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Investigating the Results of Using Betamethasone Ophthalmic Ointment in Polypoid Frontal Sinus in Endoscopic Sinus Surgery and Its Effect on Reducing the Recurrence of Polyposis After Surgery: A Randomized Clinical Trial

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Abstract

Background: Chronic rhinosinusitis with nasal polyps (CRSwNP) often recurs after endoscopic sinus surgery (ESS), particularly in the frontal recess, which topical irrigations and sprays reach poorly. We evaluated whether intraoperative betamethasone ophthalmic ointment in the frontal sinus reduces postoperative recurrence.

Methods: In this randomized clinical trial with intra-patient control, 30 patients (≥13 years) with bilateral CRSwNP undergoing primary or revision ESS (Draf 2a) at 2 teaching hospitals in Tehran, Iran, were enrolled. One frontal sinus per patient was randomly assigned to betamethasone ophthalmic ointment at the end of surgery; the contralateral sinus served as control. Patients and outcome assessors were blinded. Polyps, inflammation, and secretion were assessed endoscopically at 1.5 and 3 months. The soft tissue density ratio (STDR) was measured on 3-dimensional CT reconstructions before and 3 months after surgery and analyzed with a generalized estimating equation model. Registration: Iranian Registry of Clinical Trials, IRCT20220510054810N1.

Results: The intervention side demonstrated significantly better endoscopic outcomes than the control side at both 1.5 months (no polyps: 93% vs 70%; no inflammation: 60% vs 20%; no secretion: 63% vs 17%) and 3 months (no polyps: 63% vs 50%; no inflammation: 67% vs 30%; no secretion: 63% vs 20%) (all $P < 0.05$). STDR reduction was also significantly greater on the intervention side (time × group interaction: $\beta = -14.5$, $P < 0.001$).

Conclusion: Intraoperative betamethasone ophthalmic ointment in the frontal sinus improved endoscopic outcomes at 1.5 and 3 months and reduced postoperative STDR, including in patients with Samter's triad. Larger trials with longer follow-up are warranted.

Keywords: Rhino-Sinusitis, Effects of Betamethasone Ointment, Polyp, Surgery, Endoscopic Criteria

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Introduction

Nasal polyp is the most common benign nasal tumor that can lead to unilateral or bilateral nasal obstruction and other annoying problems such as mouth breathing and in advanced cases, dry throat, sleep disorder, night snoring, runny nose, sleep disorder, headache, etc (1). Different treatments have been discussed in recent years and with the invention of new surgical methods, including endoscopic surgery of the nose and sinuses, the importance of drug treatments has been given less attention. Endoscopic sinus surgery treatment, in addition to affecting the ventilation and function of the sinus cavity; It is effective in the treatment of nasal polyps by removing the inflammatory

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Key Messages:

↑What is "already known" in this topic:

Polyp recurrence after endoscopic sinus surgery is common, particularly in the frontal recess. Topical corticosteroids reduce postoperative inflammation, but sprays and irrigations reach the frontal sinus poorly.

→What this article adds:

Intraoperative betamethasone ophthalmic ointment placed directly in the frontal sinus improved endoscopic polyp, inflammation, and secretion findings and reduced CT-measured soft tissue opacity at 3 months. This simple adjunct to frontal sinus surgery merits confirmation in larger trials.

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tissues of the sinus (2).

The treatment of nasal and sinus polyp recurrence is more difficult, and despite various treatments, a percentage of patients experience nasal polyp recurrence. In various sources, the percentage of recurrence up to 31% is also mentioned; the real etiology of which is unclear, and several mechanisms are mentioned regarding the occurrence and recurrence of nasal polyps, which can be prevented by removing them from occurrence or recurrence (1). The current medical treatment options are designed to treat the causative agent and reduce the subsequent inflammatory reaction, or both. Among the treatments used to help treat chronic sinusitis with nasal polyps are oral antibiotics (for bacterial and fungal agents), topical and oral corticosteroids (with an effect on 5-IL and eosinophil cationic inflammatory protein), and washing with saline. Physical removal of inflammatory substances and mucous secretions (and leukotriene antagonist agents). In the frontal sinuses, involved and with polyps, lavage with saline and other local treatments do not pass through the Ostium without surgery (3, 4). CT scan to evaluate rhinosinusitis and help diagnose and choose the type of treatment is widely used (2, 5). The system that is most used in CT evaluation in CRS is the Lund-Mackay method (6).

