

**Comparative Study between Intrapolyp Corticosteroid Injection and Oral Corticosteroid in Treatment of Allergic Nasal Polyposis**

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**Abstract:**

**Background:** Sino-nasal polyps can be treated medically (with systemic and local steroids) or surgically; but a lot of patients refuse surgical intervention or are contraindicated to use systemic steroids. Intra-polyp steroid injections have recently been utilized to deliver high concentrations of steroid directly into the nasal polyp while simultaneously shielding the patient from the systemic steroid side effects.

**Objectives:** To assess the role and efficacy of intra-polyp injection of steroids in the management of allergic nasal polypi, as well as to compare these findings to those of oral steroid.

**Patients and methods:** Our study involved sixty patients that attended the outpatient clinic of the ENT department at Qena University Hospital who diagnosed with allergic nasal polypi. Their ages ranged from 17 to 63 years. They were randomly divided into 2 groups (oral steroid and intra-polyp steroid injection) according to type of treatment, each consisting of 30 patients.

**Results:** After treatment, both groups showed a statistically significant decrease in the Symptom Score, Polyp Score, and Lund-Mackay score ( $P < 0.001$ ), with a significant difference between them ( $P < 0.001$ ).

**Conclusion:** Intra-polyp injection of steroid appears to be a safe and effective treatment method for Sino- nasal polyposis, with results comparable to systemic corticosteroids.

**Keywords:** Nasal polypi, intra-polyp steroid injection, oral corticosteroids.

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## Introduction

Rhinosinusitis is a common disease worldwide, Chronic Rhinosinusitis is a major health issue affecting (five to twelve percent) of the general population (**Fokkens et al., 2020**). Adults' Chronic rhinosinusitis (with or without nasal polypi) is defined: the presence of two or more symptoms, one of which must be nasal congestion, obstruction, or nasal discharge  $\pm$  facial pressure or pain,  $\pm$  hyposmia or anosmia; for twelve weeks or more (**Fokkens et al., 2020**).

Their etiology is unknown, but they have been linked to allergies, asthma, infection, fungus, and cystic fibrosis. The major issue in the nasal polypi management is the well-known high recurrence rate. Medical therapy is commonly the 1<sup>st</sup> line of management; but many patients may not respond. Non-responders are typically candidates for surgical intervention (**Mahrous et al., 2019**). Treatment options for Sino-nasal polyposis ranged from local and systemic corticosteroids to endoscopic sinus surgery. Even though intranasal steroid spray has wide range of applications, they can sometimes fail to provide cure and may be complicated with perforation of nasal septum (**Zamzam et al., 2020**). The use of a systemic steroid to treat Sino nasal polyposis increases the possibility of systemic side effects. Intra-polyp steroid injection has recently been used to deliver high concentrations of steroid directly into the nasal polyp while simultaneously protecting the patient from systemic steroid side effects (**Ali et al., 2020**).

Intra-polyp steroid injection is an effective treatment option because high

steroid concentrations act locally and directly on the nasal polypi and adjacent nasal mucosa. Furthermore, it has a long duration of action (one to two months) with no systemic side effects, making it an alternative to oral steroids (**Lee et al., 2021**). They are a safe treatment for chronic rhinosinusitis with nasal polyposis, with no risk of visual complications (**Moss et al., 2014**). We aimed to evaluate the safety and efficacy of intra polyp injection of corticosteroid in management of allergic Sino-nasal polyposis, as well as to compare these findings to those of oral steroid.

## Patients and methods

This comparative study involved sixty patients who presented to the Otorhinolaryngology Outpatient Clinic at Qena University Hospital with allergic Sino-nasal polyps. forty (66.7%) of them were males, and twenty (33.3%) of them were females, their ages ranged from 17 to 63 years, with a mean age of 47.45  $\pm$  9.345 (SD) years. This study was performed between February 2022 and November 2022.

