Effects of Adrenaline Infiltration on Surgical Field of View in Endoscopic Sinus Surgery

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1. PURPOSE OF THE STUDY

a. Brief Summary

Minimizing bleeding during endoscopic sinus surgery is important for optimal patient outcome. Since there is a great variation in the structure of the sinuses among the population, without a clear surgical field, there may be inadvertent injury to the surrounding structures or an incomplete opening of sinuses. We hope to learn the best method for controlling bleeding i the field of view to help optimize the surgical outcome.

b. Objectives

We hope to learn the preparation for the best field of view with minimal bleeding that may interfere with the visualization for endoscopic sinus surgery. Studies in the past commonly looked at the estimated blood loss which may not reflect the actual surgical field. We would like to assess the actual surgical field to help determine the best possible technique to optimize endoscopic sinus surgery.

c. Rationale for Research in Humans

Human subjects must be used because the purpose of the study is to study the method which provides the best field of view for endoscopic sinus surgery in human.

2. STUDY PROCEDURES

a. Procedures

We will first perform chart review to screen for patients who were scheduled for endoscopic sinus surgery for rhinosinusitis that meet both our inclusion and exclusion criteria. We will check the date of the patient's next visit to meet them and explain the study protocol and ask for their consent. If they consent to the study, on the day which they have the surgery we will follow the protocol, giving topical adrenaline on both side and infiltrating lateral nasal wall with the medication according to the study (patient will receive 1% xylocaine with adrenaline (1:100,000) on one side and saline on the contralateral side, they will be randomized to which side receive which solution for infiltration). The Estimated blood loss on each side and the duration of the surgery on each side will also be recorded. The Video of the surgery will be evaluated by 2 different otolaryngologists to give grading score for surgical field of view using Wormald Surgical

Field Grading Scale. Patients will have regular post operative follow up as for endoscopic sinus surgery. At the patient's first follow up at 1 week after the surgery, the patient will be asked to fill out a questionnaire about the postoperative bloody discharge they experienced.

b. Procedure Risks

Any medications may lead to inadvertent effects, however the use of infiltration of xylocaine with adrenaline is widely accepted and has originally been used in preparation for endoscopic sinus surgery and also for variety of surgical procedures both under general and local anesthetic. With correct route and dosage given, infiltration performed by specialist under a well-controlled circumstance as under general anesthesia where patient's vital signs are closely monitored we believe that it is safe to perform the procedure. Topical adrenaline has recently gained popularity among a number of surgeons world wide in the use for endoscopic sinus surgery and has known to be safe and potent with great result in bleeding control.

c. Use of Deception in the Study

Deception will not be used to enroll the patient. We will not perform the procedure without the patient’s consent.

d. Use of Audio and Video Recordings

Video recording will be performed in the study (our department usually has all the surgeries recorded as a routine procedure). This will be reviewed by 2 otolaryngologists at Stanford's university (attendings or rhinology fellows). The otolaryngologist reviewing and grading the video will be blinded to which side of the sinus surgery was performed under only topical adrenaline or with the combination of both topical and infiltration of adrenaline. The video given will be labeled by the number and not by name of the patient and the video will be secure with passcode lock external hard disk.

e. Alternative Procedures or Courses of Treatment

Many different methods and many different agents have been used to help reduce bleeding in endoscopic sinus surgery. Currently, adrenaline has become the consensus as the best agent used for this purpose; however, there is no one consensus method of delivery, each center practices according to their experience for the best of the patients. At our center, half of the team use only topical adrenaline before the surgery and the other half combine infiltration of xylocaine with adrenaline with topical adrenaline. Therefore, the alternative at our center depends on the surgeon’s experience between topical adrenaline only and topical adrenaline combine with infiltration. In this study the participant instead of one or the other will get a combination of pure topical on one side and combine topical with infiltration on the other side of the nasal cavity. Using both topical and infiltration of adrenaline may result in less bleeding and better field of view, however infiltration of adrenaline may have potential side effect e.g. cardiovascular and central nervous system side effects. However, xylocaine with adrenaline is a widely used anesthesia and administering at appropriate dosage and route under an extremely well controlled environment as being under general anesthesia in the operating room where all patient's vital signs are monitored shouldn't be risky. Now that topical adrenaline is more

widely used than before we want to examine the benefit of additional infiltration of adrenaline to the surgical field of view to determine the best optimal practice for endoscopic sinus surgery.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

