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Comparative Study between Topical Verapamil and Topical Corticosteroids in Treatment of Chronic Rhinosinusitis with Sinonasal Polyposis

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Abstract

Background: One of the most frequent chronic conditions in adults is chronic rhinosinusitis (CRS) either with nasal polyps (CRSwNP) or without nasal polys (CRSsNP). Verapamil is a calcium channel blocker (CCB) that could be used as an immunomodulator to relieve hypersensitivity disorders by inhibiting P-glycoprotein (p-gp) and reducing inflammation.

Aim of Study: The aim of this research is to compare the efficacy of topical verapamil versus topical corticosteroids in the management of chronic rhinosinusitis with nasal polyps.

Patients and Methods: A prospective study was conducted on 60 patients with (CRSwNP) presenting to ENT clinic in Al-Azhar University Hospitals between June 2021 and April 2022. These patients were divided into two groups: Group A, which received topical corticosteroid (Beclomethasone Dipropionate Monohydrate) 2 puffs in each nostril twice daily for 3 months and group B, which received topical verapamil 2 puffs in each nostril twice daily for the same duration.

Results: Groups A and B had mean ages of 39.03 ±6.10 and 38.07±5.78 years respectively. Regarding gender, 76.7% were males and 23.3% females in group A while in group B, 80% were males and 20% females. The mean Total nasal symptom score in group A before and after management was 4.55±0.42 and 1.17±0.14 respectively while the mean Total nasal symptom score in group B before and after management was 4.01±0.22 and 1.29±0.09 respectively. It was noticed that there was statistically significant improvement in Total nasal symptom score after treatment.

The mean total nasal polyp score in group A before and after management was 4.36±0.42 and 2.89±0.45 respectively while the mean polyp score in group B before and after management was 4.29±0.43 and 2.81 ±0.19 respectively. It was noticed that there had been a statistically significant decrease in total nasal polyp score.

Conclusions: The study found that both treatments (topical corticosteroid and topical verapamil) significantly improved total nasal symptom score (TNSS) and total nasal polyp score (TNPS) with no difference between them.

There is improvement in patients of both groups (topical corticosteroid and topical Verapamil) in nasal obstruction, reduction in size of polyps, re-establishing nasal air way and nasal breathing with no marked side effects as these drugs used in atopical form and can be used as pre FESS preparation.

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Key Words: *Topical verapamil – Topical corticosteroid – Chronic rhinosinusitis – Sinonasal polyposis.*

Introduction

CRS is one of the most frequent chronic disorders in adults, impacting around 10% of the population. It is described as a chronic inflammation of the nose and paranasal sinuses that lasts longer than 12 weeks and is defined by two or more of the following symptoms: Nasal discharge, congestion, or obstruction; facial pain or pressure; and loss or reduction of smell **[1]**.

Depending on endoscopic or computed tomography (CT) results, CRS is split into two primary subgroups: CRS with nasal polyps (CRSwNP) and CRS without nasal polyps (CRSsNP). Nasal polyps are sinonasal tissue inflammation outgrowths. They're normally benign, although they might induce severe nasal blockage and a decrease or loss of smell **[2]**.

Nasal polyps are benign in this condition and normally form bilaterally in the sinonasal cavity. Only about 25% to 30% of all CRS patients have CRSwNP.

Because CRSwNP is linked to severe morbidity and poor quality of life, identifying, evaluating, and treating this disease is clinically significant. CRSwNP patients' medical therapy choices are still restricted and used as preparation prior to functional endoscopic sinus surgery (FESS) **[3]**.

As per the most current United States (US) recommendations, topical corticosteroids as well as nasal saline irrigations are both suggested as first-line treatments for afflicted patients before FES Soperation. Intranasal corticosteroids and verapamil may decrease the size of nasal polyps, alleviate sinonasal symptoms, and enhance patients' quality of life. Oral corticosteroids may also decrease the size of polyps and alleviate symptoms, although they ought to be used with caution due to their severe systemic side effects [4].