This study included all patients who presented with allergic nasal polypi, of all ages and genders, and the excluded patients were:

- Patients with a unilateral polyp, underlying neoplasm, fungal sinusitis, or Antro-choanal polyp.
- Patients with ciliary dyskinesia, cystic fibrosis, hypertelorism, proptosis, glaucoma, or herpes simplex keratitis.
- Any condition makes steroids use contraindicated e.g. (hypertension, Diabetes Mellitus, osteoporosis, pregnancy, congestive heart failure, tuberculosis, peptic ulcer). The patients were randomly allocated according to type of treatment into two groups: Group 1 (intra-polyp corticosteroid injection):

30 patients, they were given intra-polyp corticosteroid injections up to three times a month (1 mL of Dexamethasone injection) each mL contains Dexamethasone sodium phosphate.

Group 2 (oral corticosteroids): 30 patients, thirty patients were given oral prednisolone for one month, beginning with a dosage of one mg per kg per day and gradually reducing the dosage by twenty mg every five days.

#### ***Technique in injection group***

- A 3 ml syringe was used to inject one milliliter of dexamethasone injection.
- Cotton pieces were soaked in xylometazoline and then packed in the nose for 5 minutes, then the cotton was removed.
- One ml of Dexamethasone was shared among the polyps.
- Most of the cases received injections on both sides. The cases were reevaluated every one-month until they finished a series of 3 injections.
- All the participants in this study underwent:

A. History taking includes personal history, the patient's complaint, and duration, as well as a history of aspirin sensitivity or bronchial asthma.

B. Disease severity evaluation: This was performed clinically via Total Nasal Symptoms Score, endoscopically via Total Nasal Polyp Score and radiologically via Lund Mackay Score. TNSS and TNPS of both groups were evaluated before starting the treatment, monthly during the treatment and after the end of treatment, while Lund-Mackay score (LMS) scores were evaluated before and after treatment.

- **TNSS:** is a subjective method for rating disorder severity. It was used to assess the severity of a disease. Patients' manifestations such as: rhinorrhea, nasal obstruction, sneezing, hyposmia, nasal

itching and Sino-nasal pain were assessed using a questionnaire. Each symptom's severity was graded on a seven-point scale: zero = no symptoms; 1–2 = mild symptoms; 3–4 = moderate symptoms; and 5–6 = severe symptoms. The TNSS was calculated by adding the individual nasal symptom scores, which ranged from 0 to 36.

- **TNPS:** polyp size was evaluated using endoscopy and graded on a scale of zero to three: zero = no polypi; one = polyp above the inferior turbinate causing only slight obstruction; two = polyp extended downward to the inferior turbinate; causing severe obstruction; and three = severe polyposis extends much further downward to be below the inferior turbinate, causing total or almost total nasal obstruction. TNPS was computed by adding the polyp scores from both sides.

**Lund-Mackay score:** The Lund-Mackay scoring system was used to evaluate CT images of paranasal sinuses. In this score, the sinuses were divided into 6 groups: frontal, sphenoid, maxillary, anterior and posterior ethmoid sinuses, and osteo-meatal complex. The degree of mucosal sinus inflammation or fluid collection was graded as zero (complete lucency), one (partial opacity), or two (complete opacification). Unilateral Five sinuses from either the left or right side, as well as one ipsilateral osteo-meatal complex, were added to give a unilateral total Lund-Mackay score ranging from zero to twelve, and the score from each side was added to produce a total score ranging from zero to 24. Furthermore, because grading the osteo-meatal complex is difficult, it was scored as 0 (not blocked) or 2 (blocked).

**Follow up:** Results after three months were compared with baseline

measurements and results of injection were compared with those of oral steroid.

The study was approved by the Ethical Committee of Qena Faculty of Medicine and a written informed consent was taken from every patient. Ethical approval code: SVU-MED-ENT030 -1-22-2-330.

### Statistical analysis

All the statistical analyses were carried out using the IBM SPSS version 26. Quantitative measures were expressed as means  $\pm$  standard deviation (SD). TNPS, TNSS, and LMS differences among groups were analyzed with the student *t*-test, while intragroup differences were analyzed with the paired samples *t*-test. One-way repeated measures ANOVA is used to evaluate the intra-injection group

difference. Qualitative variables were expressed as frequencies and percentages and were compared by chi-square test and Cochran's Q test. A value of  $P < 0.05$  was considered statistically significant.