Patients with chronic sinusitis are at risk of other diseases such as chronic heart failure, diabetes, and chronic back pain. The high prevalence of this disease and its negative effects on people's quality of life and the high costs that its treatment imposes on the health system make the control of this disease very important. One of the basic treatments in chronic sinusitis is the use of topical steroids, which can be used for long-term control of symptoms and increasing the effect of surgery (7). Due to the side effects of systemic corticosteroids, these corticosteroids should not be used as the first line of treatment. In the studies, the use of intranasal steroid irrigation with ophthalmic betamethasone is completely safe and has no effect on the serum cortisol level, and its effect on the 24-hour urine cortisol level is also negligible (7). Since the front ethmoidal recess, with a diameter of 3.95 mm, is the first part of the mucosa that is prone to the recurrence of polyposis, scarring, and stenosis, it is necessary to perform a procedure to prevent the recurrence of polyps in this anatomical location (3, 4).

Treatment with topical corticosteroids in non-surgical sinuses has about 2% mucosal absorption, and nasal sprays before surgery have the least effect. Topical corticosteroids that are used intra-nasally improve the patient's symptoms by reducing the number of eosinophils and reducing their activity, and indirectly by reducing the secretion of chemotactic cytokines. This category of medicine is safe and well tolerated due to its locality and minimal systemic effects over time, and it has had significant effects in studies compared to the placebo sample. According to the studies, the use of only saline for washing has a positive effect. in reducing the symptoms of sinusitis (7).

Considering that chronic sinusitis has a high prevalence and negative effects on the quality of life, and the effect of corticosteroids on reducing symptoms and the possibility of recurrence after surgery has been proven, and because the first place where polyps recur after surgery is the frontal recess, Therefore, in this study, we try to use endoscopic sinus surgery in patients with polypoid frontal sinuses and the use of betamethasone ophthalmic ointment in the frontal sinus to reduce the possibility of polyp recurrence after surgery.

Methods

After obtaining ethical approval, 30 patients with bilateral polypoid frontal sinuses with almost the same volume were selected according to the initial CT scan (8). Primary endoscopy was not helpful due to the closure of the ostium before surgery. The surgical method and its extent in both frontal sinuses, the type of involvement, and the degree of polyposis of both sinuses were similar before surgery. Inclusion criteria were frontal sinuses similar in size in each patient, lack of sensitivity to corticosteroids, and polyposis of both sinuses. The exclusion criteria were sensitivity to corticosteroids, previous surgeries Draf 2b, Draf 3, frontal septal cell, trephination, or any other external intervention in the frontal sinus. Of the PNSCT patients, three different cuts were performed before surgery, and then the patient underwent surgery in all control sinuses, and surgical intervention was performed as Draf 2a.

In this surgical method, only agger cells and frontal recess cells are removed. The volume of each frontal sinus according to studies is calculated to be 4.71 cm3 maximum in women and 4.13 cm3 in men (9, 10), and an ophthalmic betamethasone ointment contains 3 mg of corticosteroid , and according to previous studies, this amount of corticosteroid through the sinus mucosa is likely has low blood absorption (7), and even if there is a possibility of blood absorption, the safety of this amount of corticosteroid can be confirmed by comparing this amount of corticosteroid with a vial of betamethasone LA, which contains about 4 mg of corticosteroid. Finally, the maximum dose of corticosteroid in the frontal sinus will be about 3 mg, which is less than one vial of betamethasone LA.

At the end of the surgery, betamethasone ointment was sterilely injected into the affected sinus using frontal suction. All patients received budesonide coronet spray every 12 hours and washing serum in the post op treatment. They did not receive oral corticosteroids after the operation. Patients were visited twice after surgery. One time, 1.5 months after surgery, it was evaluated by endoscopic examination of the nose in the clinic and evaluation of the PID criteria. Endoscopic findings were measured according to PID criteria or the Modified Lund-Kennedy endoscopy score (11, 12) and secretion, inflammation, and polyp criteria. The next appointment was the third month after the surgery, when they again underwent endoscopic examination of the nose and CT scan. By comparing the CT scan of the third month after the surgery and the CT scan before the surgery, the STDR standard was calculated for each patient and the frontal sinuses before and after the operation (13, 14). The STDR (SOFT TISSUE DENSITY RATIO) criterion was evaluated by evaluating the patient's CT scan through the PACS system. For this purpose, first, the volume of the bone walls of the right and left frontal sinuses in each patient is obtained through the

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CT scan available in the PACS system and 3D reconstruction, and then the volume of the inflammatory opacity is calculated in the same way. Based on pre- and post-operative CT scans, STDR criteria were obtained using materialize software and after 3D reconstruction and calculation of intra-sinus volume and opacity. The findings from the clinical condition and CT scan will be collected and finally calculated with statistical software.

