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Efficacy of mometasone furoate nasal spray in the treatment of acute rhinosinusitis

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Abstract

Background Acute rhinosinusitis (ARS) refers to a group of disorders characterized by inflammation of the respiratory epithelium of the nose and paranasal sinuses lasting from 7 to 28 days. In the treatment of ARS in addition to an antibiotic, intranasal corticosteroids hasten the clearance of bacteria, decrease the frequency and severity of disease recurrence, and reduce the duration of infection. The purpose is to compare the efficacy of the combination of mometasone furoate nasal spray (MFNS) with amoxicillin and amoxicillin alone in the treatment of acute rhinosinusitis. A total of 120 patients (≥ 12 years) were randomized into 2 groups: group A (*N*: 60) receiving amoxicillin 500 mg thrice daily alone and group B (*N*: 60) receiving amoxicillin 500 mg thrice daily and MFNS 200 µg twice daily for 7 days. Patients were followed up after 7 days. The Sino-Nasal Outcome Test-22 (SNOT-22) questionnaire was taken before and after. The total score of SNOT-22 was compared between the groups.

Results There was a reduction in the mean total SNOT score in both groups from 21.32 ± 11.29 to 9.37 ± 6.55 in group A and from 26.68 ± 11.97 to 3.07 ± 3.46 in group B which were statistically significant ($p < 0.001$) in both groups. The posttreatment mean score with the amoxicillin group was 9.31 ± 6.55 and that of the amoxicillin and mometasone furoate group was 3.07 ± 3.46, and their mean difference was 6.3 ± 0.95. In comparison, MFNS with amoxicillin was significantly ($p < 0.001$) superior than amoxicillin alone.

Conclusion Patients receiving amoxicillin alone or amoxillin with MFNS, both showed improvement of symptoms in ARS. However, amoxicillin with MFNS showed significantly higher improvement and relief of symptoms in ARS than amoxicillin alone.

Keywords Acute rhinosinusitis (ARS), Mometasone furoate nasal spray (MFNS), Sino-Nasal Outcome Test-22 (SNOT-22)

Background

Rhinosinusitis refers to a group of disorders characterized by inflammation of the ciliated respiratory mucosa of the nose and paranasal sinuses (PNS) [1].

The term rhinosinusitis is replaced by "sinusitis" as the inflammation of the sinus cavities is almost always accompanied by inflammation of the nasal cavities. Rhinitis is inflammation of the mucosa of the nasal cavity whereas sinusitis is inflammation of the mucosa of the paranasal sinuses [2, 3].

Most acute rhinosinusitis (ARS) begins when a viral upper respiratory infection (URI) extends into the paranasal sinuses, which may be followed by bacterial infection [4]. Both viruses and pathogenic bacteria have been shown to be involved in the pathogenesis of ARS [5–7]. It is theorized that most cases of ARS are first caused by a virus and then in some cases are complicated by bacterial co-infection or secondary infection [4, 8]. Inflammation of the mucosa of the sinus can lead to obstruction of the sinus ostia, retention of secretions, and bacterial

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invasion. The obstruction, mucus retention, and infection produce the signs and symptoms characteristic of rhinosinusitis [9].

Prevalence rate of ARS is 6–15% and is usually a self-limiting disease, but serious complications leading to life-threatening situations and even death have been described [10]. It is one of the most common reasons for the prescription of antibiotics, and proper management is extremely pertinent in the context of the global crisis of resistance to antibiotics [10].

In the treatment of acute bacterial rhinosinusitis in addition to antibiotic, intranasal corticosteroids hasten the clearance of bacteria, decrease the frequency and severity of disease recurrence, and reduce the duration of infection [11–14]. Mometasone furoate (MF) is a potent, topically active, synthetic corticosteroid, which has been formulated as a nasal spray and was approved for the treatment of seasonal and perennial allergic rhinitis [9].

Sino-Nasal Outcome Test-22 (SNOT-22) was developed in 2009 from modification of SNOT-20 with the addition of nasal blockage and loss of smell, by the National Comparative Audit of Surgery for Nasal Polyposis and Rhinosinusitis Royal College of Surgeons of England [15, 16]. It has been validated and is today one of the most frequently used survey instruments in sinonasal research. It measures rhinosinusitis health status and quality of life and will be used in this study for the assessment of improvement in patients. Lower scores imply a better health-related quality of life, and the theoretical range of the score is 0 to 110 [15, 16].

