RESEARCH PROPOSAL

A Randomized Clinical Trial Comparing Output Volume Thresholds For Drain Removal After Selective Lateral Neck Dissections

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0.0 AIM/HYPOTHESIS

This is a single-blinded randomized controlled trial to compare the outcomes of early closed suction drain removal versus output volume-based drain removal after selective lateral neck dissections (SLND). The main hypothesis of the study is that the early drain removal of closed suction drains on the first postoperative day is safe compared to the current practice of output volume-based drain removal when output is less than 30ml/24hr or 15ml/12hr. This study will also evaluate the hypotheses that output volume-based drain removal of surgical drains increases inpatient length of stay.

1.0 INTRODUCTION

The use of post-surgical closed suction drains (CSDs) for selective lateral neck dissections in head and neck surgery does not have strong evidence-based support. The use of CSDs, once routinely placed for many surgical procedures, is controversial given the recent evidence showing no definitive benefit with their use in many surgical procedures. After elective cholecystectomy, hepatectomy, and thyroidectomy with and without central neck dissections, studies have shown that the routine use of drains does not prevent complications [1-3]. A prospective randomized trial by Lee et al, showed no increased complications and a significant decrease in hospital stay in thyroidectomies with central neck dissections performed without drain placement[4]. CSDs are still routinely used by most surgeons for selective lateral neck dissections (SLNDs) performed for the treatment of carcinoma of the upper aerodigestive tract, salivary gland, thyroid, skin, and others without strong evidence supporting this practice. Surgeons generally use drains after SLND to identify, reduce, and or prevent hematomas and seromas even though evidence suggests that CSD may actually be associated with increased rates of fluid collections and infections[1]. In breast surgery, the use of CSDs was once a routine practice for the theoretical reduction of seroma formation. Several studies, however, have demonstrated an increase in morbidity with CSDs, leading many surgeons to remove them very early in the postoperative period, or to not use them at all[5].

There is a relative paucity of data related to drain management for SLNDs. Mekel et al in 2010 demonstrated the possible safety of not using CSD with SLNDs for papillary thyroid cancer[6]. A recent study demonstrated SLND drain output to average 116 ml total when drains were removed when output was less than 25ml over a 24-hour period, which took an average of 4 days[7]. Similar studies have shown average drain outputs in thyroidectomies with central neck dissections to be 130 ml total when similar removal parameters are used[4]. This suggests that an average of 130ml postoperative drain output is not clinically significant, given the data showing the lack of benefit of CSD during thyroidectomy with central neck dissections, and that the additional hospital stay associated with prolonged drain placement may not necessarily be cost effective.

Once a drain is placed for a SLND there is also limited data on the optimal timing of removal. The clinical decision of when to remove a surgically placed drain often varies with the personal preference of the surgeon without much high quality evidence to support optimal timing. At our institution, it is common practice among three of our head and neck surgeons to remove drains once the output is less than 30ml over a 24-hour period or 15ml over a 12-hour period with a downward trend. Meeting this output volume criterion often takes several days. Often, a patient will be given the decision to be discharged home with a drain or wait and continue inpatient hospitalization until drain output requirements are met. The patient perspective of having a neck drain in place is another area that lacks evidence.

The volume of inpatient neck dissections increased by approximately 25% from the years 2000 to 2006, with much of this increase occurring with the treatment of three non-upper aerodigestive tract primary neoplasm: salivary gland, thyroid, and skin[9]. The number of SLNDs performed in the United States can be estimated at 20,000 per year. According the Healthcare Cost and Utilization Project, an average inpatient hospitalization in 2009 cost $2,000 per day, and is increasing[10]. The reduction of an average of just one hospital day per patient could potential save $40,000,000 dollars a year. An evaluation of drain management may reveal unnecessary expenses related to increased hospital length of stay and could lead to significant cost savings.

