

Triamcinolone-Impregnated Nasal Dressing Following Endoscopic Sinus Surgery: A Randomized, Double-Blind, Placebo-Controlled Study

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Objectives/Hypothesis: To evaluate the impact of steroid-impregnated absorbable nasal dressing on wound healing and surgical outcomes after endoscopic sinus surgery (ESS).

Study Design: A prospective, randomized, double-blinded, placebo-controlled trial.

Methods: Chronic rhinosinusitis patients with polyposis who were to undergo bilateral endoscopic sinus surgery were recruited and randomized to receive triamcinolone-impregnated bioresorbable dressing (Nasopore; Stryker Canada, Hamilton, Ontario, Canada) in one nasal cavity and saline-impregnated dressing contralaterally. Postoperative healing assessments of edema, crusting, secretions, and scarring were done at postoperative days 7, 14, 28 and at 3 and 6 months using validated Lund-Kennedy and Perioperative Sinus Endoscopy (POSE) scores.

Results: Analysis of 19 enrolled patients having completed observation shows no significant difference between the cavity scores preoperatively using both the POSE and Lund-Kennedy scores. There was, however, a statistically significant difference at day 7 and 14 in both the Lund-Kennedy ($P = .04$ and $P = .03$, respectively) and POSE scores ($P = .03$ and $P = .001$, respectively) for the treatment and control groups, and a significant difference was also detected between

the groups at 3- and 6-month observations (Lund-Kennedy, $P = .007$ and $P = .02$, respectively; POSE, $P = .049$ and $P = .01$, respectively).

Conclusions: Data analysis suggests a significant improvement in early postoperative healing in nasal cavities receiving triamcinolone-impregnated absorbable nasal packing following ESS and is also associated with improved healing up to 6 months postoperatively.

Key Words: Nasal dressing, triamcinolone, polyposis.

Level of Evidence: 1b.

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INTRODUCTION

Since its advent in the 1980s, endoscopic sinus surgery (ESS) has replaced antrostomies and Caldwell-Luc procedures as the treatment of choice for intractable rhinosinusitis.¹ Wound healing is a significant determinant of successful outcomes in endoscopic sinus surgery. Factors that can lead to poor surgical outcomes include scarring/synechiae, ostial or middle meatal obstruction, infection, and persistent inflammation in the opened sinus cavities. Although there exists some debate as to optimal postoperative stenting or dressing materials following ESS, absorbable nasal dressing has been shown in previously published literature to trend toward improved wound healing and was subjectively preferred by patients when compared to standard nasal sponges.^{2,3}

Topical steroids used preoperatively have been evaluated and showed a lesser rate of bacterial recovery, again suggesting a beneficial role to postoperative outcomes.⁴ Intranasal triamcinolone acetonide has been evaluated in clinical trials and found to be beneficial in minimizing nasal secretory response, reducing inflammation in medical treatment of rhinosinusitis. In a risk-benefit analysis, it has been associated with markedly few adverse side effects.⁴ As such, The International Consensus Conference Proceedings on Rhinitis recommend intranasal steroids as a first line therapy in

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PERI-OPERATIVE SINUS ENDOSCOPY (POSE) SCORE

Middle Turbinate		Right	Left
Normal	0		
Synechia/Lateralized	1-2		
Middle Meatus/MMA		Right	Left
Healthy	0		
Narrowing/Closure	1-2		
Maxillary Sinus Contents	1-2		
Ethmoid Cavity		Right	Left
Healthy	0		
Crusting	1-2		
Mucosal Edema	1-2		
Polypoid Change	1-2		
Polyposis	1-2		
Secretions	1-2		
Total (16)			
Secondary Sinuses			
Frontal Recess/Sinus	0-2		
Sphenoid Sinus	0-2		
Overall Total	16 18F 18S 20		

Fig. 1. Perioperative Sinus Endoscopy (POSE) score.

allergic rhinosinusitis.⁵ However, in the postoperative time frame, the use of topical corticosteroid sprays, in an effort to prevent recurrence of chronic rhinosinusitis with polyposis, has met with mixed results.⁶ A relatively recent, well-designed study showed no impact on recurrence rates in such patients at 1 year postoperatively. In addition, it has been previously suggested that the use of nasal packs to deliver topical antibiotics in the postoperative time period may be of value.⁷

What has been demonstrated to be of clinically significant effect on objective surgical outcomes after ESS is a short course of systemic steroids given perioperatively.⁸ A randomized, double-blind, placebo-controlled study, in which patients were given 30 mg of prednisone for 9 days postoperatively, showed a clinically significant improvement in the endoscopic appearance of the sino-nasal cavity in the short (2–4 weeks) and medium term (3–6 months).

As discussed above, there remains a lack of consensus regarding optimal perioperative nasal dressing and packing as well as the optimal postoperative medical regimen. Evidence-based practice would suggest that

there is value to a course of postoperative systemic steroids but no strong evidence that topical steroids in a spray delivery system is beneficial. Based on this literature and logic, we hypothesized that a more prolonged and direct delivery of topical steroids in the immediate postoperative time frame might be able to achieve the improved objective/endoscopic appearance achieved with systemic steroids. This study, therefore, sought to assess the potential benefit of impregnating an absorbable nasal dressing with a topical steroid solution, for use as a slow-delivery modality after sinus surgery, which had yet to be evaluated in a clinical trial.