Methods

Aims and objective

- To assess the efficacy of mometasone furoate nasal spray in the treatment of acute rhinosinusitis

Inclusion criteria

- Patients aged 12 or more years with signs and symptoms of acute rhinosinusitis for more than 7 days but less than 28 attending ear, nose, and throat (ENT) OPD, NMCTH
- Patients who give consent

Exclusion criteria

- Less than 12 years
- Patient with chronic rhinosinusitis (or sinus or nasal surgery for this condition within 6 months before screening)
- Atrophic rhinitis and nasal polyps
- An allergy to corticosteroids or any other condition that would interfere with study evaluations
- An allergy to amoxicillin
- Patients who do not give consent

This study was conducted on patients aged 12 years and above who presented to the Otorhinolaryngology OPD of NMCTH, Attarkhel, Kathmandu, within a period from October 2018 to March 2020. This study was a single-blinded randomized controlled trial. In this study, patients and patient's party did not know in which treatment group they were included.

Patients presenting with symptoms of ARS and fulfilling the criteria as per the Rhinosinusitis Task Force of the American Academy of Otolaryngology-Head and Neck Surgery (i.e., 2 major or 1 major with 2 minor symptoms) were divided randomly through a computerized lottery system into groups A and group B, where group A was treated with amoxicillin 500 mg thrice daily for 7 days and group B with amoxicillin 500 mg thrice daily for 7 days with a combination of MFNS 50 μg 2 puff in each nostril two times a day for 7 days.

Detailed history using questionnaires for the patient's symptoms was taken, and any obstructive and infective causes were noted. Detailed clinical examination of nose (anterior rhinoscopy, posterior rhinoscopy), ear, throat, head, and neck examination thoroughly for any infective or obstructive cause was performed to confirm the diagnosis of ARS and probable etiology. The efficacy of treatment was assessed in terms of the Sino-Nasal Outcome Test-22 questionnaire. Patients were prescribed the same brand of drug. Patients not showing signs of improvement within 3 days or patients showing signs of complication were treated with higher antibiotics and withdrawn from the study.

Data analysis

Software Package for Statistical Analysis (SPSS) windows version 16 was used for data analysis. The graphical representations as pie chart, bar diagram, and line diagram were used for the presentation of gender, age, and symptoms score of patients before and after the treatment. Wilcoxon signed-rank test was used to compare the before and after treatment in each group. Mann-Whitney U was used to analyze the comparison of treatment between groups A and B. A p-value of < 0.05 was considered significant.

Results

Gender distribution of patients

One-hundred twenty patients were included in this study. Among them, there were 81 females (67.5%) and 39 males (32.5%).

In group A, there were 21 (58.1%) male and 39 (41.9%) female patients, and in group B, there were 30% male (18) and 70% female (42).

The age of the patients ranged from 13 to 64 years with a mean age of 28.61 ± 11.73. The mean age of patients of group A was 27.48 ± 12.62 years and that of group B was 29.73 ± 10.76 years. The majority of patients were in the 18–35 years age group, i.e., 67 (55.8%), followed by patients in the age group of 36–55 years, i.e., 22 (19.3%) patients (Fig. 1).

The mean score before the treatment was 21.32 ± 11.29 and after the treatment with amoxicillin was 9.37 ± 6.55 with a mean difference of 11.95 ± 7.41 (Fig. 2). Wilcoxon signed-rank test was used, and the mean decrease in score was found to be statistically significant with a *p*-value (< 0.001) (Table 1).

The mean score before the treatment was 26.68 ± 11.97 and after the treatment with amoxicillin and MFNS was 3.07 ± 3.46 with a mean difference of 23.61 ± 10.86. Wilcoxon signed-rank test was used, and the mean decrease in score was found to be statistically significant with a *p*-value (< 0.001) (Table 2).

It was found that after treatment, the mean score with the amoxicillin group was 9.31 ± 6.55 and that of amoxicillin with the MFNS group was 3.07 ± 3.46, and their mean difference was 6.3 ± 0.95. Mann-Whitney *U* test was used, and the mean decrease in score was found to be statistically significant ($p < 0.001$) (Table 3).