Setting

The trial is performed in 2 teaching hospitals (Rasool Akram Hospital, Tehran; Firoozgar Hospital, Tehran) in Iran. It is important to note that all patients were treated and underwent surgery by a single surgical team, consisting of surgeons working at both of the aforementioned hospitals.

Study design

A randomized clinical trial design, incorporating blinded postoperative care and outcome assessment, was conducted on 30 patients (aged 13 years and older) diagnosed with bilateral CRSwNP. These patients were selected by a single ENT surgical team as candidates for primary or revision ESS (1). The purpose of the study was to evaluate the impact of betamethasone ophthalmic ointment in reducing the recurrence of polyposis following frontal sinus surgery. The participants were randomly allocated to receive the ophthalmic ointment in one frontal sinus, while the contralateral side served as the control (3).

Exclusion criteria include previous surgery of the frontal sinus (Draf III, Denker surgery, medial maxillectomy, trephination, and any external approaches) and Allergy to corticosteroids. Furthermore, potential participants are not allowed to use any systemic corticosteroids in the post op period. The study protocol was approved by the Iranian Registry of Clinical Trials (IRCT20220510054810N1). Moreover, this research was performed in compliance with the Helsinki Declaration and was approved by the local ethics committee (IR.IUMS.FMD.REC.1400.037).

Specifications of the data collection tool and how to collect it

The data collection tool related to demographic information will be a checklist.

How to calculate the sample size?

For the sample size calculation in this study, the formula for sample size estimation in paired studies was applied. The significance level was set at 0.05, the test power was set to 80%, the standard deviation of paired differences was assumed to be 0.05, and the expected effect size was 0.80. These parameters were derived from the results of our pilot study, which included 5 patients. Based on this information and the relevant formulas, the required sample size was determined to be 30 participants.

Data analysis method

The data were analyzed using SPSS version 24 software. Central and dispersion indices will be used to describe quantitative variables. The description of qualitative variables will be done using frequency, percentage, tables, and graphs. In this study, the Generalized Estimating Equation (GEE) model was exclusively used to analyze changes in the Soft Tissue Density Ratio (STDR) over time and to compare it between the intervention and control groups. This method effectively assessed the impact of time, group, and their interaction on STDR.

- ***Randomization and Blinding:*** Since our study is a paired design, we utilized intra-patient randomization for the allocation of treatments. In this design, each patient received two different treatments: one as the intervention and the other as the control. We randomly assigned treatments to both sides of the patient's body (one sinus receiving the intervention and the other the control) using a randomization method. The process was fully randomized, and the goal of this design was to control for individual differences in response to the treatments. To randomize the sinuses, we used a dice roll method, where if the roll resulted in an odd number, the right sinus would receive the intervention, while if the roll resulted in an even number, the left sinus would be assigned to the control group. Furthermore, patients were unaware of which sinus received the intervention during surgery. The individual who recorded the outcomes and performed the data analysis was also blinded to which sinus received the intervention. Therefore, this study was conducted in a double-blind manner.

Primary, secondary, and safety outcomes:

- *Primary outcome:* The primary outcome was the reduction in the recurrence of polyposis, assessed through endoscopic criteria at 1.5 and 3 months post-surgery. Additionally, the soft tissue density ratio (STDR) was evaluated via CT scans before and 3 months after surgery to objectively quantify the reduction in opacity.
- *Secondary outcome:* Secondary outcomes included improvements in inflammation and discharge, as assessed endoscopically at 1.5 and 3 months' post-surgery. These outcomes provided further insights into the therapeutic efficacy of betamethasone ophthalmic ointment in reducing postoperative complications.
- *Safety outcome:* Safety outcomes focused on assessing adverse events related to the use of betamethasone ointment, including local reactions (e.g., irritation or discomfort) and systemic effects, such as changes in cortisol levels or other systemic corticosteroid-related side effects.

