Original Article

Is Add-on Budesonide-Impregnated Nasal Dressing Useful Following Endoscopic Sinus Surgery with Perioperative Oral Steroid?

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Background: Some chronic rhinosinusitis with nasal polyps patients undergoing endoscopic sinus surgery (ESS) have unfavorable results despite proper postoperative treatments including oral and topical steroids. Steroid-impregnated absorbable nasal dressing has been shown to improve outcomes of the surgery. In some clinical practices, budesonide-impregnated nasal dressing is used together with perioperative oral steroid but the additional benefits of it are still unknown.

Objective: To determine whether budesonide-impregnated nasal dressing had any benefits following ESS when a short course of oral steroid was given in perioperative period.

Materials and Methods: The present study was a prospective, double-blinded, randomized, placebo-controlled study conducted in tertiary care hospital. Eighteen consecutive patients (36 nostrils) with chronic rhinosinusitis with nasal polyps underwent bilateral ESS were enrolled. At the end of the surgery for each patient, one side of the ethmoid cavity and middle meatus was randomly given polyurethane foam soaked with 2 mL of budesonide inhalation solution (0.5 mg/2 mL) (budesonide side), while the contralateral side received 2 mL of normal saline-soaked polyurethane foam (control side). Postoperative care included a short course of oral steroid and budesonide nasal irrigations. Single assessor blinded to the randomize allocation evaluated mucosal inflammation and wound healing at 2 and 4 weeks after surgery using Perioperative Sinus Endoscopy (POSE) score.

Results: A total of 36 nostrils were randomized into two groups: 18 to the budesonide side and 18 to the control side. All of them were analyzed. The preoperative Lund-Mackay computed tomography score did not show a significant difference between the groups. There was no significant difference in POSE score between budesonide and control sides at 2 and 4 weeks after surgery.

Conclusion: Budesonide-impregnated polyurethane foam did not provide additional benefits on mucosal inflammation and wound healing in the patients who underwent ESS and received a short course of oral steroid perioperatively.

Keywords: Chronic rhinosinusitis, Nasal polyps, Nasal dressing/packing, Budesonide, Endoscopic sinus surgery

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Chronic rhinosinusitis with nasal polyposis (CRSwNP) is a chronic inflammation involving nasal and paranasal sinuses mucosa. Endoscopic sinus surgery (ESS) is indicated when medical therapy has failed. Despite many advance surgical techniques and equipment, there is still postoperative mucosal inflammation that may lead to poor surgical outcomes such as synechiae/scarring, ostial stenosis, polyps recurrence and finally ending up with revision surgery[1]. Treatment strategies to reduce inflammation include corticosteroids in either systemic or topical forms. Topical intranasal corticosteroid sprays are standard first-line therapy used to control postoperative mucosal inflammation[2], but this steroid delivery method may not provide adequate drug reach to the affected sinus mucosa even after ESS[3].

To improve local steroid delivery to the sinus mucosa during early postoperative period, off-label steroid-impregnated nasal dressings have been studied to evaluate effectiveness and outcomes[4-10]. In theory, these would allow for more prolonged, high concentration and direct contact of topical steroids to the sinus mucosa. Some studies using triamcinolone-impregnated absorbable nasal dressings presented

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promising results over nonsteroidal dressing[4-8]. Whereas two other studies[9,10] did not show benefits, systemic effects of triamcinolone-impregnated absorbable nasal dressings have also been reported[11].

Budesonide nasal spray has been presented to be effective in the treatment of nasal polyps[12,13]. In recent years, budesonide inhalation suspension used as nasal irrigation following ESS has shown clinical benefit in chronic rhinosinusitis patients[14,15]. Budesonide transnasal nebulization could also significantly improve symptoms and reduce polyp size in patients with eosinophilic chronic rhinosinusitis with nasal polyps[16]. Moreover, budesonide shows better drug profiles than triamcinolone including lower systemic bioavailability and higher relative glucocorticoid receptor affinity[17,18].

Although, a short course of oral steroid, antibiotics, and steroid nasal irrigations are used routinely in the authors' postoperative care treatments, some of patients still have unsatisfying outcomes. Therefore, the authors tried to find out whether budesonide-impregnated absorbable nasal dressing which had been used in some clinical practices could have any additional benefits despite those treatments. The objective of the present study was to determine additional benefits of budesonide-impregnated polyurethane foam on mucosal inflammation and wound healing following ESS when oral steroid was given perioperatively, which has not yet been evaluated in double-blinded, placebo-controlled trial.

