and Total and Partial Thyroidectomy

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A. Study Abstract:

Background: Administration of local anesthetic for cervical incisions has proven benefits in reduction of post-operative painⁱⁱⁱ, nausea, and vomiting^{iiiiiv} in prospective randomized controlled trials . Methods of applying anesthetic to cervical incisions include bilateral superficial cervical plexus block (BSCPb) and local wound infiltration (LWI). BSCPb involves the surgeon injecting 10 mL of 0.25% Marcaine solution just lateral to the SCM at the level of the planned incision prior to the operation. 5 mL of the Marcaine solution are injected intradermally while the remaining 5 mLs are injected 1 cm deep toward the planned incision. This is then repeated on the contralateral side for a total injection of 20 mL of 0.25% Marcaine. LWI involves injecting 20 mL of 0.25% marcaine solution intradermally along the planned incision immediately prior to incision. To date, there is no evidence suggesting one methodology's superiority over the other.

Methods: A prospective randomized control trial will be performed at our institution evaluating patients receiving either BSCPb or LWI with either anesthetic or placebo. The primary aim of this study will be to evaluate intra operative pain medication utilization, post-operative pain as well as pain medication use at various intervals during recovery. Secondary aims include post-operative nausea and vomiting, perioperative sequela of BSCPb and LWI, return to work, total pain medication utilization, site of pain, and return to driving will be evaluated at the first post-operative visit.

1. Primary Hypothesis

We hypothesize there is equivalent pain control between the two methods of local anesthetic administration when used in conjunction with a general anesthetic.

2. Purpose of Proposed Protocol

The primary goal of the proposed study is to compare outcomes in prospective controlled fashion between BSCPb and LWI. The collected data will include post-operative pain scores, nausea scores, number of episodes of emesis, unanticipated overnight observation, unanticipated admission, total pain medication utilization, time to return to work, and time to return to driving.

B. Prior Literature and Studies

Numerous studies have examined various methods of local pain management in neck surgery. To date the data comparing BSCP^{Bⁱ ii iii iv ix}, LWI^{vvviii}, and placebo remain equivocal. A recent meta-analysis of eight RCTs examining BSCP^B versus various controls found a small but variable benefit to BSCP^B the authors felt was not clinically significant^x. With such heterogeneity present in the data, however, continued studies adding to the power of available data and examining further variable such as post-operative nausea vomiting should be performed. Only a single study exists studying the effect of local analgesia and intraoperative pain medication utilization in thyroidectomy^x. To our knowledge there are no RCTs comparing the efficacy of BSCP^B to that of LWI.

C. Study Objectives

1. Primary Aim

Compare intraoperative pain medication utilization between the four arms.

2. Secondary Aim

Compare serial post-operative pain scores during hospital recovery, post-operative analgesic use, nausea scores, number of episodes of emesis, unanticipated overnight observation, unanticipated admission, total pain medication utilization, time to return to work, and time to return to driving in a prospective fashion.

3. Rationale for Selection of Outcome Measures

To date various studies have demonstrated variable results with local pain control therapies in conjunction with a general anesthetic. If a benefit is demonstrated with either BSCP^B or LWI it would suggest further study is warranted to determine an optimal pain control regimen for partial and total thyroidectomy procedures

D. Investigational Intervention

Patients evaluated in the outpatient offices and who are scheduled and consented for a parathyroidectomy or partial or total thyroidectomy will be approached for the study. After consenting to participate the patient will undergo his/her scheduled procedure. A research coordinator will be in charge of collecting demographic, clinical, and operative data. Patients will have a form (see Appendix A) attached to their chart that will be completed by the anesthesiologist postoperatively and by PACU/floor nursing postoperatively. In addition, a questionnaire will be provided to the patient at their first follow up visit and be collected by the research coordinator at that time.

E. Study Design

1. Overview

This is a prospective randomized control trial examining post-operative pain, nausea, vomiting, return to activities of daily living. The patients will be enrolled randomly into one of the four arms of the study as follows: BSCPb with anesthetic (0.25% marcaine), BSCPb with placebo (saline), LWI with anesthetic (0.25% marcaine), and LWI with placebo. BSCPb and LWI will be performed as described above. The surgeon will be provided 2 syringes of 10 mLs of either 0.9% normal saline or 0.25% Marcaine solution in the operating room labeled with only the patient's name and study ID number to be correlated to saline or Marcaine by the research coordinator. The anesthesiologist or nurse anesthetist providing anesthesia with standardized fentanyl and versed preoperatively (see appendix A), Fentanyl used at their discretion intraoperatively in conjunction with standardized inhalational anesthetic (Desflurane or Sevoflurane), and record the patient's medication requirements. Patients will follow up as previously scheduled 1-2 weeks post operatively. Clinical data from PACU and 24 hours observation stays will be accrued as well as a survey of post operative pain, nausea, and return to activities of daily living at the first follow up appointment.