Results

Considering that the frontal sinuses do not have a regular geometric shape and their shape is unique in different patients, in order to calculate the STDR index, there was a need to create three-dimensional images of the frontal sinuses and the opacity inside the sinus and then calculate their volume. For this purpose, version 21.0 of Materialize software was used. This software is a powerful tool for displaying 3D medical images, calculating their volume,

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and performing various analyses. In this study, to calculate the volume of the frontal sinuses using Materialize software, for each patient individually, based on the CT scan before the surgery, three-dimensional shapes of the right and left frontal sinuses were created separately. Then, the volume of each of them was calculated using the tools available in this software. Using the obtained results, the STDR index was obtained for the control sinus and the intervention sinus. In the case of post-surgery CT scans, the STDR index was calculated for each patient with the same method for the control and intervention sessions. In Figures 1 to 4, the axial, coronal, and sagittal sections of the patient's CT scan and the three-dimensional image created by the software are shown.

Figures 5 and 6 show the three-dimensional shape of the patient's right frontal sinus and left frontal sinus, respectively.

To calculate the volume of opacity inside the sinus, like the steps for calculating the total volume of the sinus, using the software, first the three-dimensional shape of the opacity inside the sinus was created, and then its volume was calculated using the software tools. Finally, by using the calculated volumes of the total sinus and the calculated volume of opacity, the STDR index was obtained. Figure 7, a sample of the three-dimensional image of opacity, and Figure 8 show the calculation image of the volume of opacity inside the right frontal sinus.

The demographic and clinical characteristics of the study population demonstrate a diverse sample with a mean age of 38.27 years, ranging from 13 to 67 years. The gender distribution was relatively balanced, with 53% male and 47% female participants. A significant proportion of the cohort had underlying respiratory conditions, with 40% diagnosed with asthma and 30% reporting a history of allergies. Additionally, a notable 67% of the participants tested positive for Samter's triad, indicating a high prevalence of aspirin-exacerbated respiratory disease within the study group. Regarding surgical history, the majority of patients (67%) were undergoing their first sinus surgery, while 23% had a history of a second surgery, and 10% were undergoing their third. At baseline, 91.4% of the patients exhibited signs of sinonasal tissue disease recurrence (STDR), reflecting a high burden of chronic and recurrent disease among the enrolled individuals (Table 1).

The analysis of the Polyp variable revealed statistically significant improvements in both the control and intervention groups at 1.5 and 3 months (all *P*-values < 0.05). In the control group, the proportion of patients with no polyps increased from 50% at 3 months to 70% at 1.5 months, while those with mild polyps decreased from 43% to 30%. In the intervention group, a more pronounced improvement was observed, with 63% showing no polyps at 3 months and 93% at 1.5 months. The absence of moderate polyps (grade 2) in the intervention group at both time points further underscores the treatment's efficacy. These findings suggest that while spontaneous improvement occurred in the control group, the intervention had a superior and more rapid effect on reducing polyp formation (Table 2).

