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Рандомизированное контролируемое исследование, сравнивающее назальные спреи будесонид и мометазона фуроат для лечения хронического риносинусита с полипозом носа: оценка симптомов и качества жизни

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Резюме

Актуальность. Хронический риносинусит с полипозом носа (ХРСсПН) — это сильно изнурительное воспалительное заболевание, которое затрагивает многих людей и значительно снижает их качество жизни. Основу лекарственной терапии составляют интраназальные кортикостероиды, и среди них наиболее часто используются будесонид и мометазона фуроат. Они используются уже долгое время, однако их эффективность сравнивалась лишь в немногих исследованиях.

Цель исследования. Сравнить эффективность назальных спреев будесонида и мометазона фуроата для лечения ХРСсПН с валидированными показателями исходов, сообщаемыми пациентами, в рандомизированном контролируемом исследовании.

Материал и методы. Проведено сравнительное, параллельное, рандомизированное, контролируемое клиническое исследование на 100 взрослых пациентах с ХРСсПН, которые были случайным образом распределены на группы с применением назальных спреев будесонид и мометазона фуроат. Для оценки степени тяжести симптомов на начальной стадии и в ходе последующих посещений использовались опросники тяжести симптомов SNOT-22, TNSS и RSDI.

Результаты. Результаты продемонстрировали значительные изменения в оценках по опросникам SNOT-22, TNSS и RSDI в обеих группах лечения с 0 по 4 неделю. Тем не менее группа, принимающая мометазона фуроат, показала более высокие общий контроль над симптомами и показатели качество жизни; улучшение по SNOT-22 и RSDI и, следовательно, лучшее терапевтическое воздействие по сравнению с группой будесонида.

Заключение. Исследования показали, что назальные спреи будесонид и мометазона фуроат были эффективны в лечении синоназальных симптомов, симптомов, специфических для полипов носа, и в повышении качества жизни у пациентов с ХРСсПН. Однако мометазона фуроат продемонстрировал в целом лучшее групповое воздействие на синоназальные симптомы и качество жизни после 1 месяца последующей терапии из-за его более высокой активности и продолжительности действия.

Ключевые слова: *мометазона фуроат, назальные спреи, будесонид, хронический риносинусит, полипоз носа.*

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A Randomized Controlled Trial Comparing Budesonide and Mometasone Furoate Nasal Spray in the Treatment of Chronic Rhinosinusitis with Nasal Polyposis: Evaluating Symptom Scores and Quality of Life

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Abstract

Background. Chronic rhinosinusitis with nasal polyposis (CRSwNP) is a highly debilitating inflammatory condition that affects many people and considerably reduces their quality of life. The mainstay of medical therapy are the intranasal corticosteroids and among them the most commonly used are budesonide and mometasone furoate. They have been used for a long time; however, only few studies have compared their efficacy.

Objective. To compare the efficacy of budesonide and mometasone furoate nasal sprays for the treatment of CRSwNP with validated patient-reported outcome measures in a randomized controlled trial.

Material and methods. This was a two arm parallel randomized controlled clinical trial on 100 adults with CRSwNP who were randomly allocated to budesonide and mometasone furoate nasal spray. SNOT-22, TNSS, and RSDI symptom severity scales were used at the baseline and follow-up visits to assess the symptom severity.

Results. The results demonstrated significant changes in SNOT-22, TNSS, and RSDI scores in both treatment groups from week 0 to 4. Nevertheless the mometasone furoate group showed a superior overall symptom control and quality of life; improvement in SNOT-22 and RSDI and hence a better therapeutic effect over the budesonide group.

Conclusion. Studies have shown that both budesonide and mometasone furoate nasal sprays were efficacious in the treatment of sinonasal symptoms, nasal polyps-specific symptoms and quality of life in CRSwNP patients, however, mometasone furoate demonstrated overall better group effects on sinonasal symptoms and quality of life at 1 month follow-up post treatment due to its higher potency and longer duration of action.

Keywords: *mometasone furoate, nasal sprays, budesonide, chronic rhinosinusitis, nasal polyposis.*

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Introduction

CRSwNP is an inflammatory sinus disease; all patients have continued sinonasal symptoms and nasal polyps that hamper their quality of life significantly [1]. CRSwNP affects a significant number of people, with the actual prevalence rates estimated to range from 4 to 5% of the general population [2]. The treatment of this diseases is also sometimes difficult and even a number of different treatment methods may need to be applied [3].

Because of their strong anti-inflammatory activity and pronounced action on polyp size, intranasal corticosteroids have become the mainstay of pharmacotherapy of CRSwNP [4]. Budesonide and mometasone furoate are some of the INCs that are preferred from the list of the available that are used in the management of CRSwNP [5].

