

# A double-blind randomized controlled trial of normal saline, lactated Ringer's, and hypertonic saline nasal irrigation solution after endoscopic sinus surgery

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## ABSTRACT

**Background:** Nasal douching is commonly performed after endoscopic sinus surgery (ESS). There is a lack of studies comparing the clinical effect of various douching solutions after ESS. This study investigated the clinical effects of normal saline, lactated Ringer's, and hypertonic saline nasal douching solutions after ESS.

**Methods:** Adult patients ( $41.8 \pm 12.9$  years) undergoing bilateral ESS for chronic rhinosinusitis at a single tertiary referral center were blindly randomized to one of the three study solutions and reviewed on postoperative weeks 1, 3, and 6. The 20-item Sino-Nasal Outcome Test (SNOT-20) scores, visual analog scale (VAS) symptom scores, digital video capture of the sinus cavities, and mucociliary clearance (MCC) times were performed at each visit. The mucosa appearances were scored by a second investigator, blinded to the douching solution.

**Results:** Seventy-four patients were recruited. All groups showed an improvement with treatment in SNOT-20 scores and VAS scores, as well as endoscopic evaluation of mucosa appearance over time. There was no improvement of MCC during the treatment period. Irrigation with lactated Ringer's solution results with better symptom scores in SNOT-20 ( $p < 0.05$ ) and VAS ( $p < 0.05$ ), compared with irrigation with normal saline or hypertonic saline solutions. Patients receiving hypertonic saline solutions had less polypoidal mucosa at week 6.

**Conclusion:** Douching with lactated Ringer's solution after ESS results in better improvement in sinonasal symptoms, compared with normal saline or hypertonic saline solutions.

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Chronic rhinosinusitis (CRS) is a common disease that affects 5–15% of the population.<sup>1</sup> CRS significantly impacts the health and quality of life of the affected individual.<sup>1,2</sup> There is good evidence to show that treatment with intranasal steroids, nasal douching, and oral antibiotics result in great improvement of symptoms and quality of life for these patients.<sup>2</sup> For patients who fail medical treatment, endoscopic sinus surgery (ESS) has been shown to be beneficial in treating the symptoms for these patients.<sup>2,3</sup>

ESS improves the drainage of the sinuses as well as delivery of topical medications to the sinuses.<sup>4</sup> Nasal douching after surgery remains one of the most important postoperative management strategies after ESS.<sup>2,5</sup> Multiple studies have confirmed the benefit of high-volume, low-pressure douching (squeeze bottle and NETI-pot; NeilMed Pharmaceuticals Inc, Santa Rosa, CA) over other methods of delivery.<sup>4,6</sup> Nasal douching post-ESS has been reported to promote wound healing and reduce nasal discharge and edema within the tissue.<sup>7</sup>

Currently, there are a variety of formulations of nasal douches on the market. Various studies have examined the efficacies of various douching solutions for the treatment of CRS in the preoperative settings.<sup>8–12</sup> There is a lack of evidence in the literature that compares the efficacy of various salt-based solutions in the postoperative settings. The aim of this study is to investigate the clinical effects of three commonly available douching solutions in

the setting of post-ESS: normal saline (0.9%), lactated Ringer's, and hypertonic saline (2.7%).

## METHODS

The Southern Adelaide Clinical Human Research Ethics Committee approved this study and informed consent was obtained from all patients. Seventy-four patients were recruited from the public waiting list from a single tertiary referral hospital, Flinders Medical Center during 2008–2011. Exclusion criteria were applied to exclude noninflammatory etiologies (Table 1). All of the ESSs were primary procedures performed by or performed under the direct supervision of the senior author (A.S.C.). All patients had bilateral ESS, involving drainage of the maxillary (conservative mucosal sparing antrostomy), anterior, and posterior ethmoid sinuses with full preservation of the middle turbinate. Frontal and sphenoid sinuses were drained only where clinically appropriate. Standard mucosal sparing ESS techniques with the assistance of a microdebrider were used in all cases.

Patients were randomly assigned to a blinded douching solution through the Pharmacy Department at Flinders Medical Center. A set of 80 envelopes with the name of three solutions were delivered to the Pharmacy Department and randomly arranged. The envelopes were opened consecutively and douching solutions were dispensed to the patients. The postoperative care of the patients were standardized across the entire cohort. The patients were advised to irrigate their sinuses three times a day for 6-weeks after surgery. Blank sachets and douching bottles were provided to the patient on the day of surgery. Patients were given standard advice on bottle cleaning to avoid microbial contamination. No oral antibiotics or oral steroids were given to the patients. Patients were started on intranasal steroid from between weeks 2 and 3. Routine postoperative nasal toilet was performed at each postoperative follow-up.

Lund-Mackay scores,<sup>13</sup> 20-item Sino-Nasal Outcome Test (SNOT-20) scores,<sup>14</sup> visual analog scale (VAS) scores,<sup>2,3</sup> and mucociliary

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