Verapamil is a CCB that attaches to the alpha subunit of voltage-dependent calcium channels of the L type, preventing calcium ions from entering the host cell. Although verapamil is most commonly utilized to relax cardiac and smooth muscle cells, new research suggests that it could potentially have immunomodulatory properties in T cells thus inhibiting p-gp and improving hypersensitivity and inflammation [5].

The goal of this research is to compare topical corticosteroids versus topical verapamil in treating (CRSwNP).

Patients and Methods

A prospective study was conducted on 60 patients diagnosed CRSwNP presented to ENT clinic in Al-Azhar University Hospitals between June 2021 and April 2022 with (CRSwNP). These patients were divided into two groups: Group A received topical Beclomethasone Dipropionate Monohydrate (2 puffs in each nostril twice a day for 3 months), and group B received topical verapamil (2 puffs in each nostril twice a day for 3 months) which was prepared by adding one ampule of verapamil over a sterilized water in form of nasal spray. This is implicated after the approval of ethical committee of the hospitals.

Inclusion criteria: Patients diagnosed with (CRSwNP), recurrent nasal polyps, aged from 18 to 60 years of both sexes. Exclusion criteria included allergic fungal sinusitis, chronic rhinosinusitis without nasal polyps, cardiac failure, hepatic failure, renal illness, muscular dystrophy, pregnant or nursing women, hypertrophic cardiomyopathy, systemic steroid dependency, any atrial or ventricular arrhythmia, resting cardiac rate of less than 60 beats per minute, baseline SBP of less than 1 10mmHg, baseline DBP fewer than 70mmHg, a baseline mean arterial pressure less than 60mmHg, a PR interval less than 0.12 secs, and those taking aspirin, beta-blockers, cimetidine, disopyramide, cyclosporin, clarithromycin, diuretics, digoxin, erythromycin, and HIV Protease Inhibitors (Nelfinavir, Indinavir, Ritonavir).

All patients were submitted to the following: Detailed general and ENT history taking, ENT examination mainly endoscopic nasal examination, full cardiac consultation with ECG and echocardiography and written concent of using these drugs. All patients have been evaluated before starting the therapy. The total nasal symptom score (TNSS) was used to assess patients' symptoms, while the total nasal polyp score (TNPS) is used to assess endoscopic examinations. The clinical disease intensity was assessed using the TNSS, a subjective disease-severity grading approach. A questionnaire was used to assess patients' symptoms, which included obstructed noses, runny noses, nasal itching, sneezing, hyposmia, and sinonasal pain. On a seven-point scale, every symptom has been graded: 0 = No symptoms; 1-2 = Mild symptoms (consistent, easily bearable symptoms); 3-4 = Moderate symptoms (difficult to tolerate symptoms that may interfere with daily activities, sleeping, or both); and 5-6 = Severe symptoms (symptoms that are so severe that the individual is unable to work for the majority of the time). The TNSS, which ranges from 0 to 36, was calculated by adding the individual nasal symptom scores.

Total Nasal Polyp Score (TNPS) according to Meltzer clinical scoring [6]: The size of nasal polyps has been evaluated via nasal endoscope and graded on a scale of 0 to 3 as follows: 0 = There are no polyps; 1 = Mild polyposis (little polyps spreading downhill from middle meatus although not under the upper edge of the inferior turbinate, creating only minor blockage); 2 = Moderate polyposis (medium-sized polyps spreading downhill from middle meatus and reaching between the upper and lower edges of the inferior turbinate, creating significant blockage); and 3 = Severe polyposis (huge polyps that extend downward from middle meatus and reach under the lower edge of the inferior turbinate, obstructing completely or nearly completely). The TNPS was calculated by adding the polyp scores from both sides according to Meltzer clinical scoring.

Patients were followed three months after medication. The follow-up visit included patient's TNSS and TNPS.

Statistical analysis:

All statistical analyses have been carried out employing either the Stat View 5.0 software package or the SAS program for Windows, version 9.2 (SAS Institute, Cary, NC). The mean ± SD is presented for continuous variables. The Student's *t*-test has been employed to compare continuous variables, whereas the X^2 test, or Fisher's exact

test, has been employed to compare discrete variables. At a p-value of <0.05, differences have been regarded as significant.