There have been few clinical trials conducted in order to test the ability of the two INCs in handling CRSwNP and some of them have been through which demonstrated that these two INCs are good in the improvement of the quality of life and the signs of CRSwNP as well as the size of the polyps in these patients [6, 7].

However, systematic reviews combining the quality data for these two corticosteroids in the treatment of CRSwNP are lacking, and even in such a study the result does not remain conclusive [8].

Moreover, a patient self-reported assessment including symptomatic scoring and patient's quality of life has been demonstrated to be important tools for overall assessment of therapeutic options for chronic rhinosinusitis [9].

These subjective measures represent patients' perceptions and how they feel about their medical care and feel the impact of illness, which is a critical factor in understanding patients' health that is presented in combination with objective clinical assessments [10—15].

The main objective of this study was to evaluate the therapeutic effectiveness of two of the most commonly used intranasal steroids, budesonide and mometasone furoate, in treating the disturbing condition of CRSwNP. To achieve a comparable objective evaluation of the impact of the two treatments on these symptoms and on the general quality of life of patients with CRS, we hence employed a randomized controlled trial design.

Material and methods

Study Design and Participants

This study was performed as a prospective, randomized, parallel-group trial. a total of 100 adults confirmed with CRSwNP were recruited and assigned to the study. Patients were randomly assigned to the budesonide group (50 patients) and mometasone furoate group (50 patients).

Ethical Considerations

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and adhered to the Good Clinical Practice guidelines. Prior to study initiation, approval was obtained from the relevant institutional review board(s) and ethics committee(s) at each study site.

Inclusion Criteria:

— Adults aged 18—65 years.
— Diagnosed with chronic rhinosinusitis with nasal polyposis based on clinical symptoms and endoscopic/radiologic findings.
— Bilateral nasal polyps on endoscopic examination.
— Total nasal polyp score ⩾5 (out of 8).

— Symptoms present for at least 12 weeks.
— Able to use nasal spray correctly.
— Willing to provide informed consent.

Exclusion Criteria:
— Pregnant or breastfeeding women.
— History of sinus surgery within the past 6 months.
— Nasal polyposis due to cystic fibrosis, ciliary dyskinesia, or granulomatous diseases.
— Uncontrolled asthma or requiring oral corticosteroids.
— Immunodeficiency or immunosuppressive therapy.
— Known hypersensitivity to study drugs or excipients.
— Nasal septal deviation or anatomical abnormalities precluding proper drug delivery.
— History of recurrent epistaxis or nasal ulceration.
— Concomitant use of systemic corticosteroids or other investigational drugs.
— Significant comorbidities that may interfere with study assessments.
— Substance abuse or inability to provide informed consent.

Drug Administration

Budesonide was administered as two sprays (64 mcg/spray) in each nostril once daily, while mometasone was given as two sprays (50 mcg/spray) in each nostril once daily.

Scoring Systems and Questionnaires

Symptom severity was assessed using the following validated instruments:

Sino-Nasal Outcome Test-22 (SNOT-22): a 22-item questionnaire evaluating nasal, paranasal, sleep, and emotional symptoms on a scale of 0 (no problem) to 5 (problem as bad as it can be).

The SNOT-22 provides a comprehensive assessment of the symptoms associated with chronic rhinosinusitis and their impact on different aspects of daily living. Higher scores indicate more severe and bothersome symptoms. The total score ranges from 0 to 110, with subscale scores for different symptom domains (nasal, paranasal, sleep, and emotional). This allows evaluation of specific symptom clusters affected by the condition and treatment.

Total Nasal Symptom Score (TNSS): Participants rated the severity of nasal congestion, anterior rhinorrhea, loss of smell, and facial pain/pressure on a scale of 0 (not present) to 3 (severe).

The TNSS focuses specifically on four cardinal symptoms of nasal polyposis — nasal congestion, runny nose, loss of smell, and post nasal drip. Each symptom is scored from 0 (not present) to 3 (severe), with a total score ranging from 0 to 12. Higher scores reflect more severe polyp-related symptoms. This targeted scale enables direct assessment of the key symptoms aimed to be improved by treatment.

Rhinosinusitis Disability Index (RSDI): Quality of life was measured using the Rhinosinusitis Disability Index (RSDI), a 30-item instrument assessing physical, functional, and emotional impairment, with higher scores indicating greater disability.

The RSDI evaluates the overall quality of life impairment caused by chronic rhinosinusitis across physical, functional, and emotional domains. Higher scores (ranging from 0 to 150) indicate greater disability and reduced quality of life. The subscale scores provide insight into specific areas of impairment, such as physical symptoms, limitations in daily activities, and emotional distress. This comprehensive measure helps understand the broader impact of the condition and treatment on patients' well-being.