2. Subject Selection and Withdrawal

a. Inclusion Criteria

- Patient \geq 18 years old
- Surgical indication for parathyroidectomy or thyroidectomy (benign or malignant pathologies)

b. Exclusion Criteria

- Patients < 18 years old
- Patient with history of chronic opioid use
- Patient with chronic pain syndromes
- Patient with allergy to marcaine, opioids, or inhalation anesthetic

c. Ethical Considerations

- All races, gender, and ethnicities of patients may be enrolled in this study

d. Subject Recruitment Plans and Consent Process

Patients who present with a disease process normally managed with the partial or total thyroidectomy will be presented with the study and given the choice of participation by the surgeon. They will be informed of all aspects of the study procedure, risks and benefits, study schedule and requirements, including multiple questionnaires. A written consent form will be provided. Patients will be given considerable time to discuss the study with their family and to make their decision.

e. Early Withdrawal of Subjects

Subjects may withdraw from participation in the research protocol at any time

3. Risks and Benefits

- a. Risks
Risks associated with surgery for which they consented, no new risks associated with study protocol or procedure, patients in the placebo arms may be introduced to more intra- and post-operative pain from the cervical incision and therefore require increased narcotic. This risk is easily assessed and treated with narcotic pain medication they will already be receiving.
- b. Benefits
Benefits associated with surgery for which they consented, no new benefit associated with study protocol or procedure.

F. Study Procedures

- 1. Screening for Eligibility
Attending surgeon will determine eligibility based on the above inclusion/exclusion criteria
- 2. Measurements
Age, sex, BMI, race, ethnicity, occupation, functional status
Medical and surgical history
History of post operative nausea/vomiting
History of motion sickness
Laboratory and imaging studies
Diagnosis
OR procedure time (from incision to closure)
Technique
EBL
Total incision size in cm
ASA class
Intraoperative pain medication administration
LOS from exit from OR until discharge time
Pain medication administered in PACU and hospital
Post-operative analgesic use
Complications from surgical procedure
Complications from performance of BSCP and LWI
Questionnaire
 - Fatigue/Stamina
 - Pain, 24 hour and 7 day versions
 - Physical Function
 - Patient Satisfaction
 - Bowel Function
 - Return to work
 - Return to driving
 - Hoarseness
 - Paresthesias

3. Treatment Visits
Visit 1: Preoperative Visit
H & P
Consent
Visit 2: Surgery
Visit 3: 1-2 week follow up
Questionnaire
4. Follow Up Visits
Follow up visits will include medical history and physical examination, with particular attention to surgical complications, pain, post-operative nausea and vomiting, return to ADLs. Patient reported outcome questionnaires will be included at these visits as described above.
5. Safety and Adverse Events
 - a. Safety and Compliance Monitoring
 - b. Medical Monitoring
 - c. Definitions of Adverse Events
 - d. Data Collection and Procedures for Adverse Events
 - e. Adverse Events Reports

G. Data Handling and Record Keeping

We recognize the importance for confidentiality of the patient's protected health information (PHI). PHI will be collected and transferred only where necessary. Patients will be identified only by generic ID's.

We require use of current passwords and log-on codes to protect sensitive data from unauthorized access. All system access requires a user name and password. All users who require full access to the University of Chicago LAN must have a unique ID assigned. The LAN ID is used to control access to data files and applications that reside on the network. Every LAN ID is required to have a password assigned. We require that all sensitive material be stored in a secure location when not in use. Study records will be maintained within the confines of the Surgical Research Office in locked cabinets.

If study results are published, no personal information will be identified.

Study records will be retained for at least 2 years following trial closure.

H. Statistics and Data analysis

Parametric outcomes such as patient demographics will be compared using analysis of variance and t-tests where appropriate. Non-parametric outcomes such as intraoperative Fentanyl and post-operative pain scores will be compared using Kruskal-Wallis ANOVA. All statistical analysis will be performed using STATA 15 (College Station, TX).