MATERIALS AND METHODS

A prospective, randomized, double-blinded, placebo-controlled trial was conducted on patients with chronic rhinosinusitis with polyposis who underwent bilateral ESS.

Patients were recruited in a subspecialized rhinology clinic among patients with chronic rhinosinusitis with polyposis refractory to medical treatment requiring bilateral sinus surgery. Consecutive adult patients with chronic rhinosinusitis were approached for inclusion. Patients were excluded if they were

TABLE I.
Baseline Data (N = 19).

	Treatment, Range (Average)	Control, Range (Average)	P Value
Lund-Mckay	1-12 (9.58)	1-12 (9.68)	>.20
POSE	8-17 (13.16)	8-17 (13.05)	.83
Lund-Kennedy	2-8 (5.32)	2-8 (5.21)	.375

POSE = Perioperative Sinus Endoscopy scores.

ineligible for informed consent, unwilling or unable to comply with the postoperative visits necessary for data collection, or had any history of intolerance to triamcinolone. Ethics approval was obtained from the Human Research Ethics Board of the University of Alberta, study ID# Pro00002016. Of the patients approached for recruitment, there were no patients declining participation.

Baseline Lund-Mckay, Perioperative Sinus Endoscopy (POSE), and Lund-Kennedy scores were collected.⁸⁻¹⁰ These objective endoscopic scoring systems for sinonasal cavities include assessments of features such as crusting, mucosal edema, polyposis, secretions, and scarring (Lund-Kennedy, two points for each category), as well as additional assessments of the middle turbinate, middle meatal antrostomy, and secondary sinuses (POSE). The POSE scoring system has been specifically developed for studies such as this, adds additional data richness in the ethmoid inflammation category, and includes scoring instructions for the baseline assessment (Fig. 1).⁸

At the conclusion of the ESS, the patient was randomized to either the left or right nasal cavity to receive 2 mL of a 40-mg/mL triamcinolone solution-impregnated bioresorbable (4 cm) dressing (Nasopore; Stryker Canada, Hamilton, Ontario, Canada), whereas the contralateral cavity received an identical 4-cm dressing soaked in 2 mL of normal saline. This was done by the nursing staff, based on standardized instructions and concealed from the surgical staff. The primary investigator left the room and nasal packing was placed in appropriate cavities according to the randomization. Nasal packing remained in situ until suctioned from middle meatus at the first postoperative visit 1 week later. Randomization allocation was placed in an envelope and remained sealed until all postoperative data was collected.

Postoperative healing assessments of edema, crusting, secretions, and scarring were done at postoperative days 7, 14, 28 and at 3 and 6 months using validated Lund-Kennedy and POSE scores. Patients were all to resume their nasal saline irrigation and intranasal steroid sprays postoperatively per routine in our center.

Sample size was calculated based on previously published literature using the POSE scoring system with a standard deviation of 3.43 as seen for a similar group of patients, with an α of 5% and a power of 80% to detect a difference in means between populations of 3.5, which was felt to be clinically relevant. The calculated sample size was 32 surgical cavities (16 patients) with patients serving as their own controls. Statistical analysis was performed using the Wilcoxon signed rank test using a significance level of $P < .05$.

RESULTS

Nineteen patients were enrolled through the rhinology clinic at the Alberta Sinus Centre and completed observation. Analysis of the preoperative POSE, Lund-Kennedy, and Lund-Mckay score shows no significant difference between the cavities (see Table I). Some

TABLE II.
Perioperative Sinus Endoscopy Scores.

	Treatment, Range (Average)	Control, Range (Average)	P Value
Baseline, n=19	8-17 (13.16)	8-17 (13.05)	.83
POD 7, n=15	3-10 (5.3)	4-11 (6.8)	.02661
POD 14, n=19	1-8 (4.6)	3-11 (6.84)	.001
POD 28, n=18	1-11 (4.7)	1-10 (5.78)	.27
3 mo, n=18	0-11 (4.5)	0-11 (5.72)	.049
6 mo, n=16	0-13 (5.2)	1-13 (6.5)	.01172

POD = postoperative day.

patients missed one or two of the postoperative clinic appointments. No adverse side effects were noted in the patient series.

A statistically significant difference is noted at the day 7 and 14 values in both the Lund-Kennedy ($P = .04$ and $P = .03$, respectively) and POSE scores ($P = .03$ and $P = .001$, respectively) for the treatment and control groups. The difference lacked statistical significance at postoperative day 28 (Lund-Kennedy, $P = .13$; POSE, $P = .27$), but a significant difference was detected between the groups at 3 and 6 month observations (Lund-Kennedy, $P = .007$ and $P = .02$, respectively; POSE, $P = .049$ and $P = .01$, respectively) (see Table II and Table III).

