Otolaryngology–Head and Neck Surgery (2008) 139, 137-142

ORIGINAL RESEARCH—SINONASAL DISORDERS

Effects of endoscopic sinus surgery and delivery device on cadaver sinus irrigation

Richard J. Harvey, MD, John C. Goddard, MD, Sarah K. Wise, MD, and **Rodney J. Schlosser, MD,** Charleston, SC; and Atlanta, GA

OBJECTIVE: Assess paranasal sinus distribution of topical solutions following endoscopic sinus surgery (ESS) using various delivery devices.

STUDY DESIGN: Experimental prospective study.

SUBJECTS AND METHODS: Ten cadaver sinus systems were irrigated with Gastroview before surgery, after ESS, and after medial maxillectomy. Delivery was via pressurized spray (NasaMist), neti pot (NasaFlo), and squeeze bottle (Sinus Rinse). Scans were performed before and after each delivery with a portable CT machine (Xoran xCAT), and blinded assessments were made for distribution to individual sinuses.

RESULTS: Total sinus distribution was greater post-ESS ($P < 0.001$). Additional distribution was gained with medial maxillectomy ($P = 0.02$). Influence of delivery device on distribution was significantly higher with neti pot > squeeze bottle > pressurized spray ($P < 0.001$). Frontal sinus penetration was greatest after surgery ($P = 0.001$).

CONCLUSION: ESS greatly enhances the delivery of nasal solutions, regardless of delivery device. Pressurized spray solutions in un-operated sinuses provide little more than nasal cavity distribution. Use of squeeze bottle/neti pot post-ESS offers a greatly enhanced ability to deliver solutions to the paranasal sinuses.

Since the 1980s, endoscopic sinus surgery (ESS) has been widely employed to manage chronic rhinosinustis (CRS) refractory to medical management. There are numerous case series and prospective studies, and a few randomized controlled trials to support its use.[1] However, the role of ESS in the management of CRS has been heavily debated and scrutinized. Our knowledge base on biofilms,[2] fungi,[3] super antigens,[4] and eosinophilic T_h2-driven[5] inflammatory processes is rapidly expanding. Consequently, the role of ESS in the overall management of CRS has become more difficult to define. Ambiguity for the role of ESS also stems from a loose definition of modern CRS, which encompasses a heterogeneous group of pathological processes leading to a common endpoint.[6] Although much of the evidence for using ESS in CRS is based on patient-centered outcomes, symptom improvement, or disease-specific quality of life measures,[1,7] little objective investigational data have been published to support the use of ESS in CRS.[8-10] Traditional concepts for surgery in CRS have centered on relieving ostial obstruction and enhancing ventilation.[11] Overall improvement in mucociliary function, perhaps not from increased ciliary action but from a more efficient mass transport of the mucous blanket, has also been postulated.[12,13] A benefit from the reduction in the overall surface area of inflammatory mucosa may also be significant in patients undergoing total frontosphenoethmoidectomy.[14]

A fundamentally held belief among those treating CRS patients is that ESS improves the delivery of topical medications to the sino-nasal mucosa, yet little evidence exists to support this claim.[15,16] This study was designed with two specific aims. The first aim was to determine the effectiveness of topical delivery to the paranasal sinuses before and after ESS. The second aim was to examine the influence of the delivery device (pressurized spray, neti pot, or squeeze bottle) under each surgical condition on the distribution of solutions. Providing objective evidence for the role of ESS in enhancing the delivery of topical solutions to the sinonasal mucosa is important both to validate our current practice, wherein we operate on those refractory to maximal medical therapy, and to define its role in the effective application of future locally delivered therapies.

METHODS

Human cadaver heads were used in conjunction with the Medical University of South Carolina (MUSC) Department of Anatomy, with institutional approval for anatomical specimen use. All aspects of the study were performed within the sinus dissection laboratory at MUSC. The MUSC Radiation Safety office approved the performance of all CT scans.

Received February 21, 2008; revised April 4, 2008; accepted April 15, 2008.