### Results

A total of sixty patients were involved in our study, males were 53.3% and 73.3% while females were 46.7% and 26.7% in groups one and two respectively. The mean age was slightly higher in group 1 than group 2 as shown in (Table .1). In our study, TNSS, TNPS, and LMS improved significantly after treatment, with a  $P < 0.001$  as shown in (Table 2).

**Table 1. Socio- demographic characteristics of both groups**

Variables	Group 1 (N=30)			Group 2 (N=30)		P value
	Total	Number	%	Number	%	
<b>Gender</b>						
Male	38	16	53.3%	22	73.3%	<b>0.108</b>
Female	22	14	46.7%	8	26.7%	
Age		Mean	SD	Mean	SD	<b>0.041**</b>
		49.9	7.039	45	10.758	
<b>History of previous surgery for nasal polyps</b>						
Yes	20	12	40%	8	26.7%	<b>0.273</b>
No	40	18	60%	22	73.3%	
<b>Need for surgery at the end of treatment</b>						
Yes	29	9	30%	20	66.7%	<b>0.004*</b>
No	31	21	70%	10	33.3%	

\*Chi square test - \*\*student's t test

**Table 2. TNSS, TNPS, and Lund-Mackay score before and after treatment in both groups**

Variables	Pretreatment				Post-treatment				P value			
	Group 1		Group2		Group 1		Group2		Intergroups		Intragroup	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Before	After	G1	G2
<b>TNSS</b>	15.6	5.06	18.13	2.9	9.467	5.79	14.13	3.4	0.022**	<0.001**	<0.001*	<0.001*
<b>TNPS</b>	4.3	0.71	4.6	0.72	2.9	0.76	4.13	0.89	0.155	<0.001**	<0.001*	<0.001*
<b>LMS</b>	17.7	4.6	19.26	4.25	13.27	4.42	17.4	4.6	0.186	0.001**	0.001*	<0.001*

\*student's t test \*\* Paired t- test

In our study, TNPS in Group 1 improved significantly throughout the course of steroid injection ( $P < 0.001$ ), as shown in (Table.2 and Fig.1). Also,

there is significant improvement in nasal obstruction along the intra-polyp steroid injection in Group 1 as shown in (Fig.2).