Follow-up and Outcome Measures Participants attended follow-up visits at 4, 8, and 12 weeks, where symptom scores (SNOT-22 and TNSS) and the RSDI questionnaire were re-administered. The primary outcome was the change in SNOT-22 score from baseline to 12 weeks. Secondary outcomes included changes in TNSS, RSDI, and endoscopic nasal polyp grading.

Statistical Analysis

Data were analyzed using standard statistical software. Baseline characteristics were compared between groups using Student's *t*-tests or chi-square tests as appropriate. Changes in symptom scores and quality of life measures from baseline to each follow-up visit were calculated and compared between groups using Student's *t*-tests or Mann—Whitney *U* tests, depending on the distribution of data. a p-value <0.05 was considered statistically significant.

Results

This **Table 1** shows the baseline demographic characteristics of the two treatment groups (budesonide and mometasone furoate). The groups were well-balanced, with no statistically significant differences in age, sex distribution, smoking history, or asthma history, indicating successful randomization.

Table 2 demonstrates the changes in symptom scores and quality of life measures in the budesonide group from baseline to 4 weeks after treatment initiation. Significant improvements were observed in all scoring systems: SNOT-22 (mean change from 53.68 to 39.04, $p<0.001$), TNSS (mean change from 7.24 to 4.38, $p<0.001$), and RSDI (mean change from 78.64 to 58.4, $p<0.001$), indicating a reduction in sinonasal symptoms, nasal polyp-specific symptoms, and quality of life impairment.

Similar to the budesonide group, **Table 3** shows significant improvements in all scoring systems for the mometasone furoate group from baseline to 4 weeks: SNOT-22 (mean change from 53.54 to 33.78, $p<0.001$),

TNSS (mean change from 7.12 to 4.22, $p<0.001$), and RSDI (mean change from 78.72 to 51.5, $p<0.001$), suggesting a reduction in overall symptoms, nasal polyp-specific symptoms, and quality of life impairment.

Table 4 compares the two treatment groups at the 4-week timepoint. The mometasone furoate group showed significantly better improvement in SNOT-22 scores (mean 33.78 vs. 39.04, $p=0.03$) and RSDI scores (mean 51.5 vs. 58.4, $p=0.002$) compared to the budesonide group, suggesting potentially superior overall symptom control and quality of life outcomes with mometasone furoate. However, there was no significant difference in TNSS scores between the groups at 4 weeks ($p=0.34$).

Table 1. **Demographics data in both study groups**

Parameter	Budosonide group, $n=50$	Mometasone group, $n=50$	p-value
Age (mean±SD)	40.94±12.42	36.7±13.48	0.52
Male, *n* (%)	33 (66)	30 (60)	0.53
Smoking history *n* (%)	19 (38)	25 (50)	0.22
Asthma history *n* (%)	25 (50)	16 (32)	0.06

Table 2. **Baseline scoring systems results vs. 4 weeks after budosonideadministartion**

Parameter	Baseline scoring	4 weeks budosonide scoring	p-value
SNOT-22 (mean±SD)	53.68±12.89	39.04±14.33	<0.001
TNSS (mean±SD)	7.24±1.37	4.38±1.62	<0.001
RSDI (mean±SD)	78.64±12.20	58.4±12.68	<0.001

Table 3. **Baseline scoring systems results vs. 4 weeks after mometasone administration**

Parameter	Baseline scoring	4 weeks mometasone scoring	p-value
SNOT-22 (mean±SD)	53.54±13.80	33.78±14.06	<0.001
TNSS (mean±SD)	7.12±1.59	4.22±2.29	<0.001
RSDI (mean±SD)	78.72±11.78	51.5±11.24	<0.001

Table 4. **Scoring systems results 4 weeks after budosonideadministartion vs. 4 weeks after mometasone administration**

Parameter	4 weeks budosonide scoring	4 weeks mometasone scoring	p-value
SNOT-22 (mean±SD)	39.04±14.33	33.78±14.06	0.03
TNSS (mean±SD)	4.38±1.62	4.22±2.29	0.34
RSDI (mean±SD)	58.4±12.68	51.5±11.24	0.002

Discussion

The primary objective of our study was to conduct a rigorous, randomized controlled trial to compare the efficacy of two widely prescribed intranasal corticosteroids, budesonide and mometasone furoate, in alleviating the debilitating symptoms of chronic rhinosinusitis with nasal polyposis (CRSwNP) and enhancing patients' quality of life. The entire validated patient-reported outcome measures consisting of SNOT-22, TNSS and RSDI were used to assess the general patient satisfaction and the quality of life in general. In this comparative study the results indicated that both the treatments were equally effective in reducing the sinonasal and the nasal polyp specific symptoms as well as the quality of life but the overall relief of the symptoms and improvements in quality of life were more for the patients who received mometasone furoate at the follow up of four weeks instead of budesonide.