0194-5998/$34.00
doi:10.1016/j.otohns.2008.04.020

Specimens

Adult paranasal sinuses were used for the study. Each head was examined endoscopically for anatomical abnormalities such as a deviated septum, evidence of prior sinus surgery, or other sino-nasal pathology. Each head underwent baseline CT scanning with a dedicated portable intraoperative CT scanner (XCAT; Xoran Technologies, Inc). Baseline CT scans were examined independently by two fellowship-trained rhinologists to look for evidence of prior sinus surgery and/or sino-nasal pathology. A total of 10 paranasal sinuses (five adult cadaver heads, two female) without evidence of prior sinus surgery or gross sino-nasal pathology were selected for use in the study.

Delivery Techniques

Pressurized spray, neti pot, and squeeze bottle delivery techniques were used on each head, first prior to any surgery, after front sphenoethmoidectomy including maxillary antrostomy (ESS), and finally after an additional modified medial maxillectomy (MMM).[17] Undiluted Gastroview was used in all three devices. Custom NasaMist Saline Spray (NeilMed Pharmaceuticals, Inc) pressurized bottles containing undiluted Gastroview were manufactured at NeilMed's facility and shipped so as to reproduce the commercial product as accurately as possible (Fig 1). The 240-mL NETI POT (NeilMed Pharmaceuticals, Inc) and 240-mL adult Sinus Rinse bottles (NeilMed Pharmaceuticals, Inc) were used and filled on site (Fig 1). Each nasal cavity was subject to irrigation using the three different delivery techniques in three different surgical states. Irrigations and surgeries were performed in a sequential fashion. To minimize bias, a single investigator performed all irrigations, and a practice run was undertaken to ensure reproducibility. The irrigation sequence was pressurized spray, then neti pot, followed by squeeze bottle. The heads were irrigated with tap water and re-scanned between irrigations to ensure removal of previously administered contrast. We performed a total of 45 CT scans for data collection purposes, with just over 45 CT scans to control for complete removal of residual contrast (a few heads required re-irrigation to remove residual Gastroview).

Figure 1 From left to right, pressurized spray bottle, neti pot, and squeeze bottle (NeilMed Pharmaceuticals, Inc).

The delivery of Gastroview via each device was performed so as to faithfully reproduce the duration, volume, pressure, and head position performed in the clinical setting. The pressurized spray bottles were used in a head-over-sink position. The pressurized spray was engaged for 8 seconds (15-20 mL) on each side. A gentle rotation of the spray nozzle was used during delivery.

Neti pots were filled with 240 mL of Gastroview, the head positioned in the horizontal plane, and the superior nostril engaged. Half of the volume (120 mL) was delivered to each nostril, with retrograde flow occurring through the inferior nasal cavity in each case.

Squeeze bottles were filled with 240 mL of Gastroview. The bottle tip was engaged in the nostril in a head-over-sink position. The bottle was squeezed several times to deliver half the contents; then the remaining half was delivered to the contralateral side. In a clinical setting, retrograde contralateral flow occurs because of velopharyngeal closure. This mechanism could not be routinely reproduced in the cadavers. Excess Gastroview exited via the oropharynx.

Surgical Techniques

Following the initial preoperative round of irrigation studies, each paranasal sinus system was subjected to ESS. This procedure included an uncinectomy, maxillary antrostomy, total ethmoidectomy, sphenoidotomy and frontal sinusotomy. Control CT scans prior to irrigation were also used to ensure the completeness of ESS. We attempted to remove the entire sphenoid face on each side and maximally widen the frontal recess. All procedures were performed by three of the authors (J.C.G., R.J.H., R.J.S.) who used standard ESS instrumentation. Irrigations with the three different delivery devices were then carried out as described with a CT scan performed between each delivery to ensure removal of previous contrast. An endoscopic MMM was then performed on each of the paranasal sinus systems. An MMM includes removal of the inferior turbinate and medial maxillary wall anteriorly, from behind the lacrimal duct to the posterior wall of the maxillary sinus. This large opening, down to the nasal floor, has also been referred to as a "mega-antrostomy" and was described previously by the senior author (R.J.S.).[17] Irrigations with the three different delivery devices were then carried out as described.

