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**Document:**

Study Protocol and Statistical Analysis Plan

**Official Title of the Study**

Effect Of Hot Saline Irrigation on the Operative Field During Endoscopic Sinus Surgery: A Randomized Controlled trial

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**Dr Jawairia Altaf, Department of ENT, Benazir Bhutto Hospital, Rawalpindi Medical University and Allied Hospitals, Rawalpindi**

## Introduction

Chronic rhinosinsusitis is an inflammatory disease of the sinonasal mucosa lasting for more than 12 weeks.[1] Endoscopic sinus surgery is the surgical procedure used to treat recalcitrant chronic rhinosinusitis. [2] It not only helps in the drainage of sinuses and removal of pathology but also prevents the disturbance of anatomy and formation of facial scars. [3,4] Control of bleeding during the procedure is a test for surgeons as well as anesthetists.[5]

Hot normal saline with a temperature of 50°C causes dilatation of vessels and nasal edema without causing mucosal necrosis, it not only helps in control of bleeding via compression of vasculature but also promotes the clotting pathways.[5]

A study conducted by Shehata A et al. showed a significant improvement in the operative field when hot normal saline at 50° C was used during endoscopic sinus surgery with a mean and standard deviation of 1.96±0.67 as compared to the control group (2.64±0.7).[5] A study by Ranford D et al. concluded that irrigation with heated saline during endoscopic sinus surgery reduced bleeding by 20 percent.[7] Moreover it also decreased the duration of patient's surgery by 9 minutes. [6]

The aim of this study is to evaluate the effect of hot saline irrigation during endoscopic sinus surgery. The additional advantages provided by irrigation of hot saline will not only provide superior post-operative results but will also reduce the duration of surgery.

## Objective

To determine the effect of hot saline irrigation on the operative field during endoscopic sinus surgery.

## Hypothesis

Hot saline irrigation provides good control of bleeding during endoscopic sinus surgery.

## Operational Definitions

**Endoscopic Sinus Surgery:** An endonasal surgery done via endoscope using instruments for drainage of sinuses and removal of sinonasal pathology.

**Hot Normal Saline:** A solution formed by dissolving 0.9 grams of NaCl in 100ml of water and warmed up to 50°C.

**Mean Arterial Pressure:** It is an average pressure present in the arteries in one cardiac cycle calculated by addition of diastolic blood pressure with 1/3rd of the pulse pressure.

**Boezaart Score:** [5]

Grades Assessment

0- No bleeding (cadaveric conditions)

1- Slight bleeding: no suctioning required.

2- Slight bleeding: occasional suctioning required.

3- Slight bleeding: frequent suctioning. Bleeding threatens surgical ſ eld a few seconds after suction is removed.

4- Moderate bleeding: frequent suctioning required and bleeding threatens surgical field directly after suction is removed.

5- Severe bleeding: constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery usually not possible.

## Methods & Materials

**Study Design:** Randomized controlled trial

**Study Setting:** Department of ENT, Benazir Bhutto Hospital

**Study Duration:** After the approval of the topic till completion of sample size

**Sample Size:**

By using WHO sample size calculator

Sample size n = 60 (30 in each group)

Level of significance = 5%

Power of test = 90%

Test value population mean = 1.96[5]

Anticipated population mean = 2.64[5]

Population standard deviation = 0.685[5]

**Sampling Technique:** Simple random sampling

## Sample Selection

**Inclusion Criteria**

Patients bilateral chronic rhinosinusitis refractory to medical treatment and requiring surgical intervention.

**Exclusion Criteria**

1. Patients with malignancies.
2. Patients with unilateral disease
3. Bleeding diathesis
4. Uncontrolled hypertension
5. Long term usage of NSAIDS and anti-coagulants.

## Data Collection Procedure

This research will be carried out after approval from the Ethical Review Board of Rawalpindi Medical University. Patients requiring surgical intervention for chronic rhinosinusitis will be selected via simple random sampling. They will be divided into 2 groups via randomization (30 patients in each group) and undergo endoscopic sinus surgery in the operation theatre of Benazir Bhutto Hospital. Double blinding will be done. Surgery will be performed by a consultant with an experience of more than 5 years. For the intervention, normal saline will be warmed in a boiler up to 50°C and temperature will be continuously checked with the help of a thermometer. Group A will have irrigation of nasal cavities with hot normal saline (of 50°C) during the operation. Group B will have irrigation with saline at room temperature. This is a double blinded RCT in which the patient and the operating surgeon will not know about the specific intervention. Bleeding score will be checked via Boezaart score. More over, duration of the procedure and mean arterial pressure of all patients will also be documented. The researcher will collect the data by herself to avoid bais.

## Data Analysis

Data will be analysed with help of SPSS version 26. Qualitative variables will be represented as frequencies and percentages. Quantitative variables will be represented via mean and standard deviation. Chi square test will be applied. Furthermore, logistic regression will be done. Data will be documented in tabular form. A P-value of <0.05 will be considered significant.

## References


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