1.2 Possible Influence On Clinical Practice

Neck dissections, and surgery in general, have evolved in an era of increased attention to patient satisfaction and cost savings. The most radical neck dissections, during which the spinal accessory nerve, sternocleidomastoid muscle, internal jugular vein, the cervical sensory nerves, and lymph node levels 1 through 5 are excised, are increasingly being replaced by more focused “functional” and “selective” neck dissections, during which the spinal accessory nerve, sternocleidomastoid muscle, internal jugular vein, and cervical sensory nerves are preserved and a more narrowly defined set of lymph node levels are excised, based on oncologic risk profiling. However, as the same CSDs are being used for these less extensive SLNDs, patients are possibly being hospitalized longer than necessary, increasing cost to both the patient and medical center. Finding no difference in outcomes with early drain removal could improve the quality of life of head and neck cancer patients who undergo neck dissections and dramatically decrease the cost of their

care. If this study were to show a no difference in post-surgical hematoma and seroma rates, a significant improvement in patient satisfaction, and/or a decrease in hospital length of stay resulting from early CSD removal after neck dissection, a future multi-institutional trial could be performed.

This study seeks to critically evaluate current clinical practice paradigms to better understand the necessity and possible drawbacks of volume-based drain removal after neck dissections and, thereby, establish the possible benefits of early drain removal. A prospective, randomized, controlled, single-blinded trial is the clearest methodology to evaluate the possible benefits of early surgical drain removal, by limiting bias and confounding variables. No clinical trial of this level has been performed on this topic; thus, our proposal is novel and the findings of the study are potentially important.

2.0 SUMMARY OF SUBJECTS AND METHODS/SCHEMA

2.1 Summary

All adult patients (18 years old and over) undergoing unilateral SLNDs either levels I-III, I-IV, or II-III, II-IV, or II-Va for oral cavity, oropharynx (if the resection does not connect to the neck), thyroid, salivary gland, parotid, and skin carcinoma by one of three Head and Neck Surgery faculty members at UCSF will be consecutively registered. A randomized packet containing the patient's research ID number will be pulled and included into the patient's chart. Randomization will be done at the initiation of the study by creating a randomization list with blocking and stratification by surgeon. An envelope containing the patients randomized group assignment will not be opened until the end of the case. The patients will be randomized to one of two groups; drains placed routinely and removed once output is less than 30ml over 24-hours or 15ml over 12-hours and drains placed routinely and removed on rounds the morning of postoperative day one if output is less than 100ml total and does not appear chylous. Exclusion criteria will be, revision neck dissections (prior surgery in the ipsilateral neck including excisional lymph node biopsy), previous radiation, need for SCM excision, need for IJ excision, pectoralis major flap reconstruction of a ipsilateral skin defect, and anticoagulant medications other than routine deep venous thrombosis prophylaxis with either weight-based subcutaneous heparin or enoxaparin within 8 days postoperatively.

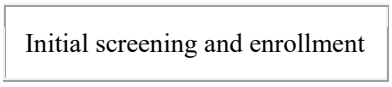
The procedure and postoperative care will be standardized to the degree described as follows: One 10 French Jackson-Pratt drain will be used. All necks will be closed with 3-0 vicryl, 4-0 monocryl, and 5-0 fast absorbing sutures. All patients will receive standardized postoperative orders including inpatient antibiotics not to exceed 24hrs (unless an infection is suspected) and DVT prophylaxis; either weight based subcutaneous heparin or enoxaparin. The chief resident will receive an email indicating when to remove drain. All patients will receive standardized postoperative instructions including wound care with and without drain. A standardized physical exam will be performed on all patients every day of inpatient stay by the chief resident and on postoperative appointment (5-8 days post-operatively) by the attending surgeon to evaluate for clinical evidence of seroma and hematomas.