Materials and Methods

The study was approved by the Institutional Review Board (IRB) of the Faculty of Medicine, Chulalongkorn University (IRB No.237/60). All participants provided written informed consents. The present study was registered in Thai Clinical Trials Registry (TCTR20180323002).

The authors used a prospective, double-blinded, within person randomized, placebo-controlled design to reduce confounding factors that could occur between patients.

Participants

The present study was conducted in King Chulalongkorn Memorial Hospital between January 2018 and August 2018. Consecutive CRSwNP patients, as defined according to EPOS 2012 guidelines[19], scheduled to undergo primary or revision ESS were approached to participate in the present study. Participants were needed to: 1) be aged between 18 to 65 years, 2) have persistent symptoms despite using topical nasal corticosteroid sprays at least 3 months, 3) have minimum preoperative Lund-McKay computed tomography score[20] of six per side and difference of score from each side of the nose were not greater than one, 4) undergo bilateral ESS of all sinuses. Surgical treatment of inferior turbinates and/or septoplasty were allowed. Patients were excluded if they were unable to give written informed consent, or had history of immunodeficiency, corticosteroid intolerance, diabetes mellitus, glaucoma, allergic fungal rhinosinusitis, mucociliary disorders, and pregnancy.

Interventions

Demographic information and baseline preoperative Lund-McKay computed tomography score of each eligible patient were recorded. Comorbidities of asthma and aspirin-exacerbated respiratory disease (AERD) were recorded if presented. Asthma was determined if patient used inhaled bronchodilator or corticosteroid regularly. AERD was defined as having a history of respiratory reactions to aspirin or nonsteroid anti-inflammatory drugs (NSAIDs), presence of nasal polyps and asthma. Preoperative medications included oral steroid (prednisolone 20 mg/day) starting 5 days before surgery and oral antibiotic (amoxicillin-clavulanic acid 1 g twice daily, or levofloxacin 750 mg once daily for penicillin allergy) starting 7 days before surgery.

ESS procedures were performed by three surgeons (Aeumjaturapat S, Chusakul S, Kanjanaumporn J) who specialize in endoscopic sinus and skull base surgery. All patients underwent bilateral middle meatal antrostomy, anterior and posterior ethmoidectomy, sphenoidotomy and frontal sinusotomy.

At the end of ESS, the assistant surgeon opened the concealed envelope and prepared the nasal dressings based on instructions inside. Firstly, polyurethane foam (Nasopore® Forte; Stryker European Operations B.V., Amsterdam, Netherlands) was cut in half longitudinally and vertically. One half was soaked with 2 mL of 0.5 mg/2 mL budesonide inhalation suspension, as intervention. The other half was soaked with 2 mL of normal saline, as control. One side of nostrils was randomized to receive intervention, whereas the contralateral side received control. The assistant surgeon placed the prepared nasal dressings in each side of the ethmoid cavity and middle meatus according to the randomization. During these processes, the outcome assessor was kept away. The nasal dressings remained in the ethmoid cavities and middle meatus until they were