Results

This study was conducted on 60 patients with chronic rhinosinusitis with nasal polyps. Thirteen (21.7%) females and 47 (78.3%) males were eligible and involved in the study. 38.55±5.91 years was the mean age.

Table (1): Demographic characteristics among the studied groups.

	Group (A) (n=30)		Group (B) (n=30)		Test value	p-value
	N	%	N	%		
Gender:	23	76.7	24	80.0	X^2=	0.754
Male	7	23.3	6	20.0	0.098	
Female						
Age (years):						
Mean ± SD	39.03±6.10		38.07±5.78		ZMWU=	0.701
Median	38.0		36.0		0.384	
Range	34.0-50.0		30.0-50.0			

p-value <0.05 is significant.
p-value <0.01 is highly significant.
SD: Standard deviation.
ZMWU = Mann-Whitney U test.
X^2= Chi-Square test.

This table displays the demographic characteristics of the two groups examined. Groups A and B regarding gender, 76.7% were males and 23.3% females in group A while in group B, 80% were males and 20% females respectively regading age the mean ages of group A and B were 39.03 ±6.10 and 38.07±5.78 years respectively.

Table (2): Comparison of the two groups regarding clinical history.

	Group (A) (n=30)		Group (B) (n=30)		Test value	p-value
	N	%	N	%		
Previousendoscopic nasal surgery:						
No	20	66.7	14	46.7	X^2=	0.118
Yes	10	33.3	16	53.3	2.44	
Yes	6	20.0	14	46.7		
Asthma:						
No	18	60.0	14	46.7	X^2=	0.301
Yes	12	40.0	16	53.3	0.693	
Smoking:						
No	11	36.7	8	26.7	X^2=	0.405
Yes	19	63.3	22	73.3	0.098	
Duration of rhinosinusitis (years):						
Mean ± SD	7.70±1.99		8.0±1.29		ZMWU=	0.316
Median	7.0		8.0		1.002	
Range	5.0-11.0		5.0-10.0			

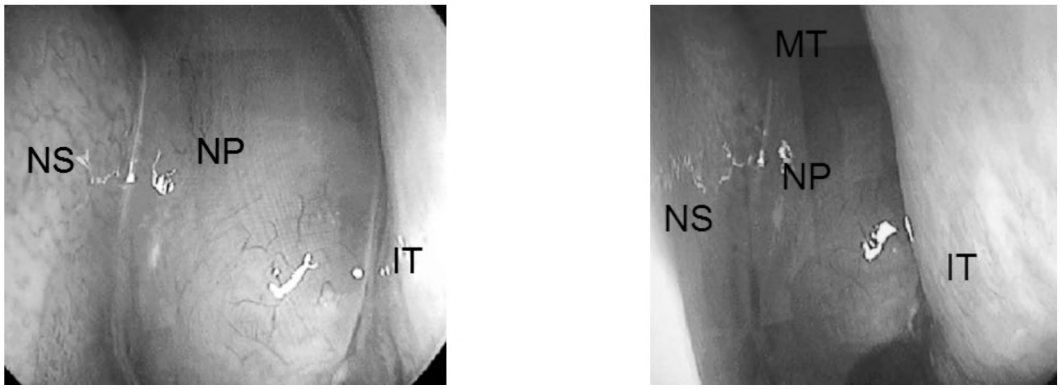
This table shows that 33.3% of cases in group A and 53.3% of cases in group B had previously undergone endoscopic nasal surgery. Asthma was seen in 40% of cases in group A and 53.3% of cases in group B. Cases in groups A and B had a smoking history of 63.3% and 73.3%, respectively. In groups A and B, the mean duration of rhinosinusitis was 7.70±1.99 years and 8.0±1.29 years, respectively. There has been no statistically significant difference among the examined groups regarding previous surgery history (p=0.118), asthma (p=0.103), smoking (p=0.405) and duration of rhinosinusitis (p= 0.316).