Discussion

This study included 120 patients who presented with symptoms of rhinosinusitis. All patients were diagnosed clinically and treated either with amoxicillin alone or with a combination of mometasone furoate nasal spray and amoxicillin.

This study demonstrated that MFNS administered twice a day along with antibiotics would help patients to get relief of symptoms in patients with ARS and help them to return to their day-to-day activity as earliest as possible.

In the study conducted by Meltzer et al., patients were treated for 21 days with amoxicillin clavulanate potassium and randomized to receive concurrent mometasone furoate nasal spray (MFNS) 400 µg, twice daily in 200 patients or placebo spray, and twice daily in 207 patients. Patient-recorded twice-daily symptom scores showed that adjunctive treatment with MFNS caused a significantly greater decrease in total symptom scores and in individual scores of inflammatory symptoms associated with the obstruction process (headache, congestion, and facial pain) compared with placebo [17].

Nayak et al. conducted a study, in which 967 outpatients with computed tomographic scan-confirmed moderate to severe rhinosinusitis received amoxicillin clavulanate 875 mg, twice daily, for 21 days with adjunctive twice-daily MFNS 200 µg, MFNS 400 µg, or placebo nasal spray. As adjunctive therapy to oral antibiotic treatment, MFNS at doses of 200 µg or 400 µg, twice daily, was well tolerated and significantly more effective in reducing the symptoms of rhinosinusitis than antibiotic therapy alone [9].