Appendix A

Thyroidectomy and Parathyroidectomy Anesthesia and PACU Protocol and Worksheet **Operating Room**

Prior to intubation (standardized):

Fentanyl: 0.5-1 mcg/kg (max 100mcg)

☐ check to confirm Fentanyl given

Versed: 1-2 mg

☐ check to confirm Versed given

Induction agent:

Propofol: 1-3 mg/kg

☐ check to confirm Propofol given

Neuromuscular blockade (if required):

Succinylcholine: 1-2 mg/kg

☐ check if Succinylcholine given

Intraoperative:

Sevoflurane maintenance (no other volatile anesthetic) check to confirm ☐

Prior to incision: Baseline MAP _____ Baseline HR _____

Intraoperative Opioid:

Fentanyl 0.5-2 mcg/kg (max 100 mcg) for MAP or HR > 20% deviation from baseline

_____ Total fentanyl administered

*if giving anti-emetic, please use Decadron (0.5mg/kg, max 10mg), check if given ☐

Please extubate patient awake

_____ Time of intubation _____ Time of extubation

PACU

Please only use Zofran for nausea and Dilaudid or Norco for pain

4 Hours Post Operatively:

Time _____

Nausea score (1-10) _____

Pain score (1-10): back of neck ____ throat ____ incision ____

Total Dilaudid administered in 4 hours _____

Total PO pain medications administered in 4 hours _____

Anti-emetics administered (total) _____

Post Operative Check

Post Operative Day #1:

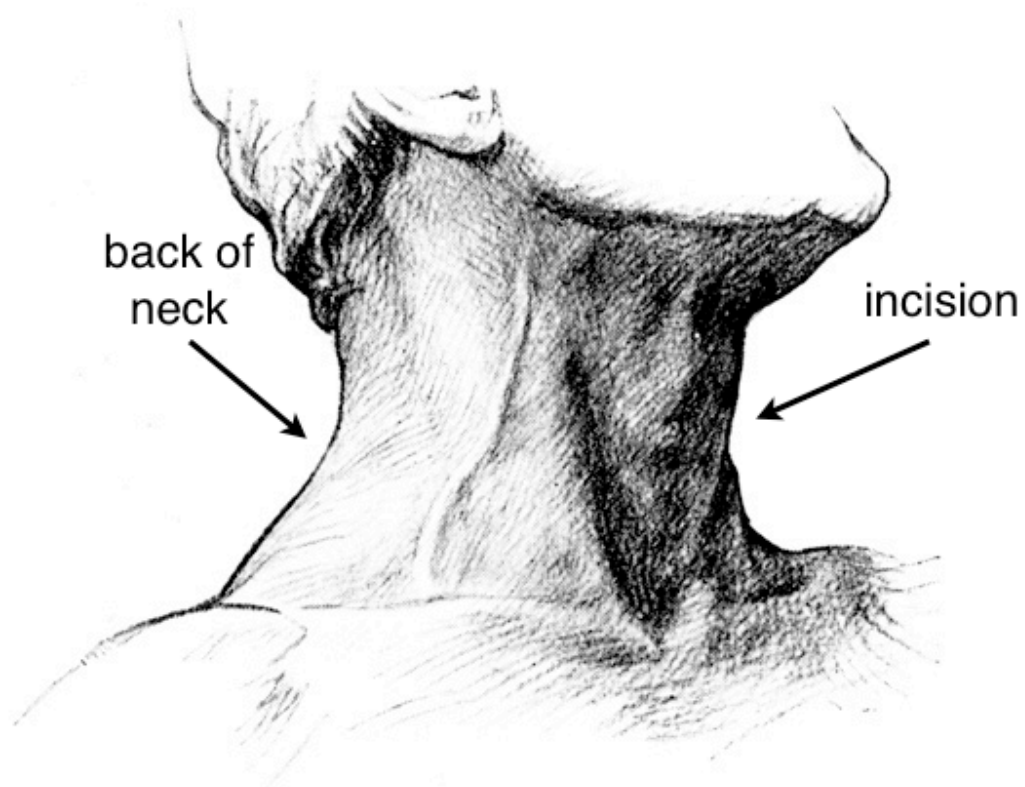
Time _____

Nausea score (1-10) _____

Pain score (1-10): back of neck ____ throat ____ incision ____

Total PO pain medications administered _____

Anti-emetics administered (total) _____



<http://karenswhimsy.com/public-domain-images/anatomy-of-the-neck/full/anatomy-of-the-neck-3.jpg>

Please score pain in the back of your throat or pain with swallowing from 1-10



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