Table (3): Comparison of the two groups as regarding total nasal polyp score before and after management.

Total nasal polyp score	Group (A) (n=30)	Group (B) (n=30)	Mann-Whitney U test	
			ZMWU	p-value
Before management:				
Mean ± SD	4.36±0.42	4.29±0.43	1.170	0.242
Median	4.30	4.20		
Range	3.80-4.90	3.70-4.90		
After management:				
Mean ± SD	2.89±0.45	2.81±0.19	1.486	0.236
Median	3.05	2.80		
Range	2.20-3.40	2.20-3.10		
Wilcoxon Signed Ranks Test:				
Z	4.802	4.841		
p-value	<0.001	<0.001		

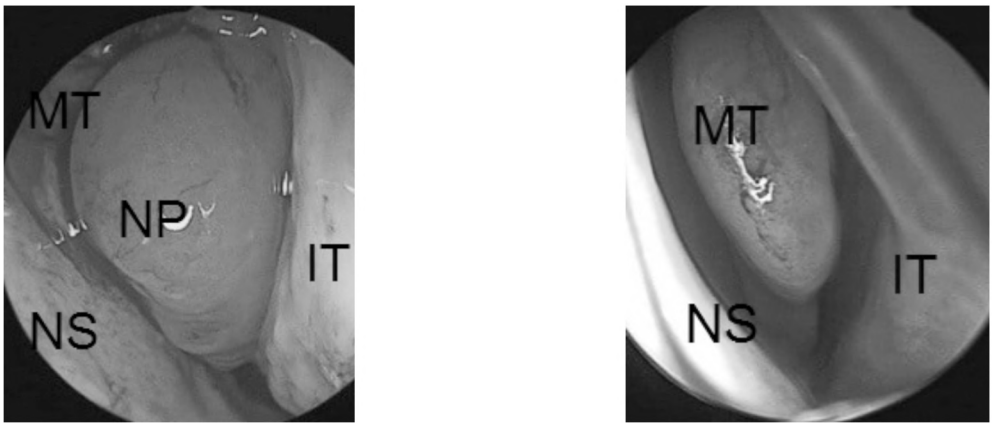
The previous table shows that the mean total nasal polyp score in group A before and after management was 4.36±0.42 and 2.89±0.45 respectively while the mean polyp score in group B before and after management was 4.29±0.43 and 2.81± 0.19 respectively. It was noticed that there had been a statistically significant decrease in polyp score after management compared to before management in both groups A (p<0.001) and B (p<0.001).

The previous table shows that the mean Total nasal symptom score in group A before and after management was 4.55±0.42 and 1.17±0.14 respectively while the mean total nasal symptom score in group B before and after management was 4.01 ± 0.22 and 1.29±0.09 respectively. It was noticed that there was statistically significant improvement in Total nasal symptom score after management compared to before management in both group A (p<0.001) and group B (p<0.001).



(A): Lt nasal cavity. (B): Lt nasal cavity.

Fig. (1): Female pt 37 years old presented with history ofbil nasal obstruction of 3 years duration diagnosed CRSwNP.
Picture (A) TNPS grade 3 before using Beclomethasone Dipropionate Monohydratepicture. (B) TNPS grade 2 after 3 months using BeclomethasoneDipropionate Monohydrate.
NS = Nasal septum. NP = Nasal polyps. IT = Inferior turbinate. MT= Middle turbinate.



(A): Lt nasal cavity. (B): Lt nasal cavity.

Fig. (2): Male pt 43 years old presented with history of bil nasal obstruction of 4 years duration diagnosed CRSwNP.
Picture (A) TNPS grade 3 before using topical verapamil.
Picture (B) TNPS grade 1 after 3 months using after 3 months using topical verapamil.
NS = Nasal septum. NP = Nasal polyps. IT = Inferior turbinate. MT = Middle turbinate.

Table (4): Comparison between the studied groups regarding-Total nasal symptom score before and after management.

