Effect of Intranasal Prednisone Irrigations in Chronic Rhinosinusitis Patients

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ABSTRACT

Introduction: Topical therapies in chronic rhinosinusitis allow higher concentrations of the pharmacological agent to be distributed in the nasal cavities with fewer systemic effects. Topical corticosteroids in high doses, provides a greater volume and concentration of these to the nasal-sinus mucosa. Although budesonide improves symptomatology in CRS patients is not largely available in most countries. The objective of this study was to determine whether nasal irrigation using prednisone has an inhibitory effect on the hypothalamic-pituitary-adrenal axis or on intraocular pressure.

Methods: phase 2 queasy-experimental study. Two groups of patients operated on for chronic rhinosinusitis (either with and without polyps) and that use corticosteroid inhalers were given high-flow nasal irrigation. Group 1 received 2.5 mg/day of prednisone and Group 2 received 5 mg/day. The clinical parameters, endoscopies, the cortisol in urine and intravenous cortisol awakening response levels and IOP were measured before and after the 12 week treatment.

Results: Seven patients in Group 1 and eight patients in Group 2 completed the study. There were no significative changes in the levels of intravenous cortisol awakening response or cortisol in urine levels or IOP. There was a tendency for quality of life to improve according to the SNOT 22 survey and on a symptomatic scale, which had no statistical significance. There were no side effects.

Conclusion: The use of high-flow nasal irrigation with doses of 2.5 mg and 5 mg of prednisone a day did not decrease cortisol awakening response serum or cortisol in urine levels, nor did it increase IOP in this series, meaning that the number of patients studied could be increased to test for safe use better.

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INTRODUCTION

Topical therapies have emerged as a promising strategy in managing chronic rhinosinusitis (CRS) by offering the advantage of targeted drug delivery to the nasal cavities while minimizing systemic side effects. High-dose topical corticosteroids, in particular, hold the potential to provide increased drug volume and concentration within the nasal-sinus mucosa. Nevertheless, it is important to note that despite the demonstrable efficacy of budesonide in symptoms in CRS patients, its accessibility remains limited in many countries. In light of this, our primary research objective is to determine whether nasal irrigation using prednisone has an inhibitory effect on the hypothalamic-pituitary-adrenal axis or on intraocular pressure.

METHODS AND MATERIALS

A phase 2 quasi-experimental study was conducted at a tertiary rhinology center in Santiago, Chile, following approval from Institution Research Ethics Board.

Eligible participants were 18 years of age or older, had CRS and had undergone endoscopic sinus surgery at Hospital del Salvador.

There were 2 arms of the study:

- Group 1: prednisone nasal irrigation 2.5 mg/day
- Group 2: prednisone nasal irrigation 5 mg/day

Recruitment of patients took place from the fourth week after surgery. Once patients agreed to participate in the study, a baseline assessment was conducted, followed by two additional assessments every 6 weeks. Demographic and clinical variables, including, asthma status, current medications, and other comorbidities, were collected from the patients´medical charts. Additionally, patients completed series of surveys that included the Spanish-validated version of 22-item Sino-Nasal Outcomes Test (SNOT-22) and visual analog scale.

The main outcome measures of this study were intraocular pressure (IOP) and corticoid levels. Secondary outcome measure included assessment of nasal symptoms using the validated Spanish version of the SNOT-22 survey and visual analog scale to evaluate nasal obstruction, rhinorrea, posterior nasal drainage, olfaction and facial pressure. Endoscopic evaluation was conducted using the Modified Lund-Kennedy scoring system.

Data analysis was performed using STATA12.

RESULTS

A total of 23 patients initially met the study criteria. However, two patients received oral steroids during follow-up and six patients were lost during follow-up period. Therefore, a final analysis was conducted on 15 patients. Seven patients in Group 1 and eight patients in Group 2 completed the study. (Table 1))

There were no significant changes in the levels of intravenous cortisol awakening response (Figure 1) or cortisol in urine levels (Figure 2) or IOP.

There was a tendency for quality of life to improve according to the SNOT 22 survey and on a symptomatic scale, which had no statistical significance (Figure 3).
There were no side effects.

Table 1: Patient characteristics

Characteristics	Total (n=15)	Group 1 (n= 7)	Group 2 (n=8)
Gender (F / M)	12 / 3	5 / 2	7 /1
Age (years)	61 (54-65)	60 (51-65)	62 (57.5-65.5)
Comorbidities			
-Hypertension	5	2	3
-Asthma	5	1	4
Aspirin Sensitivity	2	1	1

Figure 1: Cortisol awakening response

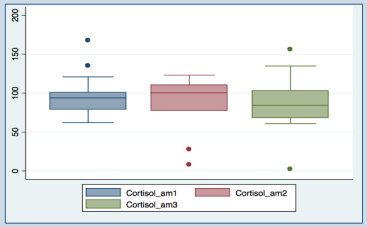
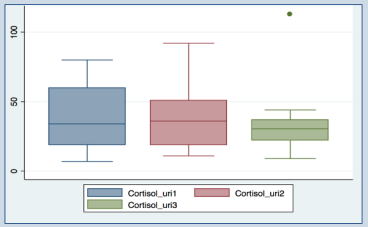


Figure 2: Urine Cortisol



DISCUSSION

Intranasal corticosteroids are the primary treatment for CRS. An alternative treatment involves high-dose corticosteroids, delivering a more concentrated medication volume to the sino-nasal mucosa. Much research has focused on budesonide suspension irrigation, indicating minimal systemic absorption, thus reducing associated risks linked to oral corticosteroids.

Several studies, including those by Seiberling et al. and Thamboo et al., reported no increased intraocular pressure (IOP) or adrenal suppression during follow-ups after budesonide irrigation. Our study supports these findings, showing no elevated IOP or adrenal suppression after 12 weeks of prednisone suspension use at daily doses of 2.5 mg and 5 mg. During follow-up, no adverse effects were reported, except for one patient with a transient burning sensation.

In one case, a patient in Group 2 unintentionally doubled the prednisone dose to 10 mg, leading to inhibited cortisol awakening response but no clinical consequences. Although our study didn't find significant differences based on prednisone dosage, it revealed a trend toward improved quality of life, indicated by SNOT-22 scores, and symptomatic enhancement with high-dose corticosteroids.

CONCLUSIONS

The use of high-flow nasal irrigation with doses of 2.5 mg and 5 mg of prednisone a day did not decrease cortisol awakening response serum or cortisol in urine levels, nor did it increase IOP in this series.

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