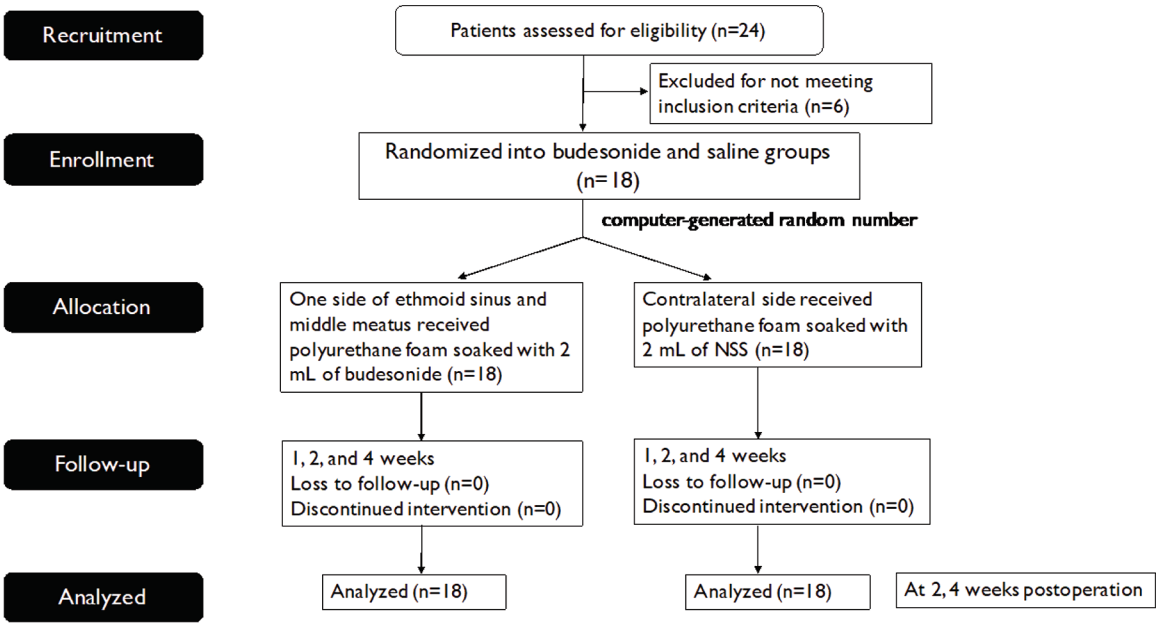

Figure 1. Consolidated Standards of Reporting Trials flow diagram.

NSS=normal saline

removed by suctioning at the first postoperative visit.

Postoperative management protocol included oral antibiotics (amoxicillin with clavulanic acid 1 g twice daily, or levofloxacin 750 mg once daily for penicillin allergy) for 7 days and oral steroid tapered off over 12 days (prednisolone 20 mg/day for the first 4 days, tapered to 10 mg/day for 4 days, and 5 mg/day for another 4 days). Nasal irrigations were started at 48 hours after ESS, which consisted of 2 mL of 1 mg/2 mL budesonide inhalation suspension in 250 mL of normal saline in the morning and 250 mL of normal saline in the evening. All patients underwent in-office endoscopic debridement at postoperative week 1 (day 6 to 8), week 2 (day 13 to 15), and week 4 (day 27 to 29).

Outcomes

As the primary outcome, mucosal inflammation and wound healing following ESS in each side of the sinus cavities were assessed with the validated Perioperative Sinus Endoscopy (POSE) scoring system[21] at 2 and 4 weeks after surgery. Secondary outcomes were postoperative infection rates and satisfaction to debride postoperative sinus cavities. Postoperative infection was defined as the presence of frank pus in the sinus cavities. Satisfaction to debride the postoperative sinus cavities was assessed using 10-cm visual analogue scale (VAS) which 0 referring to "not satisfied" and 10 referring to "most satisfied". All assessments were done by the same single outcome assessor (Taweewuthisub O), blinded to randomization allocation. The flowchart of the present study was shown in Figure 1.

Sample size

Sample size was calculated using G*Power software based on repeated measures, within factors analysis of variance (ANOVA) statistical test with estimated medium effect size of 0.25, an alpha of 5%, a power of 80%, correlation among repeated measures of 0.8, two groups (budesonide and control groups) and two measurements (postoperative week 2 and 4). Initial calculated sample size was 16 patients (32 nostrils) with an assumption of 15% potential dropout, therefore, final sample size was 18 patients (36 nostrils).

Randomization

Research staff at the Rhinology Clinic generated randomization sequences, achieved by computer-generated random number from http://www.randomizer.org, which assigned either left or right nostril as intervention and contralateral nostril as control. Randomization for each patient was concealed in the envelope until revealed in the

operating room at the end of the surgery. Research staff kept the assignment results confidential until all of the postoperative data were collected.

Statistical analysis

As patients served as their own controls and each nostril was assessed two times (at postoperative week 2 and 4), two-way repeated measures ANOVA was used to compare both POSE score and VAS of satisfaction to debride between intervention and control sides. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY, USA). A p-value of less than 0.05 was considered statistically significant.

Results

Twenty-four consecutive eligible patients were recruited. Six of them were excluded: three were immunocompromised patients, two aged >65 years, and one had preoperative Lund-McKay computed tomography score less than six in one side of the nose. Therefore, a total of 18 CRSwNP patients were enrolled in the present study. Demographic characteristics were shown in Table 1. All patients completed the 4-week follow-up period. No perioperative complications and adverse side effects occurred. Preoperative Lund-Mackay CT score of budesonide and control groups were 10.00±2.00 and 9.89±1.71, respectively, and did not show significant difference (p=0.58).