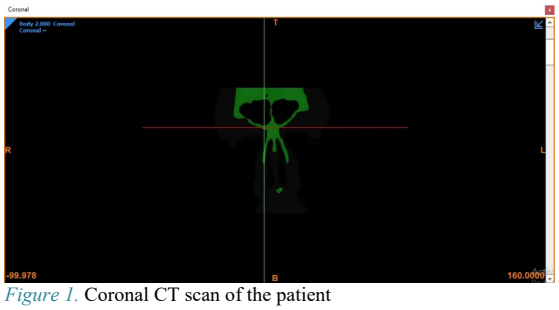


Figure 1. Coronal CT scan of the patient

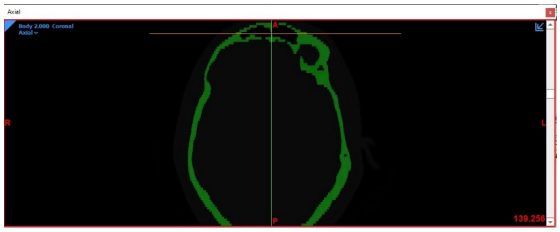


Figure 2. CT-scan axial cut of the patient

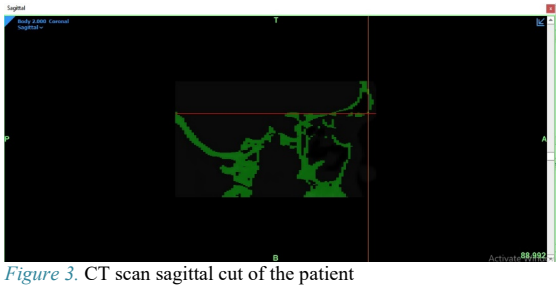


Figure 3. CT scan sagittal cut of the patient

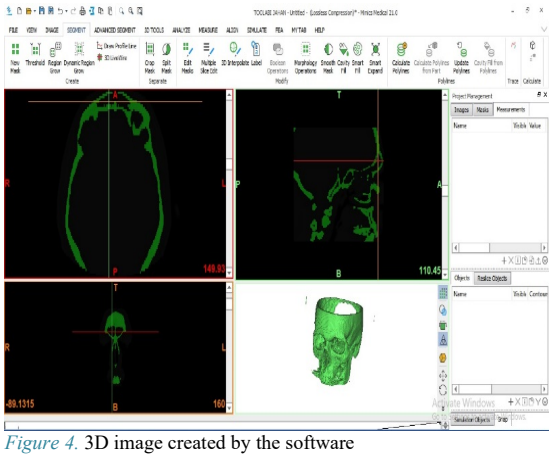


Figure 4. 3D image created by the software

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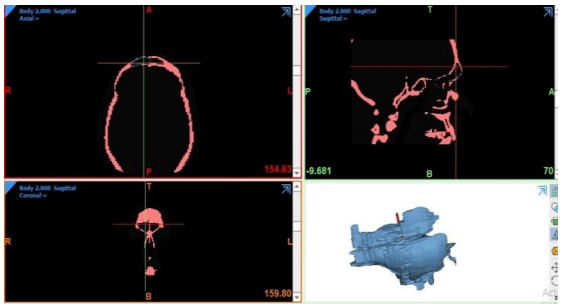


Figure 5. 3D image of the patient's right frontal sinus

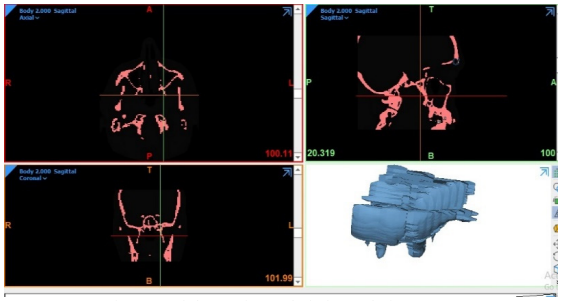


Figure 6. 3D image of the patient's left frontal sinus

Regarding the Inflammation variable, a notable reduction in inflammatory response was observed across both groups, with all P-values indicating statistical significance ($P < 0.05$). In the control group, 30% of participants were inflammation-free at 3 months, increasing slightly from 20% at 1.5 months. The intervention group, however, exhibited a more substantial reduction in inflammation, with 67% and 60% of patients showing no inflammation at 3 and 1.5 months, respectively. These results indicate that the anti-inflammatory effects of the intervention were both faster and more pronounced than those observed in the control group, emphasizing the therapeutic potential of the applied treatment in minimizing mucosal inflammation (Table 2).

The findings for Secretion further support the effectiveness of the intervention. In the control group, only 20% and 17% of patients were free of nasal secretion at 3 and 1.5 months, respectively, suggesting limited spontaneous improvement. In contrast, the intervention group showed a substantial and sustained reduction, with 63% of patients exhibiting no secretion at both time points. The statistical significance of all comparisons ($P < 0.05$) confirms that