Course of the disease based on the treatment with budesonide nasal spray suggested that this drug is able to affect the relief of CRSwNP symptoms as well as the quality of life of patients suffering from this disease. The results showed good improvement in-reported sinonasal symptoms and quality of life impairment as well as nasal polyp specific symptom scores at four week follow up. This gives a notion that budesonide could minimize the signs and symptoms that have been linked with CRSwNP. According to the results of the current study, budesonide proves to be effective as a treatment for nasal polyps as documented by earlier findings. Other researches demonstrated that patients who took budesonide for four months also had better symptom scores and reduced nasal congestion compared with the placebo group [16].

One specific study reviewed the benefits of BNI in CRSwNP patients for up to 36 months of BNI treatment. a significant difference was demonstrated in endoscopic sinus scores and symptoms and reduction in the use of oral steroids and antibiotics from baseline levels [17]. One other clinical trial (NCT03687515) is focused on examining the efficacy and safety of budesonide inhalation suspension in CRSwNP. Budesonide is another type of corticosteroid which works directly on the nasal passages by decreasing their inflammation [18].

This decrease in the inflammation then leads to the reduction of the nasal polyps as well as congestion of the nasal passage and hence the improvement on the nasal breathing. The reduction in symptoms observed in the current study (SNOT-22, TNSS) probably corresponds to these anti- inflammatory and bronchodilatory effects which results in reduced mucosal swelling and increased air flow. Since RSDI improved, it indicates that the decrease in the symptoms also contributed to enhanced quality of life for the patients.

The current study results of the mometasone group showed the similar results as corresponding to the budesonide group, with significant improvements across all the scoring system (SNOT-22, TNSS, RSDI) in the mometasone furoate group after 4 weeks. This implies a decline in the severity of sinonasal conditions, nasal polyps-related problems, as well as its effect on quali-

ty of life. Several recent studies also suggest that mometasone furoate may be effective for nasal polyps and correlate with the results of the study in the present article. a study on the use of mometasone furoate in children with chronic rhinosinusitis with nasal polyps (CRSwNP). It found significant improvements in symptom scores and nasal endoscopy findings compared to placebo after 12 weeks [19]. Another research delves into the real-world use of mometasone furoate for CRSwNP in adults. This study validates the safety and efficacy of mometasone furoate in the real-world setting by showing reduction in symptoms and use of the oral steroids [20]. Another study evaluated the efficacy of mometasone furoate for CRSwNP and also compared it with fluticasone propionate. Both medications were proved to be safe and effective; however, mometasone furoate had a tendency to be better in efficacy due to its faster effect [21]. Several clinical trials comparatively had assessed the usefulness of mometasone furoate in CRSwNP and was systematically reviewed. Mometasone furoate has been shown to be safe and effective in CRSwNP patients and could replace surgery for amelioration of the disease manifestations and size reduction. Mometasone furoate is another version of corticosteroid drug whose structure will likely have alikeness to budesonide. It does this by combating the means of alleviating the inflammation in the nose and the diminution of the polyps' dimensions and thus improving the breathing and congestion. This might be attributed to the reduced inflammation as justified in the degree of improvement of the SNOT-22, TNSS, and RSDI scores from the current study. This study was conducted to determine the response of CRSwNP to budesonide and mometasone furoate nasal sprays after four weeks of medication. The analysis revealed that higher overall treatment success and greater quality of life was recorded in the mometasone furoate group as compared to the budesonide group. The particular relevance of this result is that the mometasone group had less symptom severity and quality of life impairment as compared to the budesonide group but both treatments were effective. But they could not have any distinct differences on the nasal polyp specific symptoms. The same level of potency of the drug cannot be achieved in the case of budesonide, and the same is true for its duration of effect compared to mometasone furoate. In this regard, enhanced anti-inflammatory effects could be a probable explanation to why mometasone treatment outcomes in significant reductions in mucosal swelling and polyp size for better nasal airflow and symptomatic relief [20—22].

This is corroborated by its other identified pharmacological properties such as potent inhibition of inflammatory mediators and cytokines [20].

Conclusion

This study has provided valuable information on chronic rhinosinusitis with nasal polyposis treatment outcomes associated with budesonide and mometasone furoate nasal sprays and this observation points to the fact that mometasone furoate provides upper hand overall symptom control and quality of life than budesonide. Significant statistically better outcomes in terms of overall sinonasal symptom severity and QoL impairment, measured using the SNOT-22 and RSDI scales, respectively, were also found in the mometasone furoate group compared with placebo. These results might be explained by the fact that mometasone furoate has a higher and sustained potency as compared to budesonide, thus leading to better reduction of mucosal inflammation and polyp size.

The author declare no conflicts of interest.

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