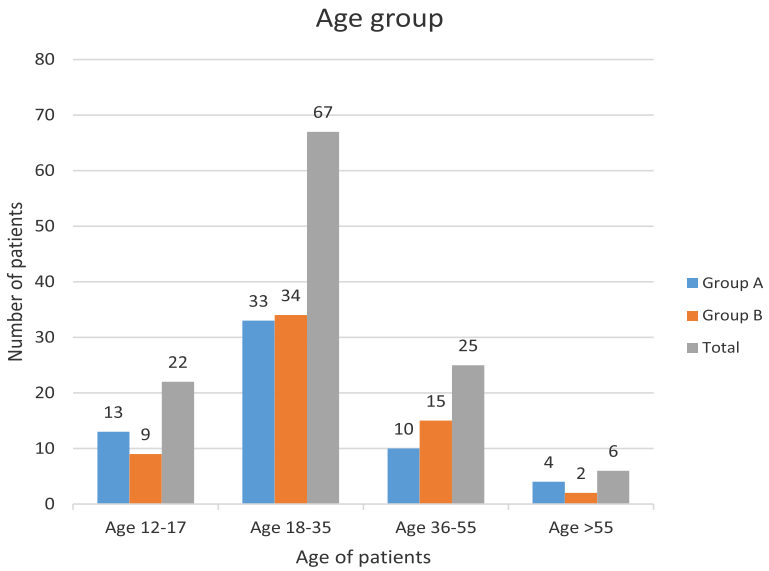

Fig. 1 Different age groups in patients

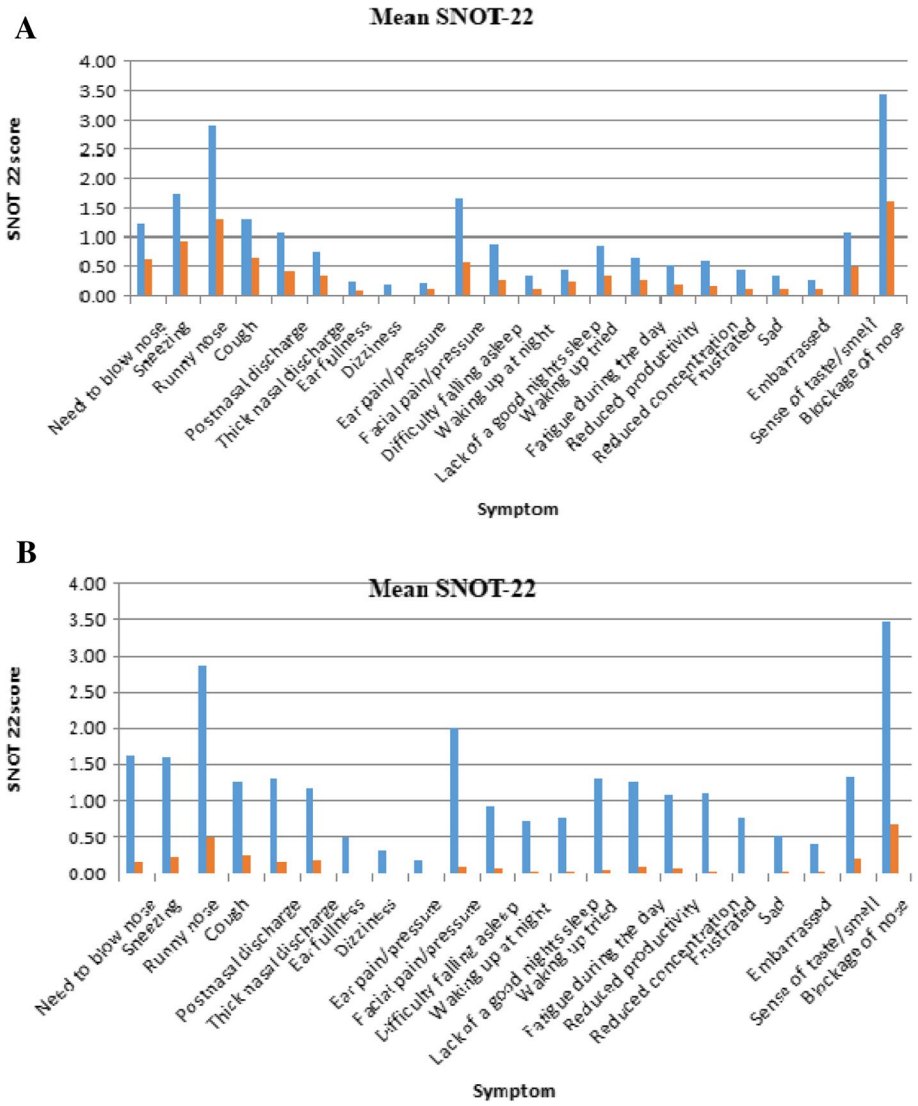

Fig. 2 Mean score of individual symptoms from SNOT-22 score in both groups. Blue color represents before treatment score, and orange color represents after treatment score. **A** Comparison of before and after treatment individual mean SNOT-22 score in group A patients. **B** Comparison of before and after treatment individual mean SNOT-22 score in group B patients. The mean score of all the symptoms was reduced in both groups

Table 1 Mean SNOT-22 score before and after treatment in group A

	Mean SNOT-22 score	Standard deviation	Mean difference	Standard deviation	|Z|	*p*-value
Before treatment	**21.32**	**11.29**	**11.95**	**7.41**	**6.74**	**< 0.001***
After treatment	**9.37**	**6.55**				

* **Wilcoxon signed-rank test**

In our study, the age ranged from 13 to 64 years with the mean age being 28.6 years. In a study done by Nayak et al. [9], the mean age of patients was 39 years, and the age ranged from 8 to 78 years. In another study done by Meltzer et al. [17] in 2000, the mean age of patients was 40.3 years, and the age ranged from 12 to 73 years. In a similar study conducted by Meltzer et al. [18] in 2005, the mean age of patients was 35 years. The majority of patients in our study were in the age group of 18–35 years, i.e., 67 (55.8%) followed by patients in the age group of 36–55 years, i.e., 22 (19.3%) patients. Similar to our study in all the abovementioned studies, the mean

Table 2 Mean SNOT-22 score before and after treatment in group B

	Mean SNOT-22 score	Standard deviation	Mean difference	Standard deviation	|Z|	*p*-value
Before treatment	**26.68**	**11.97**	**23.61**	**10.86**	**6.73**	**< 0.001***
After treatment	**3.07**	**3.46**				

* **Wilcoxon signed-rank test**

Table 3 Comparison between mean SNOT-22 of group A and group B

After treatment	Number	Mean	Standard deviation	Mean difference	Standard deviation	|Z|	*p*-value
Group A	60	9.37	6.55	6.300	0.95	5.89	< 0.001*
Group B	60	3.07	3.46				

* **Mann-Whitney *U* test**

age of the patients was in the adult group; we can say that ARS is more common in adults.