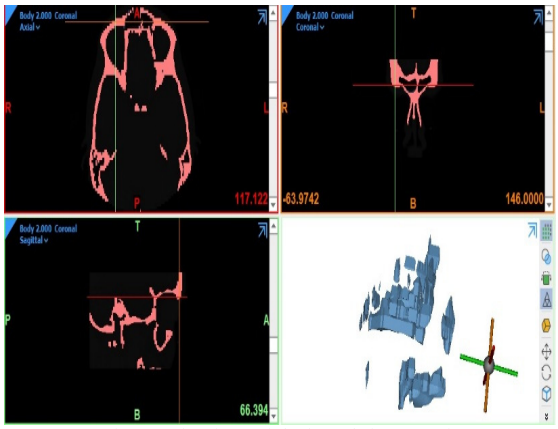


Figure 7. 3D image of patient's right frontal sinus opacity

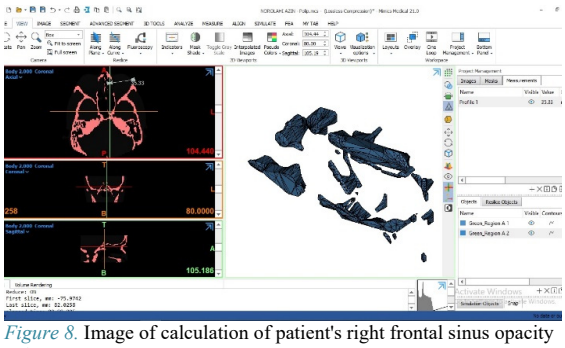


Figure 8. Image of calculation of patient's right frontal sinus opacity volume

these changes were not due to chance. These results strongly support the hypothesis that the intervention considerably reduced mucosal secretion and may contribute to improved clinical outcomes in patients suffering from nasal or sinus-related conditions (Table 2).

In Figures 9 and 10, the STDR criteria of people before surgery are shown for the intervention sinus and control sinus, respectively. As it is clear in these figures, in both intervention and control sinuses, most people have an STDR index above 90%. In terms of statistical analysis, the P-value in the control group is equal to 0.043, and in the intervention group it is equal to 0.045 and is statistically significant.

In Figures 11 and 12, the STDR criterion is shown for intervention and control sinuses after surgery, respectively. Based on the figures shown, the STDR criterion in the sinuses of the intervention group is lower compared to the

Table 1. Baseline characteristics

Characteristic	Value	Number
Mean Age (years)	38.27	--
Age Range (years)	13-67	--
Male	53.3%	16
Female	46.7%	14
Asthma	40%	12
Allergy	30%	9
Positive Samter's Triad	66.7%	20
Number of First Surgeries	66.7%	20
Number of Second Surgeries	23.3%	7
Number of Third Surgeries	10%	3
Baseline STDR	91.4%	--

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Table 2. Comparison of Polyp, Inflammation, and Secretion Percentages in Control and Intervention Groups at 1.5 and 3 Months Post-Surgery

Variable	Time Point	Group	None (%)	Mild (%)	Moderate (%)	Estimated Coefficient (β)	*P*-value
Polyp	3 months	Control	50%	43%	7%	0.32	0.043
		Intervention	63%	37%	0%	-0.05	0.045
	1.5 months	Control	70%	30%	0%	0.45	0.038
		Intervention	93%	7%	0%	-0.10	0.032
Inflammation	3 months	Control	30%	70%	0%	0.52	0.045
		Intervention	67%	33%	0%	-0.08	0.035
	1.5 months	Control	20%	80%	0%	0.56	0.034
		Intervention	60%	40%	0%	-0.12	0.029
Secretion	3 months	Control	20%	80%	0%	0.48	0.038
		Intervention	63%	37%	0%	-0.03	0.034
	1.5 months	Control	17%	83%	0%	0.58	0.032
		Intervention	63%	37%	0%	-0.07	0.027

control sinuses, which shows the effect of using betamethasone ointment. Also, based on the statistical analysis, the value of *P*-value in the control group is 0.0334, and in the intervention group is 0.0443 both less than 0.05 and significant. For a better comparison of the results, Figure 13 shows the STDR index of the intervention and control sinuses after surgery. As shown in this figure, the STDR index of the intervention sinus is lower compared to the control sinus in all subjects, which indicates the use of betamethasone ointment and its anti-inflammatory effects. However, the percentage difference of this index is not the same in all people, and it shows more improvement in some people.