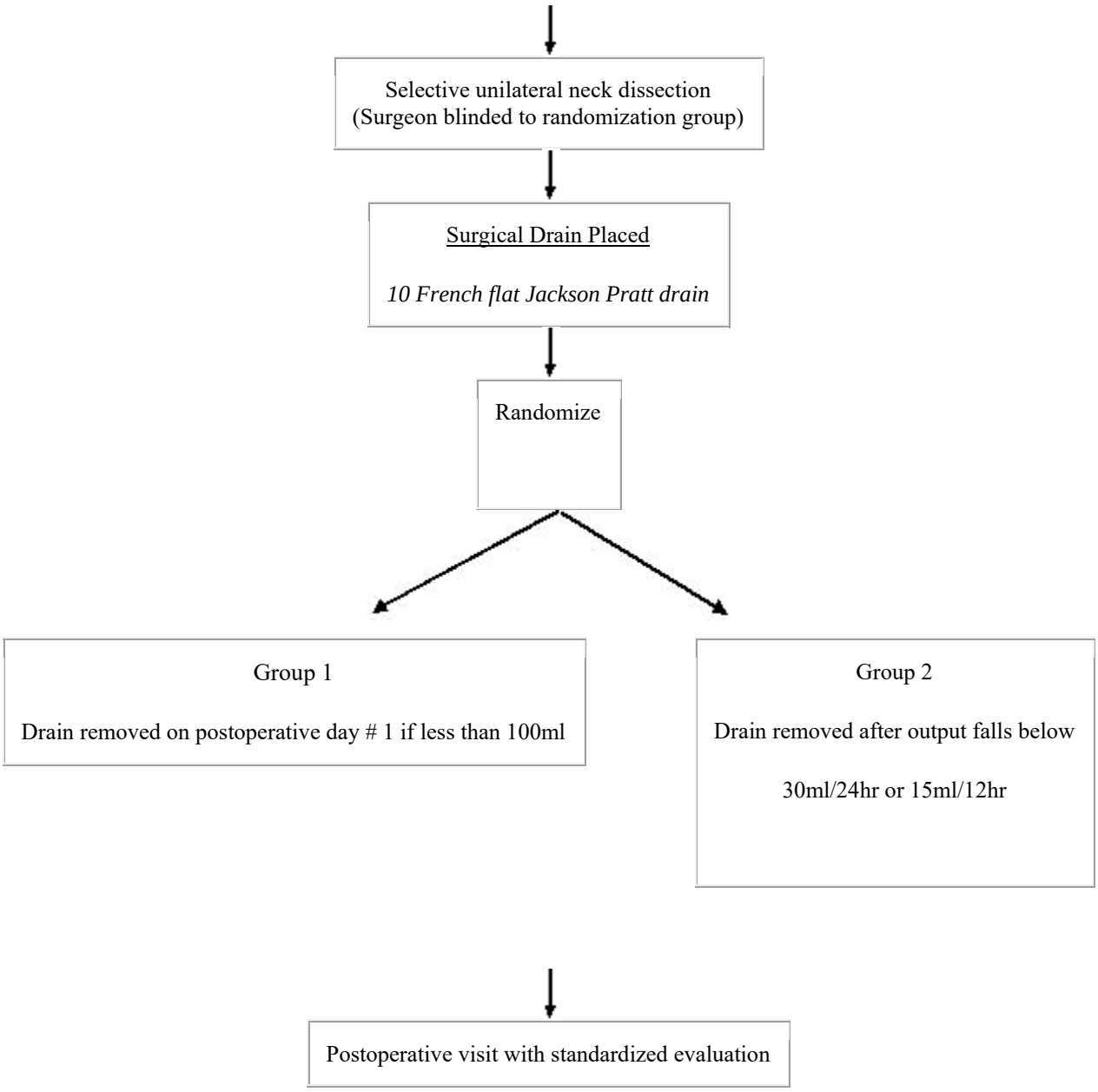
Physical exam will specifically include:

1. Inspect and palpate for presence fluctuance.
2. Inspect for color change, erythema or ecchymosis
3. Palpate for tenderness

Outcome Assessment: The primary outcome of this study will be the presence or absence of hematoma or seroma. Secondary outcomes will be the hospital length of stay and the need for any additional procedures. We will also collect data on the number of lymph nodes removed from the pathology report, the presence of carcinoma in the lymph nodes, and the need for home health care.

SCHEMA





3.0 PATIENT SELECTION

3.1 Registering Patients

Eligibility will include consecutively seen adult patients in the Division of Head and Neck Oncologic Surgery in the Department of Otolaryngology-Head and Neck Surgery at University of California-San Francisco (UCSF) who will be undergoing unilateral SLNDs for oral cavity, oropharynx (if the resection does not connect to the neck), thyroid, salivary gland, parotid and skin carcinoma by one of three Head and Neck surgery faculty members. Patients will be enrolled in the study after completing the eligibility checklist and signing the study-specific consent form either preoperatively or on postoperative day 1. The study will be conducted at UCSF.

