ORIGINAL ARTICLE

The Efficacy of Double-Dose Mometasone Furoate Nasal Spray in Postoperative Management of Nasal Polyps: A Randomized Controlled Trial

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Background: Nasal polyps are benign growths of nasal mucosa associated with inflammation and topical nasal corticosteroids are the medical treatment of choice. Surgical removal is indicated for patients not responding adequately to medical treatment. There is little evidence on the efficacy of double-dose mometasone furoate nasal spray and conventional dose to prevent the recurrence of nasal polyps and decrease nasal symptom score following endoscopic sinus surgery.

Objective: To compare the efficacy of double-dose mometasone furoate and conventional dose to prevent the recurrence of postoperative nasal polyps.

Materials and Methods: The present study was a randomized controlled trial. Thirty patients who met the inclusion criteria were randomly divided into two groups, 15 patients in each group. Group I patients were given mometasone furoate two sprays in each nostril twice a day (400 µg) and Group II received mometasone furoate two sprays in each nostril once a day (200 µg) as a conventional dose for six months. Grading of nasal polyps and nasal symptom score were recorded before and after treatment at the first, second, fourth, twelfth and twenty-four weeks.

Results: After six months of the endoscopic sinus surgery, Meltzer clinical scoring system of nasal polyps showed an average score of 0.67±0.72 in the conventional dose, which was significantly reduced to 0.07±0.26 ($p<0.01$) in the double dose of mometasone furoate. The average nasal symptom score in the conventional dose was 0.70±0.70, which was not significantly decreased to 0.30±0.50 ($p=0.25$) in the double dose. There were no side effects in both groups.

Conclusion: Double-dose of mometasone furoate nasal spray might be recommended for preventing the recurrence of nasal polyps and decreasing nasal symptom score following surgery.

Keywords: Nasal polyps; Intranasal corticosteroid; Endoscopic sinus surgery; Mometasone furoate; Recurrent nasal polyps; Nasal spray; Nasal symptom score; Randomized controlled trial; Postoperative management

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Nasal polyps are benign growth of nasal mucosa associated with inflammation with clinical symptoms including nasal obstruction, nasal discharge, postnasal drip, and loss of smell[1,2]. Nasal polyposis has a significant impact on the quality of life[3]. Worldwide, the prevalence is estimated to be up to 4%[4]. Topical Intranasal corticosteroids (INCS) reduce the inflammation associated with polyposis and are effective treatments of this condition[5]. Mometasone furoate nasal spray became the first U.S. Food and Drug Administration (FDA) approved treatment for nasal polyps. The benefit of mometasone furoate is to reduce the nasal polyp grade and symptoms[6]. Surgical removal of nasal polyps is indicated for patients not responding adequately to medical management[7]. Postoperative treatment with INCS is required because it helps to slow the rate of recurrence of nasal polyps[8].

In searching the literature, there are a few studies available regarding the comparison of the efficacy of double-dose mometasone furoate nasal spray and conventional dose to prevent the recurrence of nasal polyps and decrease nasal symptom score following endoscopic sinus surgery (ESS).

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Materials and Methods

The present study was approved by the Ethics Committee of Burapha University on November 25, 2021 (IRB1-091/2564) and registered at the Thai Clinical Trials Registry, TCTR20211225001.

Sample size was calculated by the comparison of two independent population means. The standard deviation of the nasal polyp grading in the double-dose group was 0.5 and in the conventional group was 0.51[9]. The number of samples per group was 13. When calculating a dropout rate of 20%, the number of samples per group was 15.

Participants

Participants were chosen from patients who had nasal polyps and had been referred to the Department of Otorhinolaryngology, Faculty of Medicine, Burapha University between 2021 and 2023 for ESS. The study was performed as a randomized controlled trial. The authors enrolled 30 nasal polyps patients. Participants were all adults aged 20 to 60 years who met the following inclusion criteria, 1) bilateral nasal polyps patients did not respond adequately to medical management and underwent ESS, and 2) no previous treatment. The exclusion criteria were 1) the presence of a nasal neoplasm, 2) a history of acute infection in the nasal cavity, 3) a history of nasal surgery or trauma, 4) recent use of oral steroid, 5) pregnancy or breast-feeding, 6) a history of steroid allergy, 7) the presence of immunocompromise, 8) a history of Churg-Strauss syndrome, dyskinetic ciliary syndromes, or cystic fibrosis, and 9) a history of glaucoma or posterior subcapsular cataracts.