DISCUSSION

Success in outcomes of ESS in patients with chronic rhinosinusitis with polyposis is heavily dependant on reducing postoperative scarring, edema, and crusting that can inhibit natural ciliary function and sinus drainage. To this end, many rhinologists advocate aggressive use of saline irrigation and nasal steroid sprays postoperatively along with meticulous debridement of the ethmoid cavities and secondary sinus outflow tracts. With this practice, incidence of synechiae formation in the nasal cavity is lessened. A separate evaluation of the synechia data from the POSE and Lund-Kennedy scores was performed. Synechiae were rare in both the treatment and control groups; there was a trend to less synechia formation in the cavities assigned to the treatment group, but the data lacked statistical significance ($P < .25$).

TABLE III.
Lund-Kennedy Scores.

	Treatment, Range (Average)	Control, Range (Average)	P Value
Baseline, n=19	2-8 (5.32)	2-8 (5.21)	.375
POD 7, n=14	1-4 (2.43)	1-4 (3.07)	.039
POD 14, n=17	1-5 (2.65)	1-7 (3.59)	.027
POD 28, n=17	0-4 (2.35)	1-5 (3.06)	.129
3 mo, n=16	0-4 (2.0)	0-5 (2.88)	.007
6 mo, n=16	0-4 (2.25)	1-5 (2.94)	.02

POD = postoperative day.

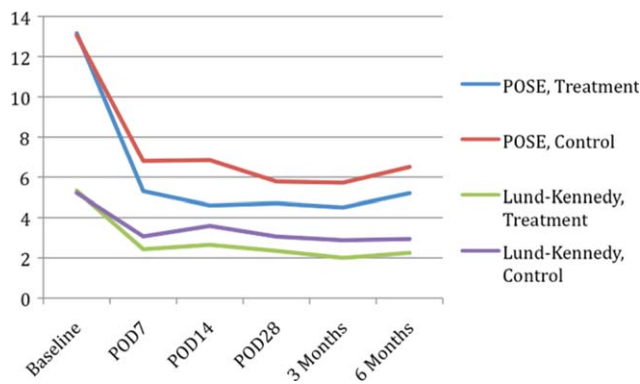


Fig. 2. Perioperative Sinus Endoscopy (POSE) and Lund-Kennedy scores postoperatively in the treatment and control groups. POD = postoperative day. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

Perioperative systemic steroids have also been proposed as an adjuvant to topicals to reduce recurrence of edema and polyposis, but liberal use has been limited by the side effect profile of systemic steroids. A previously published study evaluating 30 mg of perioperative prednisone found a difference in cavities of treatment patients up to 6 months postoperatively when compared to the nasal cavities of controls, with the most significant difference noted at 2 weeks postoperatively.⁸

The present study presents a perfectly matched, double-blinded, placebo-controlled trial that demonstrates that a bioresorbable sinonasal dressing soaked in triamcinolone, when used as an adjuvant to saline irrigation and conventional topical steroid sprays, is associated in a statistically and clinically significant fashion with improved objective sinonasal cavity findings up to 6 months postoperatively (see Fig. 2). These significant improvements, in both established objective outcome measures (Lund-Kennedy and POSE), combined with the benign side effect profile of topical triamcinolone compared to systemic steroids, has led to a change in standard practice at our institution whereby all chronic rhinosinusitis patients with polyposis routinely receive this nasal dressing impregnated with triamcinolone following ESS.

Previous studies have attempted to address the challenge of postoperative ostial stenosis or synechia formation by application of topical antiproliferative agents.^{11,12} Although these attempts have, in some cases, demonstrated limited success, limitations of study design and follow-up, as well as concerns regarding toxicity and long-term deleterious effects such as malignancies, remand this practice out of the mainstream. In addition, a recent systematic review demonstrated little value in other wound-healing modifiers, such as retinoic acid or hyaluronic acid, after ESS.¹³ One animal study using a sheep mucosal model found no difference in epithelialization and ciliation when the hyaluronic acid was impregnated with prednisolone.¹⁴ The present study offers an alternative to these agents that provides evidence of overall improved surgical outcomes, including measures of edema, crusting, secretions, and scarring.

Limitations to our study include the likely variable consistency and duration of delivery of the triamcinolone.

Although Nasopore as a biologically inert absorbable dressing was an effective choice for slow delivery in the middle meatus, one study suggested that it may be associated with a slight delay in healing when compared to Meroceol (Medtronic Meroceol, Mystic, CT).¹⁵ Additionally, the ideal dosing remains to be clarified to achieve maximal clinical benefit using this method. These are both areas of future investigation. This practice-modifying result has led us to reflect on further potential targets of this postoperative concept. Examples of this include the role for triamcinolone-impregnated packing in postsurgery recurrence of sinonasal inflammation and polyposis and stenting of the sphenoid ostium or frontal recess after surgery, which has yet to be established. Such innovations are likely to become commonplace in the next several years as biomaterials and pharmacology of same continues to evolve.

CONCLUSION

The results of this study reveal a significant improvement in early postoperative healing in sinonasal cavities receiving triamcinolone-impregnated absorbable nasal packing following ESS and is also associated with significantly improved healing up to 6 months postoperatively.

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