3.2 Specific Conditions for Patient Eligibility

3.2.1 Patients undergoing unilateral SLNDs either levels I-III, I-IV, II-III, II-IV, or II-Va for oral cavity, oropharynx (if the resection does not connect to the neck), thyroid, salivary gland, parotid, and skin carcinoma.
3.2.2 A treatment plan involving levels I-III, I-IV, II-III, or II-IV, as recommended by National Comprehensive Cancer Network (NCCN) Guidelines.
3.2.3 Patient must be 18 years of age or older.
3.2.4 The patient must have capacity to be able to sign a study-specific informed consent prior to study entry.

3.3 Conditions for Patient Ineligibility

3.3.1 Pregnancy (for female patients).
3.3.2 Patients with history of prior radiation therapy or radioactive iodine to the head and neck.
3.3.3 Patients with neck dissection connected to upper aerodigestive tract.
3.3.4 Patients found to require sternocleidomastoid muscle or internal Jugular vein excision.
3.3.5 Patients who will require anticoagulant medications other than routine DVT prophylaxis within 8 days postoperatively
3.3.6 Patients undergoing bilateral neck dissection
3.3.7 Patients undergoing neck skin defect reconstruction

3.4 Randomization

After surgery is completed, the patients will be randomized into two groups:
- Intervention group: Neck drain removed on rounds on morning of POD#1 if less than 100ml total.
- Control group: Neck drain removed once output falls below 30ml/24hr or 15ml/12hr.

3.5 Blinding

The Surgeons will be blinded to the randomization group of the patients until after the surgery is completed.

4.0 Statistical Analysis

All statistical analysis will use intention to treat and a two tailed 0.05 level for significance. The primary outcome of this study will be the presence or absence of hematoma or seroma. This is a dichotomous variable that will be evaluated with the Fisher's exact test. Secondary outcomes will be the hospital length of stay (Wilcoxon rank-sum test), the need for any additional procedures (Fisher's exact test), and the quantitative outcome from the patient satisfaction questionnaire (Wilcoxon rank-sum test). We will also collect data on the number of lymph nodes removed from the pathology report (Wilcoxon rank-sum test), the presence of carcinoma in the lymph nodes (Fisher's exact test), and the need for home health care (Fisher's exact test). We estimate the necessary sample size to be 62 neck dissections with 31 in each group to detect a 33% increase in hematoma and seroma rates with a 0.05 significance level and 0.8 power assuming an average hematoma and seroma rates of 7% in current literature.

5.0 SURGERY/POSTOPERATIVE CARE

Standardization of surgery will be obtained by following the procedure technique described in Section 2.1. The procedure and postoperative care will be standardized as much as possible. All necks will be closed with 3-0 vicryl, 4-0 monocryl, and 5-0 fast absorbing sutures. All patients will receive standardized postoperative orders including inpatient antibiotics not to exceed 24hrs (unless an infection is suspected) and DVT prophylaxis; either weight based subcutaneous heparin or enoxaparin. The chief resident will receive an email indicating when to remove drain.

6.0 PATHOLOGY

Pathology reports must document the following:
5.1 Site of the primary
5.2 Extent of disease
5.3 Neck dissection information (number of nodes removed; number of nodes involved, extracapsular invasion, and involvement of adjacent structures).

7.0 PERSONNEL

Special personnel required for this study have been addressed (e.g. subspecialists, technicians, etc.):

None. Subspecialists required for this study are already party of the multidisciplinary head and neck oncology team.

Sufficient support staff available for study completion:

Yes. Research assistants, medical assistants, nurses, and physician assistant in head and neck surgical/radiation oncology clinic will assist Dr. Ryan, Dr. Wang, Dr. George and Dr. Heaton.

Who will do your consenting, data & sample collection, and regulatory?

Consenting: Dr. William R. Ryan, Dr. Chase Heaton, Dr. Jonathan George, and Dr. Stephen J. Wang and research assistants and physician assistant from the head and neck surgical oncology clinic.

Data and sample collection: Dr. William R. Ryan, Dr. Chase Heaton, and Dr. Stephen J. Wang and research assistants, medical assistants, nurses, and physician assistant in head and neck surgical oncology/radiation oncology clinic.

Regulatory: Dr. William R. Ryan and research assistants.

8.0 FUNDING

Support is in place from the Departments of Otolaryngology-Head and Neck Surgery to carry out initial enrollment and data collection.

Other applications for funding are under consideration.

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