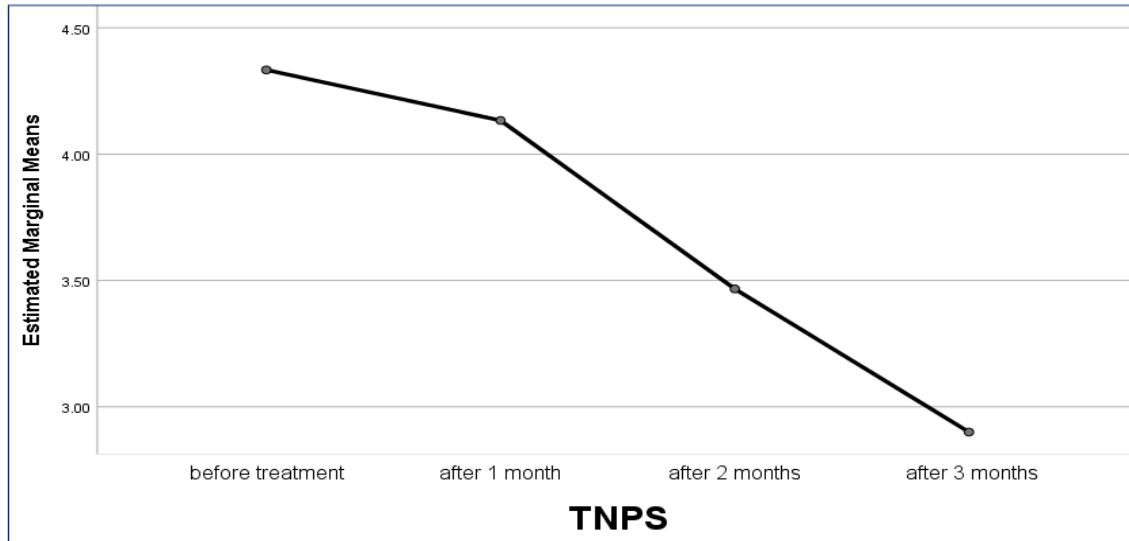


Fig .1. Effect of intra-polyp steroid injection on TNPS

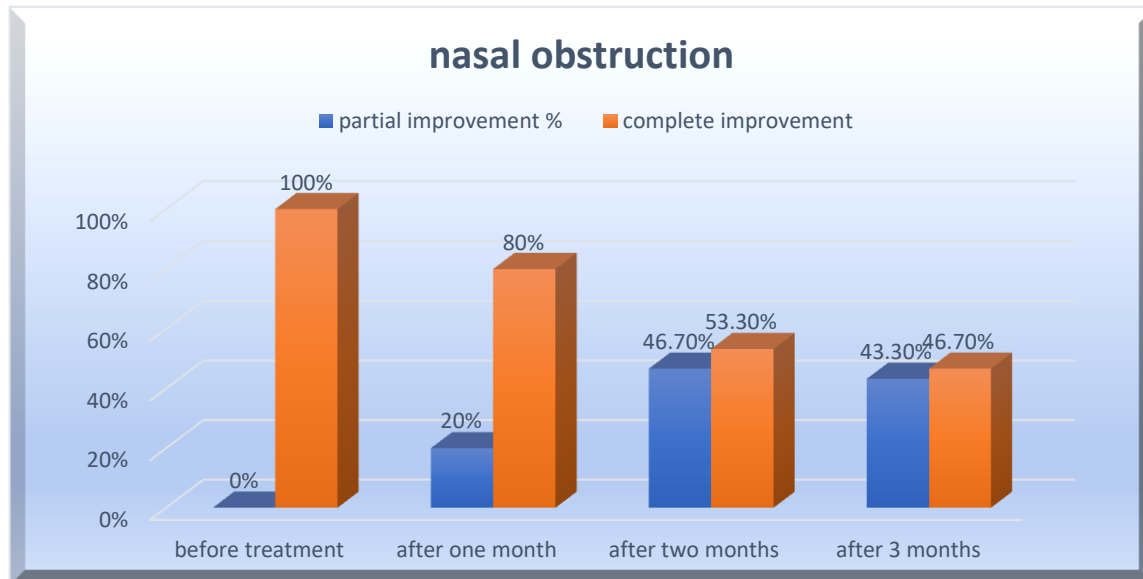


Fig. 2. Degree of nasal obstruction during intra-polyp steroid injection

There is partial and complete improvement in 60% and 10% of patients in Group 1, respectively. And only 26.7% of patients in Group 2 showed partial improvement. The

difference is statistically significant with a ( $P$  value = 0.002) as shown in (Table .3).

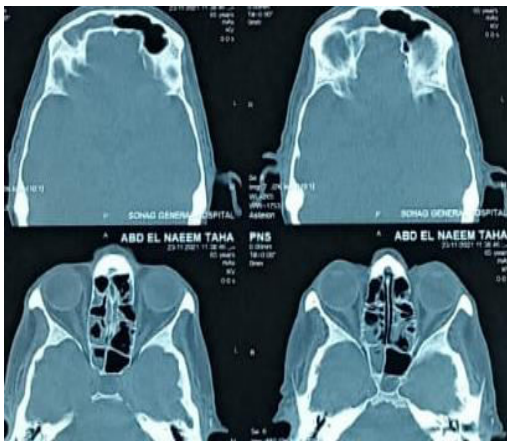
**Table 3. Comparison between the outcome among the two groups**

Outcome	Total	Group 1 (N=30)		Group 2 (N=30)		P value
		Number	%	Number	%	
No response	31	9	30%	22	73.3%	<b>0.002*</b>
Partial improvement	26	18	60%	8	26.7%	
Complete improvement	3	3	10%	0	0%	