Outcome Measures

A digital record for each CT scan was created and then coded for storage (Xoran Technologies, Inc). A semiquantitative grading scale was used to assess each of the following cavities: frontal sinus, maxillary sinus, anterior ethmoid region, posterior ethmoid region, and sphenoid sinus. Each side represented its own distinct paranasal sinus system. The values for the grading scale were 0 = no contrast, 1 = trace

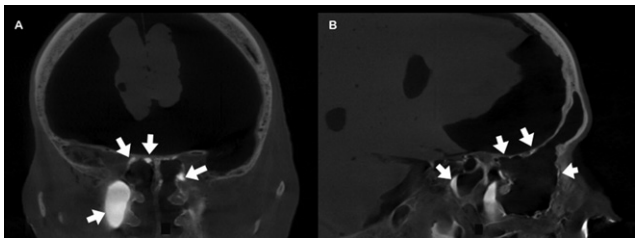

Figure 2 **(A)** Coronal CT scan demonstrating pooling of contrast within the right maxillary sinus cavity. **(B)** Sagittal CT scan demonstrating contrast within the ethmoid cavity (*arrows* indicating contrast).

contrast (present on one wall of the sinus cavity), 2 = contrast present on two or more walls, 3 = pooling of contrast (Fig 2A and B). The total sinus score for each paranasal sinus system ranged from a minimum of zero to a maximum of 15. All CT scans were read by two blinded assessors. Both assessors were trained otolaryngologists, not involved in the irrigations or scanning. The interobserver correlation for the assessment of all CT scores was 0.96 (Spearman rho for ordinal data).

Statistical Analysis

Data were treated as ordinal and analyzed with Wilcoxon/Mann-Whitney *U* nonparametric algorithms. Spearman correlation coefficient was used to compare CT scan assessments between assessors. Statistical calculations were performed with the Statistical Package for the Social Sciences software (SPSS, version 15.0; SPSS Inc, Chicago, IL).

Role of the Funding source

NeilMed Pharmaceuticals, Inc, provided irrigation devices as well as financial support for all other study materials. Xoran Technologies, Inc, donated the XCAT portable CT scanner for use in this study. Neither funding source had any involvement in study design, data collection, analysis or interpretation, manuscript preparation, or decision to publish.

RESULTS

The nasal cavity proper demonstrated evidence of contrast on all CT scans performed following Gastroview irrigations. Imaging of each of the heads occurred within 60 seconds of each contrast irrigation.

Effect of Surgery on Distribution

Contrast distribution within the un-operated paranasal sinuses was limited, regardless of delivery technique employed (Fig 3). The sphenoid and frontal sinuses were poorly accessed in the un-operated state (Fig 4A). Mean total sinus score prior to any surgical intervention and with any delivery technique was 4.32 ± 3.30. After surgical intervention (ESS or ESS + MMM), the distribution by any delivery technique was significantly greater at 10.04 ± 3.32 ($P < 0.001$; Fig 5). With each device, surgical intervention significantly improved total sinus distribution scores (all $P < 0.05$; Fig 3). MMM offered no greater distribution than those obtained with ESS alone for individual sinuses (all $P > 0.05$). However, total sinus irrigation for MMM was greater than ESS (9.15 ± 0.62 vs 10.93 ± 0.56; $P = 0.016$). Frontal and sphenoid sinuses were most affected by surgery (Fig 4A and B). Compared with the post-ESS state, preoperative distribution was especially poor to the frontal (0.33 ± 0.18 vs 0.78 ± 1.17; $P = 0.001$) and sphenoid sinuses (0.13 ± 0.57 vs 2.38 ± 1.11; $P < 0.001$).