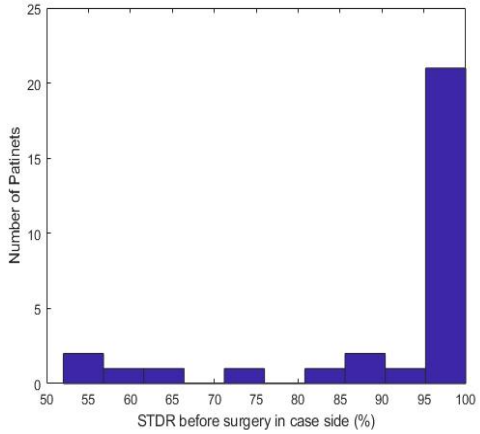


Figure 9. Intervention sinus STDR criteria before surgery

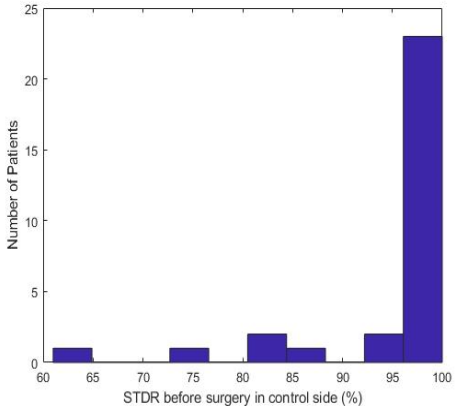


Figure 10. STDR measure of control sinus before surgery

Based on the results obtained from the GEE model, soft tissue density ratio (STDR) significantly decreased after surgery ($P < 0.001$), indicating a strong temporal effect of the surgical procedure on reducing this parameter in both groups. While no significant difference was observed between the intervention and control groups at the preoperative stage ($P = 0.141$), the interaction effect between time and group revealed that the reduction in STDR was significantly greater in the intervention group compared to the control group ($P < 0.001$) (Table 3).

Discussion

In the study conducted by Ameet Singh and colleagues in 2018 (4), which was prospective, 160 patients were selected, all of whom had involvement of both frontal sinuses according to CT scan. A type of surgical procedure was performed for both frontal sinuses. In each person, one FSO (Frontal Sinus Ostia) was selected for intervention, and an implant containing steroids was placed in it, and the opposite side was selected as a control. Patients were evaluated within 90 days. According to the results, it was found that the side with the implant reduced the need for intervention after surgery by 46.8% and the need for re-surgery by 51.2%, and oral steroids were used 37.2% less. On the 90th day after surgery, a statistically significant reduction in the need for post-surgery interventions is reported. The degree of obstruction, stenosis, and inflammatory criteria based on endoscopic evaluation are reduced, and the estimated diameter in FSO is increased. According to this study, the use of steroid-absorbable implants improves the results of frontal sinus surgery within 90 days. In our study, as in the above study, the effect of topical steroid on reducing the recurrence of polyposis in the frontal sinuses was investigated, and the endoscopic criteria showed improvement in the intervention side compared to the control side. In this study, the evaluation criteria for all indicators were objective. In the current study, based on the frequency analysis of the age of people, the average age was 38.27 years, and the highest frequency was between 25 and 40 years old, and most of the patients were 25 years old.

Among the studied subjects, the youngest age was 13, and the oldest was 67 years. Also, in terms of age, 53% of people were male and 47% were female. The analysis of the data on people suffering from asthma and allergies showed that 40% of people have asthma and 30% of peo-

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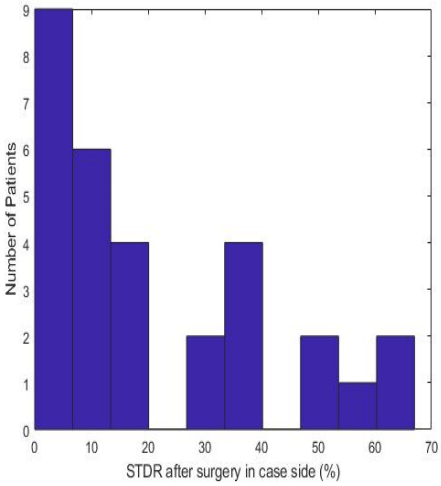