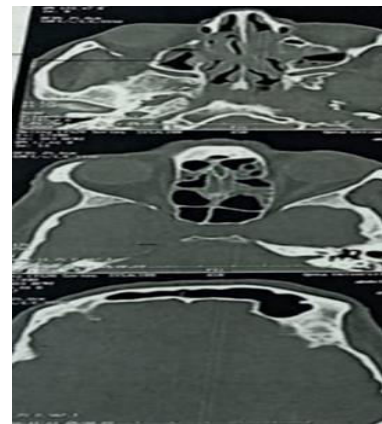
\* Chi square test

The effect of Intra-polyp steroid injection and oral steroid on Lund-Mackay score as shown in **Figs. (3,4)** and **(5,6)** respectively, the effect of Intra-

polyp injection of steroid and oral steroid on polyp score as shown in **(Fig. 7,8)** respectively.



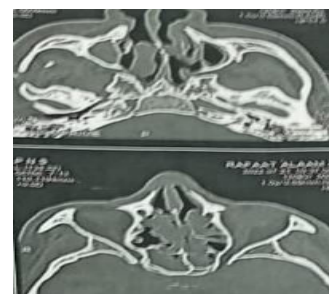
**Fig. 3.** CT Nose of a case from the injection group, before treatment.



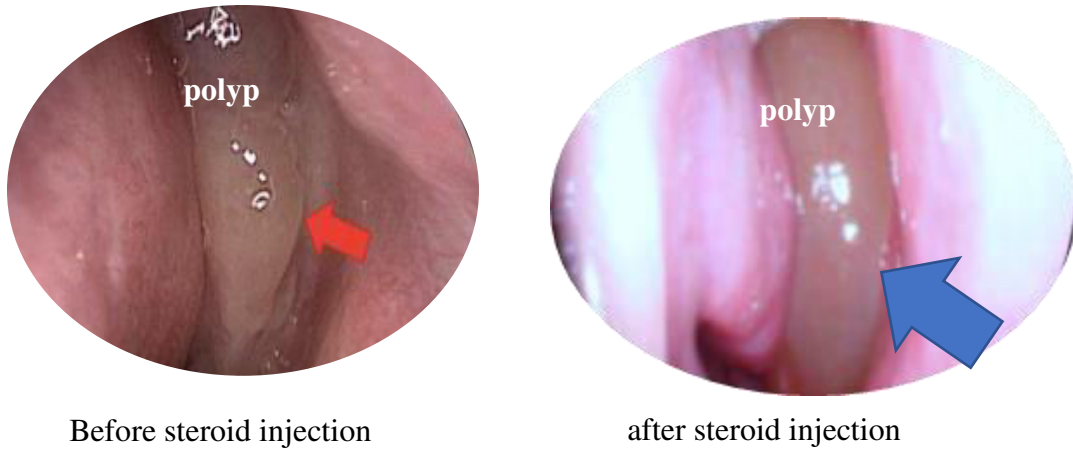
**Fig. 4.** CT Nose of the same case after three intra-polyp steroid injection, shows partial improvement



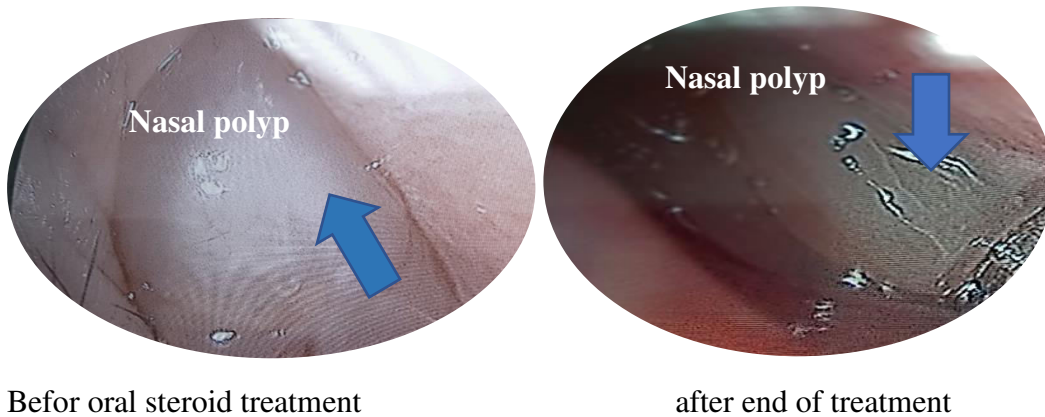
**Fig .5.** CT Nose of a case from the oral steroid group, before the treatment