Total nasal symptom score	Group (A) (n=30)	Group (B) (n=30)	Mann-Whitney U test	
			ZMWU	*p*-value
Before management:				
Mean ± SD	4.55±0.42	4.01±0.22	3.524	0.047
Median	3.70	3.50		
Range	2.80-4.70	2.80-4.70		
After management:				
Mean ± SD	1.17±0.14	1.29±0.09	3.730	<0.001
Median	1.14	1.30		
Range	1.0-1.40	1.20-1.40		
Wilcoxon Signed Ranks Test:				
Z	4.802	4.843		
p-value	<0.001	<0.001		

Table (5): Comparison between the studied groups regarding adverse effects of both medications.

	Group (A) (n=30)		Group (B) (n=30)		Test value	*p*-value
	N	%	N	%		
Adverse effects:						
Epistaxis	1	3.3	0	0.0	FET	1.00
Crustations	0	0.0	2	6.7	FET	0.492
Dizziness	0	0.0	4	13.3	FET	0.112
Facial pain	2	6.7	5	16.7	FET	0.424
Nasal itching	2	6.7	0	0.0	FET	0.492
Dryness of nose and throat	4	13.3	5	16.7	FET	0.403

This table shows that in group A, 3.3% patients had mild epistaxis, 6.7% patients had facial pain, 6.7% had nasal itching, 13.3% had dryness of nose and throat. In group B, 6.7% patients had crustations, 13.3% patients had dizziness, 16.7% patients had facial pain, 16.7% had dryness of nose and throat.

Discussion

Chronic rhinosinusitis (CRS) is one of the most common chronic disorders in the developed world, affecting 32 million persons (16.3% of the population) in the United States alone [7]. Annual health care costs for CRS are estimated at $6 billion, which is probably an underestimate because of the indirect costs from lost productivity and the effect on general and lower airway health outcomes [7-9]. Chronic rhinosinusitis with nasal polyposis, a distinct pathologic subtype of CRS with an estimated prevalence of 3% to 5%, has a greater burden of symptoms and a higher relapse rate after treatment [10,11]. Despite the high prevalence and significant morbidity associated with CRS with nasal polyposis, evidence to guide practitioners on initiation and maintenance of therapy is limited. Current international guidelines [11] recommend that primary care physicians diagnose CRS with nasal polyposis on the basis of such symptoms as nasal blockage, discharge, facial pain or pressure, and reduction in the sense of smell for more than 12 weeks.

Verapamil represents a calcium channel blocker (CCB) that binds to the alpha subunit of L-type voltage-dependent calcium channels, thereby blocking the influx of calcium ions into the host cell. [12]. Although verapamil is classically used to promote the relaxation of cardiac and smooth muscle cells recent evidence has suggested that it may also function as an immunomodulator in a T cells, Further research has demonstrated that verapamil is capable of both specifically reducing T helper2 (Th2)-associated inflammation in asthma and inhibiting P-glycoprotein (P-gp) in sinonasal epithelial cells [13]. The main aim of this study was to compare topical Verapamil and topical corticosteroids in the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). This study was conducted on 60 patients who are diagnosed chronic rhinosinusitis with nasal polyps (CRSwNP). All patients were divided into 2 groups: Group A included 30 patients received topical corticosteroid (Beclomethasone Dipropionate Monohydrate) 2 puffs in each nostril twice daily for 3 months and group B included 30 patients received topical verapamil 2 puffs in each nostril for the same duration.

Our study showed that the mean total nasal polyp score in group A before and after management was 4.36±0.42 and 2.89±0.45 respectively while the mean total nasal polyp score in group B before and after management was 4.29±0.43 and 2.81± 0.19 respectively. It was noticed that there was statistically significant decrease in total nasal polyp score after management compared to before management in both group A (p<0.001) and group B (p<0.001).

Comparison between the studied groups regarding total nasal symptom score before and after management, showed that the mean Total nasal symptom score in group A before and after management was 4.55±0.42 and 1.17±0.14 respectively while the mean Total nasal symptom score in group B before and after management was 4.01 ±0.22 and 1.29±0.09 respectively. It was noticed that there was statistically significant decrease in Total nasal symptom score after management compared to before management in both group A (p<0.001) and group B (p<0.001).