Thirty patients were included according to the inclusion and exclusion criteria. At baseline, physical examinations with nasal endoscopy, computerized tomography scan, and routine pre-operative examination were performed.

Treatment procedures

The thirty patients were randomly and equally assigned to two groups. Group I received double-dose of mometasone furoate nasal spray, and Group II received a conventional dose. The randomization technique was a consecutive allocation by the visit sequence. Groups I and II were treated for six months. Group I was given mometasone furoate two sprays in each nostril twice a day (400 μg), and Group II was given mometasone furoate 2 sprays in each nostril once a day (200 μg). Patients were followed-up at week 1, week 2, month 1, month 3, and month 6. Thirty patients completed the study with 15 in each group.

Criteria for outcome

Nasal symptom score and nasal endoscopic examination were performed before ESS and postoperative follow-up at first week, second week, first month, third month, and sixth month. Nasal symptom score and grading of nasal polyps were collected by three surgeons. The primary outcome was the average of postoperative nasal polyp grade, which was compared between the two groups. The Meltzer Clinical Scoring System is a 0 to 4 nasal polyp grading system with 0=no polyp, 1=polyps confined to the middle meatus, 2=multiple polyps occupying the middle meatus, 3=polyps extending beyond middle meatus, and 4=polyps completely obstructing the nasal cavity[10]. All surgeons used this system to evaluate the nasal polyps based on the nasal anatomy. Therefore, there was no interpersonal variance.

The secondary outcome was average post-operative nasal symptom score that included nasal congestion, nasal discharge, hyposmia, epistaxis, facial pain and headache[11], which was compared between the two groups.

Statistical analysis was performed using Stata, version 14.1 (StataCorp LP, College Station, TX, USA). Two-sample independent t-test was used to compare continuous variables. The treatment effects in the two groups were compared using the chi-square test. The level of statistical significance was p-value of less than 0.05.

Results

Thirty patients were randomized into two groups with 15 patients in the double-dose group and 15 patients in the conventional group. The final number of patients who met the inclusion and exclusion criteria, followed up for 1 week, 2 weeks, 1 month, 3 months, and 6 months after treatment, and enrolled in statistical analysis, was 15 patients in each group.

The demographics of the patients are summarized in Table 1, which showed no significant difference between the two groups.

Table 2 shows the comparison of postoperative nasal polyp grade at 1, 2, 4, 12, and 24 weeks in the two groups. After six months of the ESS, Meltzer clinical scoring system of nasal polyps showed an average score of 0.67±0.72 in the conventional dose, which was significantly reduced to 0.07±0.26 ($p<0.01$) in the double dose of mometasone furoate.

Table 3 and Figure 1 shows the comparison of

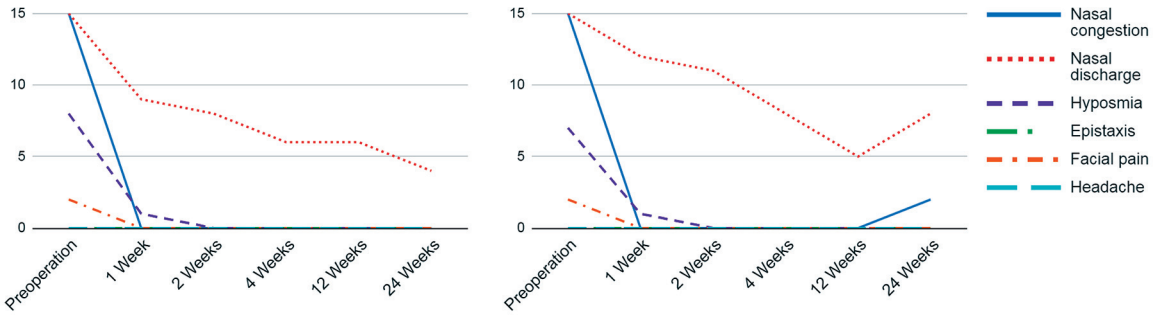

Figure 1. Nasal symptom score of patients in the two groups. (A) nasal symptom score of patients in double-dose group. (B) nasal symptom score of patients in conventional group.