Mean POSE score of budesonide side did not show a statistically significant difference compared to control side at both postoperative weeks 2 and 4 (p=0.23 and 0.58, respectively). However, both sides had a significant improvement of POSE score over time (p=0.017, 0.016). The results of VAS for debridement were similar to POSE score except for a better score in the control side at 2 weeks after surgery (p=0.013) (Table 2).

According to the two-way repeated measures ANOVA, two factors that could affect POSE score were treatment (budesonide vs control) and follow-up time after surgery. Table 3 demonstrated the effects of these two factors on each outcome and the interaction between the two factors. For the effect of treatment factor, there was no overall statistically significant difference in POSE score between budesonide and control sides in the 4-week study period (p=0.3). When the effect of treatment factor was not considered, the effect of follow-up time after surgery showed a statistically significant difference in POSE score between postoperative weeks 2 and 4 (p=0.004). On average, the mean difference was

Table 1. Demographic characteristics

Participant characteristics (n=18)	n (%)
Age (year); mean (range)	45.6 (20 to 64)
Male	13 (72.2)
Comorbidities	
Asthma	6 (33.3)
AERD	3 (16.7)
No. of prior bilateral ESS	
0	13 (72.2)
≥1	5 (27.8)

AERD=aspirin-exacerbated respiratory disease; ESS=endoscopic sinus surgery

Table 2. POSE score and VAS for debridement at postoperative week 2 and 4

	Week 2; mean (SD)	Week 4; mean (SD)	p-value
POSE score			
Budesonide	7.06 (2.60)	5.11 (3.61)	0.017*
Control	6.33 (2.42)	4.67 (3.85)	0.016*
p-value	0.23	0.58	
Mean difference (95% CI)	0.72 (–0.49 to 1.94)	0.44 (–1.21 to 2.10)	
VAS			
Budesonide	7.08 (1.78)	7.89 (1.66)	0.007*
Control	7.48 (1.86)	8.11 (1.63)	0.034*
p-value	0.013*	0.436	
Mean difference (95% CI)	0.39 (0.09 to 0.69)	0.22 (–0.36 to 0.79)	

POSE=perioperative sinus endoscopy; VAS=visual analogue scale; CI=confidence interval; SD=standard deviation

* Significant at p<0.05

Table 3. Effect of factors on outcomes and interaction between factors

Outcome factor	Mean difference	95% CI	p-value
POSE score			
Treatment (budesonide vs. control)	0.58	–0.57 to 1.74	0.3
Time (2 week vs. 4 week)	1.81	0.68 to 2.93	0.004*
Treatment x Time			0.745
VAS			
Treatment (budesonide vs. control)	0.31	–0.10 to 0.71	0.13
Time (2 week vs. 4 week)	0.72	0.19 to 1.25	0.01*
Treatment x Time			0.39

POSE=perioperative sinus endoscopy; VAS=visual analogue scale; CI=confidence interval

* Significant at p<0.05

1.81 (95% CI 0.68 to 2.93). In addition, there was no statistically significant two-way interaction between treatment factor and follow-up time factor (p=0.745). The effects of these two factors on outcomes were not dependent on each other. The analysis of VAS for debridement showed similar findings (Table 3).

Discussion

In the present study, the authors evaluated the additional benefits of budesonide-impregnated absorbable nasal dressings (polyurethane foam) on mucosal inflammation and wound healing within 4 weeks following ESS in CRSwNP patients. The present study results demonstrated that it could not provide additional benefits when a short course of oral steroid was combined in perioperative care. The only factor that obviously affected study outcomes was the period of time after surgery. Usually, the degree of inflammation in the postoperative sinus cavities are gradually decreased over time. Therefore, it was not surprising that the POSE score at 4 weeks after surgery were significantly lower than the score at postoperative week 2 in both budesonide and control groups. Satisfaction to debride the postoperative sinus cavities using 10 cm-VAS had almost similar outcomes. Although, the score of control side was statistically significantly higher than budesonide side score at postoperative week 2, the difference might be too small to affect the clinical outcome, with a lower confidence limit of 0.09. Postoperative infection was not found in both sides.