Effect of Delivery Device on Distribution

Mean total sinus score ± standard deviation for each device in the un-operated sinus was pressurized spray 0.45 ± 0.69, neti pot 7.35 ± 1.27, and squeeze bottle 5.15 ± 2.33 (Fig 3). Delivery via neti pot and squeeze bottle techniques were significantly better than the pressurized spray technique in the un-operated sinuses ($P < 0.001$). The neti pot provided the best overall distribution preoperatively ($P = 0.035$). All devices offered greater distribution post-ESS or post–ESS + MMM (Fig 3). The neti pot offered the greatest distribution after any surgery ($P < 0.001$; Fig 3). The combined influence of surgery and delivery device on the distribution to all sinuses is depicted in Figure 6.

DISCUSSION

Nasal irrigations and sprays are commonly employed in the management of sino-nasal conditions. Topical nasal saline has become a routine part of many management paradigms in treating chronic sino-nasal symptoms, and evidence of its

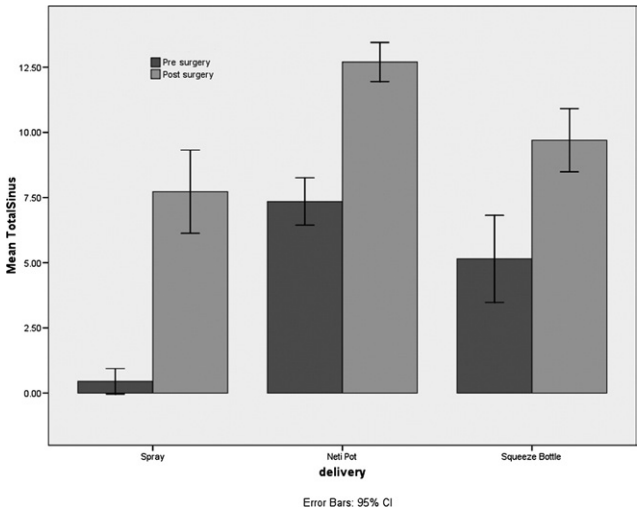

Figure 3 Mean total sinus score plotted as a function of delivery device in the un-operated (*dark shade*) and post-ESS (*light shade*) states. Error bars represent 95 percent confidence intervals.

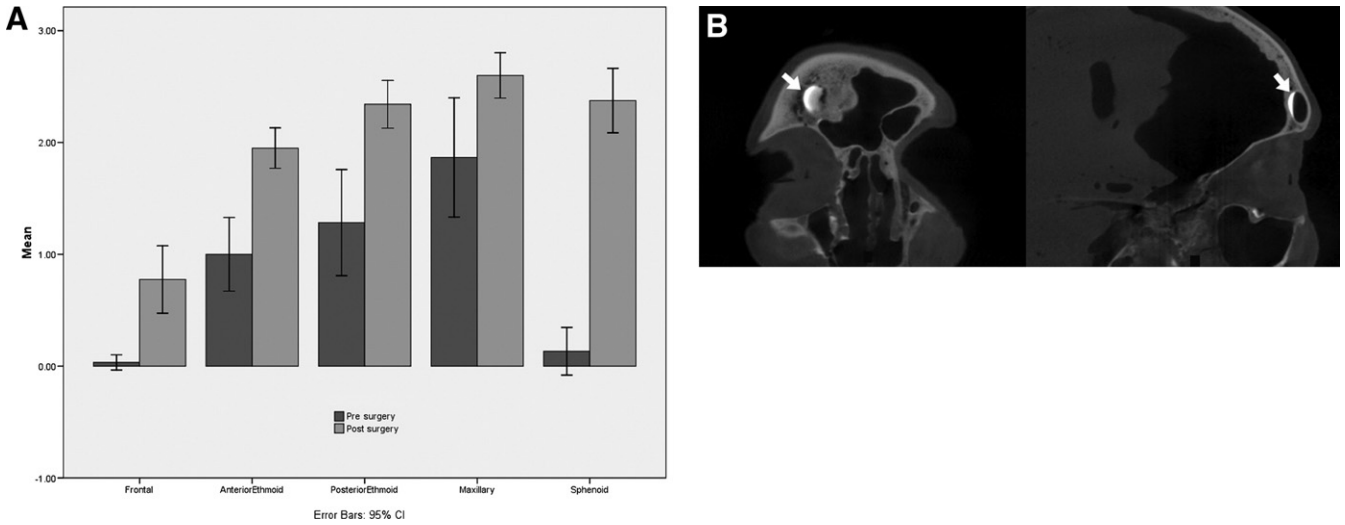

Figure 4 **(A)** Mean individual sinus score plotted as a function of sinus cavity in the un-operated and post-ESS states for all three delivery techniques. **(B)** Coronal and sagittal CT scans demonstrating irrigation of the frontal sinus with neti pot use after modified medial maxillectomy.