The current study can be compared with Ali et al., [14] aimed to evaluate the role of intrapolyp steroid injection in the treatment of nasal polyposis and its efficiency, and to compare these results with that of oral and topical nasal spray corticosteroid. The study included 60 patients with CRSwNP were randomly divided according to type of treatment (nasal corticosteroid spray, oral corticosteroid and intranasal injection of corticosteroid) into 3 groups, each consisted of 20 patients. There were 13 males and 7 females in the nasal steroid spray, 11 male and 9 female in the oral steroids group and 10 males and 10 females in the injection group.

The study by Ali et al., [14] reported that nasal polyp score (TNPS) of the three groups were not significantly different before treatment. After treatment, the nasal spray Corticosteroids group were not statically significant while oral corticosteroid groups andinjection groups showed highly statistically significant. The disagreement between the two studies may be due to the differences in sample characteristics and treatment protocol.

However, in disagreement with our results Ali et al., [14] reported that TNSS of the three groups were not significantly different before treatment. After treatment, the nasal spray group were not statically significant while oral corticosteroid groups and injection groups showed highly statistically significant, with no significant difference in the three groups scores at the end of the treatment. The disagreement may be due to the differences in sample characteristics and treatment protocol.

Similarly, Zhou et al., [15] reported thatat the end of treatment, the 4 major symptoms and total nasal symptom score were significantly improved from baseline in groups oralCortico steroids and

nebulization groups (p<0.05). But the nasal spray group were not statically significantly improved in total nasal symptom score.

Furthermore, Miyake et al., **[16]** aimed to assess the efficacy of verapamil for patients with chronic rhinosinusitis with nasal polyps. The study enrolled 18 patients 10 from the verapamil group and 8 from the placebo group.

Furthermore, our results were supported by Miyake et al., **[16]** who reported that the least squares mean (LSM) change between baseline and week 8 Sinonasal Outcome Test (SNOT-22) score was 227.3 (95% CI, 242.56 to 212.05) in the verapamil group and 0.4 (95% CI, 214.85 to 15.66) in the placebo group, resulted in a final LSM difference of 227.7 between groups (95% CI, 249.36 to 26.05; p=.01). Similarly, the final LSM difference in Visual Analogue Score (VAS) between groups was 237.97 (95% CI, 260.01 to 215.93; p=5.001). The LMS demonstrated a significant difference favoring the verapamil group with an absolute mean difference of 25.20 (95% CI, 29.66 to 20.74; p=.02; intraclass correlation coefficient, 0.97). This trend continued through week 8; however, the LSM difference between groups was no longer significant at 21.05 (95% CI, 22.88 to 0.77; p=.25; intraclass correlation coefficient, 0.84).

Furthermore, Miyake et al., **[16]** reported that low-dose verapamil monotherapy is well tolerated by patients with less side effects and lower costs than those reported in previous studies using biologic agents.

Also, Workman et al., **[17]** aimed to determine the safety and tolerability of a topical verapamil HCl irrigation in patients with Chronic rhinosinusitis (CRS). The study enrolled 6 patients with 47.3 ± 10.8 years age, 1 female and 5 males.

He stated that the initial subject tested tolerated the full dose escalation from 10mg to the MAD of 120mg BID. This patient experienced a transient IT event of bradycardia during monitoring at a dose of 80mg but was cleared to proceed per protocol and did not experience any subsequent bradycardia or other IT/DLT at higher doses. At the MTD/MAD of 120mg BID, there was a 0% rate of ITs or DLTs after 1 week of use in all six patients. Similarly, no serious adverse events (SAEs) were seen in any patient. With regard to nasal tolerability, the least satisfactory scores were evident with regard to immediate taste (4.4 ± 1.8; e.g., neither satisfied nor dissatisfied) and aftertaste (3.8 ± 1.3; e.g., somewhat satisfied).