Figure 11. Intervention sinus STDR criterion after surgery

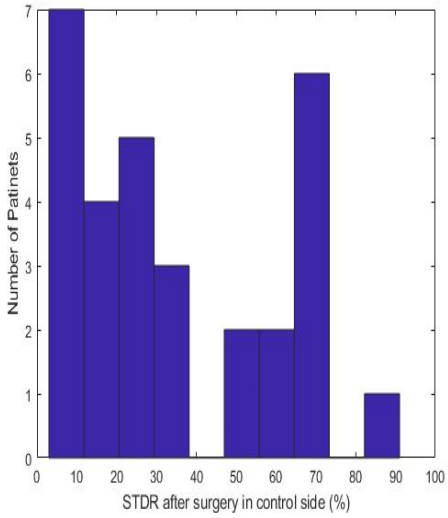


Figure 12. STDR measure of control sinus after surgery

ple have allergies. In terms of frequency of surgery, the relevant frequency analysis shows that 67% of patients underwent surgery for the first time, 23% for the second time, and 10% of patients for the third time. The selection of intervention and control sinuses was based on the Random Number Generation Sampling method, according to which, in the left frontal sinus, 63% were interventions and 37% were controls, and in the right frontal sinus, 37% were interventions and 67% were controls. In a part of the study, subjects with Samter's triad positive who had asthma, allergies to NSAIDs, and polyps were compared with other study subjects in terms of endoscopic criteria and STDR index after surgery. Based on the results, the average percentage of endoscopic criteria in intervention group patients who received betamethasone ophthalmic ointment, both at 1.5 months after the operation and at 3 months after the operation, compared to the control group, showed improvement in all three points. The analysis of

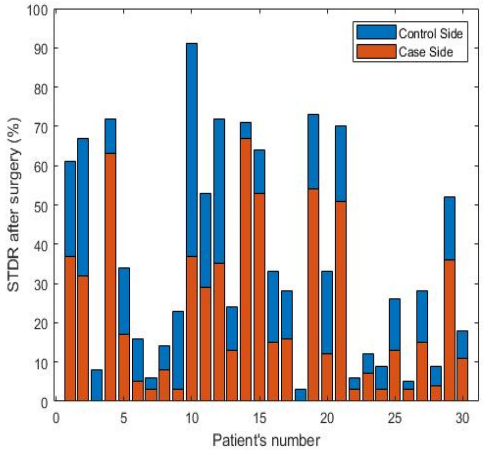


Figure 13. Comparison of the STDR criteria of intervention and control sinuses after surgery

Table 3. GEE Model Results for Comparing STDR Before and After Surgery in Intervention and Control Groups

Variable	Estimated Coefficient (β)	*P*-value
Intercept	91.4	< 0.001
Time (Post-Surgery)	-70.2	< 0.001
Group (Intervention)	-2.5	0.141
Time × Group Interaction	-14.5	< 0.001

the obtained results shows that the use of betamethasone ointment shows a higher percentage of recovery in all endoscopic criteria at 1.5 months and 3 months after surgery in the intervention group. Also, comparing the results of endoscopic indicators for people with positive Samter's Triad with all the people in the group, it states that, like other patients, according to the results of being outside this group, there has been an improvement in the intervention side of endoscopic criteria. Based on clinical examinations and statistical results, the effects of betamethasone eye ointment in the first 1.5 months after surgery compared to 3 months after surgery have been greater in reducing inflammation, polyps, and secretions. The results of this study show that using betamethasone ointment had a positive effect in reducing all endoscopic indicators for both time periods of 1.5 months and 3 months after surgery. Also, in the post-surgery CT scan, there was a decrease in opacity in the sinus where betamethasone ointment was used compared to the control side. Due to the existence of different backgrounds in people, whether or not they have asthma or allergy to NSAIDS, as well as the frequency of surgery, the percentage of recovery varies for different people, but the percentage of recovery is different in all people.

Conclusion

In this study, the unique percentage of STDR for all patients and the average percentage of STDR before and after surgery were calculated for all people, according to which it can be stated that in the intervention group that received betamethasone ointment, the percentage of STDR after surgery compared to the control group that did

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not receive betamethasone ointment, it is less and this indicates the effectiveness of betamethasone ointment in reducing the recurrence of polyposis after surgery. Also, the average percentage of STDR before and after surgery was assessed as positive for people with Samter's Triad. Examining the results shows that the use of betamethasone ointment in reducing STDR after surgery has been effective for this group of patients as well as all the participants in this study.

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Conflict of Interests

The authors declare that they have no competing interests.

Authors' Contributions

Zeinab Emamgholizadeh: Conceptualization, Data curation, Investigation, Writing – original draft, Writing – review & editing.

Shahin Rajaeih, Hesam Jahandideh, and Saleh Mohebbi: Supervision, Methodology, Validation, Writing – review & editing, Project administration.

Ethical Considerations

This study was approved by the local ethics committee of Iran University of Medical Sciences (IR.IUMS.FMD.REC.1400.037). The study protocol was also registered in the Iranian Registry of Clinical Trials (IRCT20220510054810N1).

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Data Availability

The datasets used and/or analysed during the current study are available upon reasonable request.

AI Use Statement

No artificial intelligence (AI) was used in the design, analysis, and interpretation of this manuscript.

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