**Fig. 6.** CT Nose of the same patient after oral steroid treatment, shows partial improvement.



**Fig .7.** Endoscopic view of a case before and after 3 intrapolyp steroid injection showing shrinkage of polyp size



**Fig .8.** Endoscopic view of a case from oral steroid group before oral steroid and after end of treatment showing partial decrease of polyp size

## Discussion

In the current study, we have found that there is a statistically significant difference in the outcome between both groups ( $P=0.002$ ). In the injection group, 10% of patients showed complete improvement compared to 0% in the oral steroid group. 60% of those received injection showed partial improvement compared to 26.7% in those received oral steroid. These findings are closely like a study conducted by **Zamzam et**

**al. (2020)** who found that 72.33% of the cases in the injection group achieved clinical improvement, and **Ali et al.(2020)** who stated that 75% of the cases showed clinical improvement (10% complete improvement and 65% partial improvement). The degree of clinical improvement is lower than in a study conducted by **Moss et al.(2015)** who found that 84% of patients reported clinical improvement after receiving intranasal injections. This can be interpreted by saying that this study

included a combination of patients with Chronic Rhinosinusitis with Nasal Polyps (CRS<sub>w</sub>NP) and patients without polyp (CRS<sub>s</sub>NP), whereas in our study all patients had nasal polyps. A study performed by **Tuncer et al., 2003** found that there is a complete improvement in 30.5% of patients who treated with oral steroid, this study stands in opposite with our findings, where (0%) of patients showed complete improvement. This can be interpreted by that **Tuncer et al.(2003)** used combination of oral steroid and nasal spray.

Also, we found that the total nasal symptom score, total nasal polyp score, and Lund-Mackay score were statistically significantly different among both groups after receiving treatment ( $P = <0.001$ ,  $<0.001$ , and  $0.001$  respectively). Total nasal symptoms score was lower in the injection group (mean  $\pm$ SD=  $9.4667 \pm 5.7997$ ) compared to the oral steroid group (Mean  $\pm$ SD=  $14.133 \pm 3.4012$ ). Total nasal polyps score was lower in the injection group (mean  $\pm$  SD=  $2.9 \pm 0.7589$ ) compared to the oral steroid group (mean  $\pm$ SD=  $4.133 \pm 0.8995$ ). Lund-Mackay score was lower in the injection group (mean  $\pm$  SD =  $13.267 \pm 4.417$ ) compared to the oral steroid group (mean  $\pm$ SD=  $17.4 \pm 4.6$ ). These findings agree with a study performed by **Ali et al.(2020)**, who found that there was a statistically significant difference in TNSS, TNPS and radio-endoscopic analysis.

After a 3-month course of intra-polyp steroid injection, the severity of nasal obstruction showed a statistically significant decrease ( $P < 0.001$ ). Whereas there was severe nasal obstruction in 100% of patients before the treatment, there was a complete nasal obstruction in

14 patients (46.67%), moderate nasal obstruction in 13 patients (43.3%), and no residual nasal obstruction in 3 patients (10%) after the complete injection steroid series. These findings agree with a study done by **Mahrous et al.(2019)** who discovered that 46.67% of patients had complete nasal obstruction after a combination of medical treatment (intra-polyp steroid injection, systemic steroid, and local steroid nasal spray), but disagree with the same study where 20% of patients had no residual nasal obstruction after a combination of medical treatment.

In our study, after steroid injection, Total nasal symptoms score were  $9.4667 \pm 5.7997$  compared to ( $15.6 \pm 5.0624$ ) before treatment, which is nearly like a study performed by **Kiris et al.(2016)** who found that Total nasal symptoms score were  $9.3 \pm 3.5$  after 3 months control and lower than a study done by **Zamzam et al.(2020)**, who found that TNSS were  $10.89 \pm 4.62$  and **Mahrous et al.(2019)**, who stated that TNSS were  $13.7 \pm 3.035$ , and higher than a study conducted by **Ayman et al.(2022)** (TNSS were  $1.17 \pm 0.14$ ) after 3 months of topical Beclomethasone Dipropionate Monohydrate compared to  $4.55 \pm 0.42$  before treatment. The difference is highly statistically significant ( $P < 0.001$ ).