Conclusions:

The study found that both treatments (topical corticosteroid and topical verapamil) significantly improved total nasal symptom score (TNSS) and total nasal polyp score (TNPS) with no difference between them.

There is improvement in patients of both groups (topical corticosteroid and topical Verapamil) in nasal obstruction, reduction in size of polyps, re-establishing nasal air way and nasal breathing with no marked side effects as these drugs used in atopical form and can be used as pre FESS preparation.

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دراسة مقارنة بين فيرابااميل الموضعى والكورتيكوستيرويد الموضعى فى علاج الإلتهاب المزمن للأنف والجيوب الأنفية المصحوب بالزوائد اللحمية بهما

الخلفية العلمية : يعد إلتهاب الجيوب الأنفية المزمن أحد أكثر الأمراض المزمنة شيوعاً عند البالغين وينقسم إلى التهاب جيوب أنفية مصحوب بزوائد لحمية والتهاب جيوب أنفية مصحوب بزوائد لحمية. فيرابااميل عبارة عن غالق لقنوات الكالسيوم يمكن استخدامه كمنظم مناعى للتخفيف من اضطرابات فرط الحساسية وتقليل الالتهابات.

الهدف من البحث : مقارنة فعالية فيرابااميل الموضعى ضد الكورتيكوستيرويدات الموضعية فى علاج التهاب الجيوب الأنفية المزمن مع الزوائد الأنفية.

المرضى وطرق البحث : تم تقديم دراسة استباقية إلى ٦٠ مريضاً من مرضى جيوب أنفية مصحوب بزوائد لحمية قدموا إلى مستشفيات جامعة الأزهر بين يونيو ٢٠٢١ وأبريل ٢٠٢٢. تم تقسيم هؤلاء المرضى إلى مجموعتين المجموعة أ، التى تلقت العلاج الموضعى بالكورتيكوستيرويد (بختان لكل فتحة أنف مرتين. يومياً لمدة ٣ أشهر) والمجموعة ب والتى تلقت العلاج الموضعى بالفيرابااميل ٢ بخه فى كل فتحة أنف لنفس المدة.

النتائج : كان متوسط أعمار المجموعتين A و 39.03±6.10 B و 38.07±5.78 سنة على التوالى. فيما يتعلق بالجنس، كان ٧٦.٧٪ ذكور و ٢٣.٣٪ إناث فى المجموعة أ بينما فى المجموعة ب ٨٠٪ ذكور و ٢٠٪ إناث. كان متوسط مجموع أعراض الأنف فى المجموعة (أ) قبل وبعد العلاج 4.55±0.42 و1.17±0.14 على التوالى بينما كان متوسط مجموعة أعراض الأنف فى المجموعة (ب) قبل وبعد العلاج 40.1±0.22 و1.29±0.09 على التوالى. لوحظ وجود تحسن معتد به إحصائياً فى مجموع أعراض الأنف بعد العلاج. كان متوسط مجموع نقاط السلائل الأنفية فى المجموعة (أ) قبل وبعد العلاج 4.36±0.42 و2.89±0.45 على التوالى بينما كان متوسط درجة الزوائد اللحمية فى المجموعة (ب) قبل وبعد العلاج 4.29±0.43 و2.81±0.19 على التوالى. لوحظ انخفاض معتد به إحصائياً فى مجموع نقاط السلائل الأنفية.

الاستنتاج : وجدت الدراسة أن فى كلا العلاجين الكورتكزستيرويد الموضعى والفيرابااميل الموضعى تحسن بشكل ملحوظ فى مجموع نقاط أعراض الأنف ودرجة السلائل الأنفية الكلية مع عدم وجود فرق بينهما. هناك تحسن فى انسداد الأنف وتقليل حجم الزوائد اللحمية وإعادة فتح مجرى الهواء الأنفى والتنفس الأنفى بدون آثار جانبية ملحوظة حيث تستخدم هذه الأدوية فى شكل موضعى ويمكن استخدامها كإعداد مسبق لمنظار الجيوب الأنفية.