Table 1. Demographics of patients in the two groups

	Double-dose group (n=15)	Conventional group (n=15)	p-value
Age (years); mean±SD	42.73±14.83	44.33±13.37	0.8844
Sex (male:female); n	8:7	10:5	0.4560
Preoperative polyp grade; mean±SD	4±0	4±0	-
Preoperative symptom score; mean±SD	2.7±0.6	2.6±0.6	0.2058

SD=standard deviation

Table 2. Postoperative nasal polyp grade

Grading of nasal polyps	Double-dose group (n=15) mean±SD	Conventional group (n=15) mean±SD	p-value
Week 1	0±0	0±0	-
Week 2	0±0	0±0	-
Week 4	0±0	0.13±0.35	0.15
Week 12	0.07±0.26	0.27±0.46	0.15
Week 24	0.07±0.26	0.67±0.72	0.0057

SD=standard deviation

Table 3. Postoperative nasal symptom score of patients in the two groups

Nasal symptom score	Double-dose group (n=15) mean±SD	Conventional group (n=15) mean±SD	p-value
Week 1	0.7±0.6	0.9±0.5	0.28
Week 2	0.5±0.5	0.7±0.5	0.30
Week 4	0.4±0.5	0.5±0.5	0.25
Week 12	0.4±0.5	0.3±0.5	0.15
Week 24	0.3±0.5	0.7±0.7	0.25

SD=standard deviation

postoperative nasal symptom score at 1, 2, 4, 12, and 24 weeks in the two groups. After six months of the ESS, nasal symptom score showed an average score of 0.70±0.70 in the conventional dose, which was not significantly reduced to 0.30±0.50 (p=0.25) in the double dose of mometasone furoate.

No serious complications were observed in either group after treatment.

Discussion

The effective treatment for postoperative nasal polyposis is INCS, which helps to reduce the rate of recurrence of nasal polyps[8]. There are few studies available regarding the comparison of the efficacy of double-dose mometasone furoate nasal spray and conventional dose to prevent the recurrence of nasal polyps.

Dijkstra et al.[11] study groups received fluticasone 400 µg bid and 800 µg bid for 12 months after ESS. Their control group received a placebo. The study group had no significant difference in symptoms and recurrence rate, which was different from the Rowe-Jones et al.'s study[12], which had better polyp score in fluticasone-treated patients than placebo (p=0.04) but no significant improvement in symptoms score.

Hartwig et al.[13] patients received budesonide 400 µg for six months while the control group received placebo. The study group had a lower polyps score. Karlsson et al.[14] study group received beclomethasone 400 µg for 12 months. Their control group received a placebo. The study group had a significant effect on polyp score.

Stjärne et al.[15] study group received mometasone furoate 200 µg after ESS. Their control group received a placebo. The primary outcome was the time to relapse. The median time to relapse was 173 and 61 days for the mometasone and placebo groups, respectively. The study group had a longer relapse-free period and significantly better score for the rhinorrhea component of symptom score.

The different results obtained from these studies can be explained by the difference of drugs, and dosage of administration.

Furthermore, there was a study of mometasone furoate 400 µg for six months after postoperative recurrence of nasal polyps. High-dose application had significantly decreased the average score of the symptoms and polyp size for the treatment of recurrent nasal polyps in the postoperative follow-up[9]. However, the study did not start with a high dose after surgery, so it could not indicate the prevention of recurrent nasal polyps.

The present study showed the comparison of the efficacy of double-dose mometasone furoate nasal spray and conventional dose to prevent the recurrence of nasal polyps and decrease nasal symptom score after ESS.

There are limitations in the present study due to small sample sizes and a single institution. A multicenter study may better overcome this problem.

Future studies are recommended with larger sample size and different kinds of INCS to reduce the rate of recurrent nasal polyps.

Conclusion

Double-dose of mometasone furoate nasal spray might be recommended for preventing the recurrence of nasal polyps and decreasing nasal symptom score following surgery.

What is already known on this topic?

Treatment of postoperative nasal polyps.

What does this study add?

The efficacy of double-dose mometasone furoate nasal spray for prevention of the recurrent rate of postoperative nasal polyps.

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Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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