effectiveness exists.[18] As our understanding of the pathophysiology of CRS improves, new medical treatments are likely to be developed, with local nasal delivery serving as a valuable therapeutic route. The degree to which these locally delivered therapies come into contact with the affected mucosa has been a source of debate for many researchers.[19] Objective evidence validating the notion that endoscopic sinus surgery enhances the delivery of topical solutions to the paranasal sinus cavities has been lacking. In the present study, we set out to determine the effectiveness of topical delivery to the paranasal sinuses before and after surgery.

Our results suggest that surgery significantly improves distribution to all sinuses and that neti pot use provides the most effective distribution of solution to the paranasal sinuses. The pressurized spray device in un-operated sinuses performed poorest in our study (Fig 6). There has been some prior research into the distribution of fluid into the un-operated paranasal sinuses,[16,19] with findings consistently showing poor delivery beyond the nasal cavity. Wormald et al[16] examined three un-operated healthy controls in a technetium-based assessment of irrigation techniques and similarly demonstrated poor distribution.

Many irrigation devices can be categorized on the basis of volume and force of delivery (Table 1). We have compared low- and high-volume positive-pressure devices and a high-volume gravity-dependent device. Overall acceptance, ease of use, training, cost, and head position may all contribute to the overall effectiveness of these devices.[20] Demonstration of correct technique is important for reliable patient use. Although spray bottles may seem convenient,

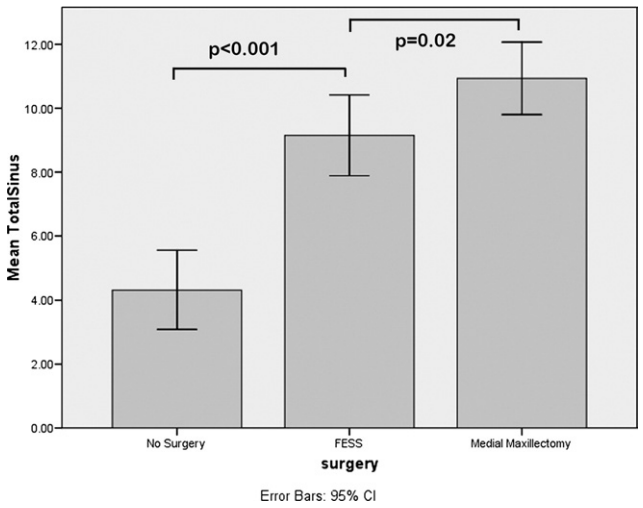

Figure 5 Total sinus distribution by surgical state.

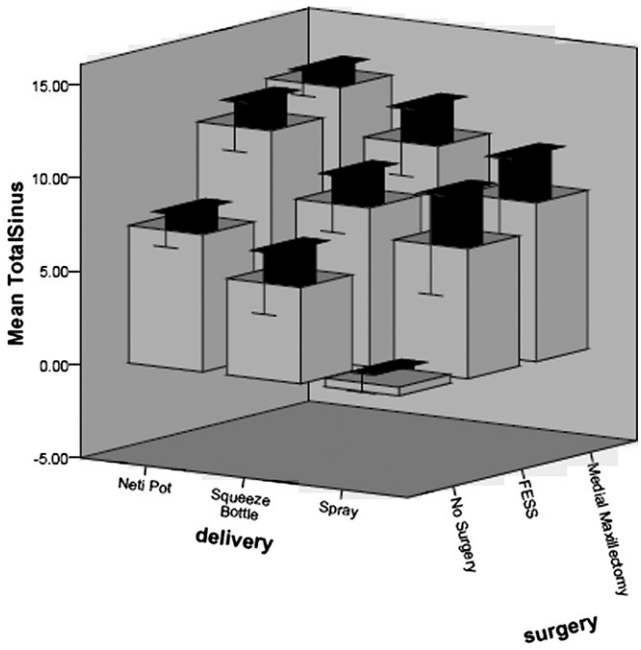

Figure 6 Three-dimensional bar graph depicting mean total sinus score as a function of both delivery technique and surgical state.