After the study, the participants will be able to use any therapy that is appropriate for them.

g. Study Endpoint(s)

The study will end after the required number of participant has been enrolled. Since both method is the standard we currently perform at the department we do not expect any harmful results to the participants.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

In the past there have been studies which tried to address the best methods to help optimize the surgical field. However, none has actually compared the injection of adrenaline to the control using a proper endoscopic grading score (which is a more accurate way of assessing visual field in comparison to using the estimated blood loss). Since estimated blood loss may give just a crude estimate of the surgical field, we suspect that it may be the reason why the previous studies couldn't demonstrate the significant of infiltration of adrenaline to the surgical field of view in endoscopic sinus surgery.

b. Findings from Past Animal Experiments

Animal studies were not identified in our literature review.

4. RADIOISOTOPES OR RADIATION MACHINES

N/A

5. DEVICES USED IN THE STUDY

N/A

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

a. Investigational Drugs, Biologics, Reagents, or Chemicals

N/A

b. Commercial Drugs, Biologics, Reagents, or Chemicals

Commercial Product 1	
Name:	1%Xylocaine with adrenaline
Dosage:	1%
Administration Route	Intranasal infiltration
New and different use? (Y/N)	No

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

N/A

8. PARTICIPANT POPULATION

a. Planned Enrollment

(i) 40 participants to be enrolled at Stanford
(ii) total of 40 participants overall (the study will only be performed at Stanford)
(iii) the participants will be the patients from the rhinology clinics who have sinusitis that have failed medical treatment and were scheduled for endoscopic sinus surgery

b. Age, Gender, and Ethnic Background

Age range 18-75 years old
Both males and females
All ethnic backgrounds

c. Vulnerable Populations

Potentially vulnerable subjects (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students) will not be enrolled in the study.

d. Rationale for Exclusion of Certain Populations

Women and minorities are included, however children are not included since endoscopic sinus surgery is not widely perform in children.

e. Stanford Populations

The study will not involve participants who are laboratory personnel, employees and students.

f. Healthy Volunteers

We do not take healthy volunteers for the study since they would have no indications for the surgery.

g. Recruitment Details

We will identify the participants for recruitment by chart review prior to their preoperative visit. No flyers or other advertisement will be used in the study.

h. Eligibility Criteria

i. Inclusion Criteria

1. Patients between the age of 18-75 years old who were diagnosed with recurrent acute or chronic rhinosinusitis that are recalcitrant to medical treatment and were scheduled for endoscopic sinus surgery

ii. Exclusion Criteria

1. Patients who have asymmetrical disease on the two sides (Lund Mackay score difference of 2 or more)
2. Patients who have endoscopic sinus surgery for treatment of tumor or disease other than sinusitis
3. Patients with nasal polyps
4. Patients with underlying uncontrolled hypertension
5. Patients with bleeding disorder or are unable to discontinue antiplatelet or anticoagulant before the surgery
6. Patients who are allergic to adrenaline or to xylocaine
7. Patients who are not consent to the procedure

i. Screening Procedures

Screening will be done by chart review. Personal health information, e.g., patient's history, symptoms, prior treatment, endoscopic and computer tomography of paranasal sinus findings may be reviewed to see if the patient may fit the inclusion criteria. If the patient meets the criteria then on the patient's preoperative visit we will explain the study and discuss enrollment. No additional laboratory test apart from their routine preoperative test will be required.

j. Participation in Multiple Protocols

Participants will not be enrolled in more than one study. The consent form will include the question to whether they are enrolled in other studies or not and the protocol director taking the consent will ask the question before explaining the research protocol.