Until now, there are five prospective, within person randomized, placebo-controlled studies[5,22-25] that have evaluated the role of off-label steroid-impregnated nasal dressings following surgery. Various kinds of steroids and nasal dressings have been used including triamcinolone, mometasone furoate, dexamethasone; polyurethane foam, chitosan gel, calcium alginate. All of them demonstrated that steroid-impregnated nasal dressings showed statistically significant improvement of postoperative endoscopy scores compared with normal saline-soaked nasal dressings. However, the differences were quite small. Of these studies, four studies[5,22-24] reported the differences of POSE score between treatment and control groups ranging between 1.3 to 3 from total score of 20; the other study[25] reported the difference of 0.39 from total score of 6 in Lund-Kennedy endoscopy score. Also, these studies showed inconsistent data regarding time after surgery at which steroid-impregnated nasal dressings had significantly affected postoperative sinus cavities. Three studies[22,24,25] showed significant results in only one visit from 3, 4, and 4 follow-up visits, respectively. Whereas the other two studies presented significant results at multiple follow-up visits varying between 7 days to 6 months[5,23].

There are a few possible explanations why the present study showed different results from the others. First, the present study patients had more extensive disease as shown by higher preoperative CT score (10 of 12 vs. 7.5 to 9.6 of 12). Six of 18 patients had asthma and three of them had AERD as comorbidity. These factors associate with poor surgical outcomes[19]. Second, early nasal irrigations started on postoperative day 2 may dilute and wash out budesonide in the nasal dressing. In previous studies, the day after surgery that nasal irrigations were started varied from day 4 to 14. The authors instructed the patient to start early nasal irrigation because the authors wanted to know whether there was any benefit of this adjunctive treatment in addition to the authors' routine standard protocol of perioperative and postoperative care. Third, perioperative short course oral steroid and postoperative budesonide nasal irrigations could also mask the effect of budesonide-impregnated nasal dressing on the sinus mucosa. One study[22] from the five previously mentioned used low-dose oral methylprednisolone tapered in 3 weeks in postoperative management. The result did not show significant differences in POSE score between triamcinolone and saline groups at 1 and 4 weeks after surgery, whereas a significant difference was found at 8 weeks after surgery. The results were surprising because the effectiveness of steroid-impregnated absorbable nasal dressings would not last more than 1 month. Last, the dosage of topical steroid solution may be one of the factors that affect the outcomes. As in a recently published study[23], higher dose of mometasone furoate that soaked biodegradable nasal dressing showed better endoscopic score.

Unlike commercial bioabsorbable steroid-eluting sinus stent/implant that gradually release mometasone furoate to the sinus mucosa over a certain period of time, the stability and duration of action of budesonide in absorbable nasal dressing have yet to be studied. The optimal dosage of the drug to achieve clinical benefit using this method of delivery remains to be elucidated.

The present study was the first prospective, double-blinded, randomized, placebo-controlled study of budesonide-impregnated absorbable nasal dressing used in ESS. The authors used within person randomized design which comparisons between

interventions were within people. Interindividual variability can be decreased. Due to the limited number of patients, though, it was difficult to perform subgroup analysis according to underlying or severity of diseases such as AERD, revision cases, nasal polyps endotypes that might affect results of the study. The trends of the outcomes in this subpopulation were unclear and inconsistent.

The follow-up times were relatively short as healing of the sinus cavities takes at least 12 weeks. The reason the authors did not follow the patients after 4 weeks because the foam was partially suctioned out of the ethmoid cavity since the first visit (1 week) and totally dissolved within 2 weeks, so budesonide-impregnated polyurethane foam could affect only in early postoperative period and could not provide long lasting effects on healing of the sinus cavities.

Conclusion

Budesonide-impregnated polyurethane foam did not provide additional benefit in reducing mucosal inflammation and improving wound healing following ESS, when a short course of oral steroid was combined in perioperative management

What is already known on this topic?

Steroid-impregnated nasal dressing showed better surgical result over nonsteroidal dressing in ESS.

What this study adds?

In ESS which systemic steroids were given perioperatively, using steroid-impregnated nasal dressing did not give more benefit.

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Conflicts of interest

The authors declare that there is no conflict of interest with respect to the research, authorship, and/or publication of this article.

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