Table 1
Summary of delivery techniques

Positive pressure
Douche/irrigation
Pot
Sprays
Pulsatile jet
Negative pressure
Nasal inhalation
Nebulized/atomization

qualitative research demonstrates that many patients appreciate the ability to control the pressure, temperature, volume, and tonicity of their irrigation solution.[20] Reuseable products also offer a lower cost per irrigation compared with prepared sprays, although there is concern about contamination risks.[21,22]

Many commercial products recommend a head-down, over-sink, with nose-to-ground position for irrigation. This position is practical and makes runoff easy to collect. Studies on head position for the efficacy of delivering drops to the middle meatus demonstrated that the "Mygind" and "Ragan" (lateral and supine positions) were superior to the "Mecca" and "Head Back" positions.[23] For neti pots, the lateral head position may also be important, because fluid in the contralateral nasal cavity follows a gravity-dependent pathway to the lateral nasal wall and sinuses (as in the Mygind position). The relevance of positioning with positive pressure applications may be less significant. For pressurized spray devices, the volume, spray angle, and velocity of different devices have not shown a difference in distribution on technetium scintigraphy.[24]

Although one of the methodological goals of this study was to reproduce the clinical situation of topical nasal irrigation, squeeze bottle usage may be suboptimally represented. During clinical use, velopharyngeal closure allows continued oral breathing, which forces the irrigation back down the contralateral side with a retrograde flow similar to that observed with the neti pot. It is possible that, in the clinical setting, little difference may exist between neti pot and squeeze bottle delivery. The positive pressure effects of squeeze bottles also were not assessed. The mechanical debridement provided by a high-pressure flow may also be of benefit with squeeze bottles compared with neti pots.

Distribution into the maxillary sinus was excellent after ESS or ESS + MMM. An expected finding was that sphenoid and posterior ethmoid distribution was not affected by the addition of an MMM to ESS ($P > 0.05$).

CONCLUSION

ESS is important in optimizing the delivery of topical solutions to the paranasal sinuses. Larger-volume fluids delivered by squeeze bottle or neti pot are most effective. Limited distribution to the sinuses exists without concomitant ESS, regardless of delivery method. The findings support the concept that ESS significantly improves delivery of solutions to sinus mucosa.

AUTHOR INFORMATION

From the Department of Otolaryngology–Head and Neck Surgery (Drs Schlosser, Harvey, and Goddard), Medical University of South Carolina, Charleston, SC; and the Department of Otolaryngology–Head and Neck Surgery (Dr Roh), Emory University, Atlanta, GA.

Corresponding author: John C Goddard, MD, 135 Rutledge Avenue, PO Box 250550, Charleston, SC 29425.

E-mail address: goddarjc@musc.edu.

This paper won third place for the resident research paper prize at the 2008 annual meeting.

AUTHOR CONTRIBUTIONS

Rodney Schlosser, study design, data collection, writer; **Richard Harvey,** study design, data collection, writer; **John Goddard,** data collection, writer; **Sarah Wise,** writer.

FINANCIAL DISCLOSURES

Rodney Schlosser, consultant: BrainLAB, Gyrus, Medtronic; speaker's bureau/advisory board: Schering-Plough, GlaxoSmithKline; Grant support: Johnson & Johnson, Xoran Technologies, Inc, NeilMed Pharmaceuticals, Inc, Acclarent, FAMRI, CF Foundation; **Richard Harvey,** advisory board attendance: Schering-Plough; **John Goddard,** none; **Sarah Wise,** grant support: Xoran Technologies, Inc.

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