k. Payments to Participants

There is no payment for enrolling in the study.

l. Costs to Participants

There will be no charge to the participant.

m. Planned Duration of the Study

The probable duration of the entire study is 10 months. The estimated total time per participant is approximately 2 weeks, starting on the day for screening and asking for consent from the participant which will usually be on the preoperative visit which is usually about a week before the surgery. Conducting the actual study will happen during the time the participant is in the operating room, then at the first postoperative visit which usually take place 1 week after the surgery, a short questionnaire will be given for the participant to fill out.

9. RISKS

a. Potential Risks

i. Investigational devices

The study doesn't involve an investigational device.

ii. Investigational drugs

The study doesn't involve an investigational drug.

iii. Commercially available drugs, biologics, reagents or chemicals

Irritation to infiltration site, persistent paresthesia, central nervous system excitatory or depressant effect which may cause headache, nausea, ringing in the ear, confusion, cardiovascular effect such as bradycardia, hypotension and cardiovascular collapse or tachycardia, palpitations and hypertension, hypersensitivity reaction.

Correct route and dosage of the medication is important to avoid the adverse effects, the medication will be infiltrated by specialist the study.

iv. Procedures

The procedure is intranasal infiltration of 1% xylocaine with adrenaline which is a routine procedure in endoscopic sinus surgery.

v. Radioisotopes/radiation-producing machines

There will be no use of radioisotopes/radiation-producing machine for the study.

vi. Physical well-being

We do not anticipate that participants in this study will be placed at risk in terms of physical well-being.

vii. Psychological well-being

We do not anticipate that participants in this study will be placed at risk in terms of psychological well-being.

viii. Economic well-being

We do not anticipate that participants in this study will be placed at risk in terms of economic well-being.

ix. Social well-being

We do not anticipate that participants in this study will be placed at risk in social well-being.

x. Overall evaluation of risk

Low risk

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b. International Research Risk Procedures

N/A

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c. Procedures to Minimize Risk

Overall potential risk to the patient should be very low. The patient will get the infiltration right before the surgery after general anesthesia where the vital signs will be closely monitored in the intra operative setting by anesthesiologist. Also any intranasal bleeding from the surgery is easily controlled in the operating room under endoscopic view with medications and equipment set up ready for the surgery.

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d. Study Conclusion

The participants will only be given one dose of the infiltration throughout the study. If any adverse effects were to happen, the participant will be terminated from the study and will be closely taken care of. As the infiltration will take place in the operating room after the patient is under general anesthesia, where the patient will be fully monitored, any adverse effects would be easily detected at a very early stage and best appropriate treatment will be given.

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e. Data Safety Monitoring Plan

i. Data and/or events subject to review

Monitoring will include bleeding intraoperatively and postoperatively, the visual field grading scale score, patient's vital sign intraoperatively, the overall blood loss on each side, the operative time on each side.

ii. Person(s) responsible for Data and Safety Monitoring

The protocol director, co-protocol director and academic sponsor will be responsible for data and safety monitoring of the study.

iii. Frequency of DSMB meetings

The protocol director will meet with the other researchers conducting the study on a weekly basis (every Monday evening) to review the protocol.

iv. Specific triggers or stopping rules

Any major complications secondary to the study will terminate the study. However, this is very unlikely since intranasal infiltration of xylocaine with adrenaline is a routine procedure perform for endoscopic sinus surgery and infiltration at correct dosage and by specialist under well controlled environment shouldn't result in any major complications.

v. DSMB Reporting

The IRB will be informed if any abnormal outcomes were to occur.

vi. Will the Protocol Director be the only monitoring entity? (Y/N)

Yes

vii. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)

No

f. Risks to Special Populations

N/A

10. BENEFITS

The study will help determine the best surgical field for endoscopic sinus surgery which will lead to optimal sinus surgery with the best result for the patient in the future.

11. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.