After intra-polyp steroid injection, our patients experienced a mean reduction of Total nasal polyps score from  $4.33 \pm 0.71$  to  $2.9 \pm 0.76$  which is consistent with the  $\approx 1.5$ -point decrease seen in a study conducted by **Yao et al.(2020)** who found that patients had reduction of NP



grade score from 3.1 to 2.4 after 24-weeks of topical corticosteroid nasal sprays. At the end of treatment, Total nasal polyps score were  $2.9 \pm 0.76$  which is like a study performed by **Ayman et al.(2022)** who found that Total nasal polyps score were  $2.89 \pm 0.45$ , and lower than a study performed by **Mahrous et al.(2019)** who found that TNPS were  $3.2 \pm 1.474$ , and **Zamzam et al.(2020)**, who found that TNPS were  $3.33 \pm 1.82$ , and higher than a study performed by **Kiris et al.(2016)** who found that TNPS were  $1.7 \pm 1.7$  after 3 months control. The distinction is highly statistically significant ( $P < 0.001$ ). LMS were  $13.267 \pm 4.417$  compared to  $17.533 \pm 4.833$  before treatment, which is lower than a study performed by **Zamzam et al.(2020)**, who found that Lund-Mackay score were  $15.48 \pm 8.60$  and higher than a study performed by **Mahrous et al.(2019)**, who observed that LMS were  $11 \pm 0.66$ . The difference is highly statistically significant ( $P = 0.001$ ).

In the current study, we found that after oral steroids, TNSS were  $14.133 \pm 3.4$  compared to  $18.133 \pm 2.9212$  before treatment, which is higher than a study performed by **Kiris et al.(2016)** who, found that TNSS were  $9.4 \pm 3.1$  after 3 months control. The difference is highly statistically significant ( $P < 0.001$ ). TNPS were  $4.133 \pm 0.899$  compared to  $4.60 \pm 0.7239$  before treatment, which is higher than a study performed by **Zamzam et al.(2020)**, who found that TNPS were  $2.6 \pm 2.04$  after treatment. The difference is highly

statistically significant ( $P < 0.001$ ). LMS were  $16.8 \pm 5.967$  compared to  $19.267 \pm 4.258$  before treatment which is higher than a study performed by **Zamzam et al. (2020)**, who found that LMS were  $12.67 \pm 8.38$  after treatment. The difference is highly statistically significant ( $P < 0.001$ ).

In our study, we found that there is a statistically significant reduction in TNSS, TNPS, and LMS in the patients that received injection steroid compared to those that received oral steroid ( $P < 0.001$ ) TNSS was lower in the injection group ( $9.4667 \pm 5.7997$ ) compared to the oral steroid group ( $14.133 \pm 3.4012$ ). TNPS was lower in the injection group ( $2.9 \pm 0.7589$ ) compared to the oral steroid group ( $4.133 \pm 0.8995$ ). LMS was lower in the injection group ( $13.267 \pm 4.417$ ) compared to the oral steroid group ( $17.4 \pm 4.6$ ). These findings agree with a study performed by **Steven et al.(2016)** who found that there is a significant reduction in TNSS, TNPS and Lund-Mackay score of the cases who received injection.

The risk of visual disturbance in our patients was 0.00%, which is similar to **Kiris et al. (2016)** and **Ali et al. (2020)** studies, and less than **Moss et al. (2015)** study, which estimated the risk as 0.003%.

## Conclusion

Intra-polyp steroid injection may be considered as one of the treatment options for Sino nasal polyposis, particularly for patients who are at high

risk of using systemic steroids or surgical intervention, as it appears to be a safer and more effective method of treating Sino- nasal polyposis than oral short-term steroid treatment.

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