In our study, among 120 patients, most of them were females, i.e., 67.5% (81), and 32.5% were males (39) with male to female ratio being 1:2. The study conducted by Meltzer et al. in 2000 had 64% females (260) and 36% males (147) with male to female ratio being 1:1.7 [17]. In the study conducted by Nayak et al., there were 58.4% females (564) and 41.6% males (403) with male to female ratio being 1:1.4 [9]. Similar to this study, all the abovementioned studies had a higher incidence of ARS among females. Also, in all the abovementioned studies, most of the patients were in the reproductive age group. Females tend to have more close contact with young children who are more prone to upper respiratory tract infections. Therefore, females in their reproductive age group were more prone to acquire ARS.

In our study, there was a significant improvement in symptoms of blockage of the nose, thick nasal discharge, and facial pain in both groups. Similar to the abovementioned study, there was a decrease in the mean score of blockage of the nose, thick nasal discharge, and facial pain in both groups. However, there was a greater improvement in the symptom in patients using amoxicillin with MFNS (Fig. 3).

In our study, there was a significant improvement in cough and postnasal discharge in both groups. However, the study conducted by Nayak et al. [9] and Meltzer

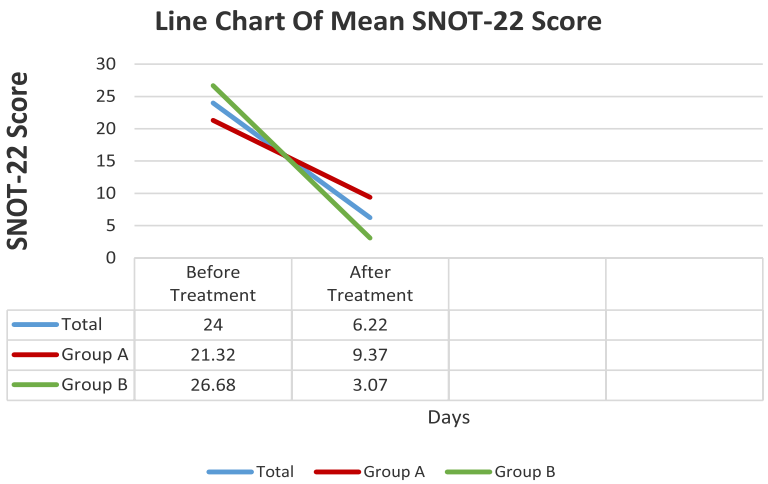

Fig. 3 Mean total SNOT-22 score of groups A and group B before and after treatment. Blue color represents all patients receiving the treatment. Red color represents all patients in group A. Green color represents all patients in group B. The overall SNOT-22 mean score in all patients before the treatment was 24 ± 11.87 and after the treatment was 6.22 ± 6.1. The overall SNOT-22 mean score in patients before the treatment in groups A and group B was 21.32 ± 11.29 and 26.68 ± 11.92, respectively. The overall SNOT-22 mean score in patients after the treatment in group A was 9.37 ± 6.55 and in group B was 3.07 ± 3.46. The line graph shows greater improvement in the mean SNOT-22 after treatment in patients in group B receiving amoxicillin and mometasone furoate nasal spray

et al.[27] in 2000 did not show a significant improvement in symptoms in amoxicillin with the MFNS group compared to the amoxicillin group.

Our study was able to see the effect of ARS on a patient's life causing a troublesome impact on daily activities. Symptoms like difficulty falling asleep, waking up at night, lack of a good night's sleep, waking up tired, fatigue during the day, reduced productivity, reduced concentration, frustration, sad, and embarrassed were assessed. All the patients receiving MFNS had significant improvement in these symptoms.

Our study showed significant improvement in overall SNOT-22 symptoms score in patients receiving MFNS with amoxicillin. It was similar to the studies conducted by Nayak et al. and Meltzer et al. in 2000 that showed an addition of intranasal corticosteroid; MFNS to antibiotics significantly reduces symptoms of acute rhinosinusitis compared with amoxicillin alone [9, 17].

Conclusion

In this study, there was an improvement in symptoms of ARS in both the groups receiving amoxicillin alone or amoxicillin combined with MFNS. We can conclude that amoxicillin alone or amoxicillin combined with MFNS was effective in reducing the symptoms of ARS. However, as adjunctive therapy to oral antibiotic treatment, mometasone furoate nasal spray was significantly more effective in reducing the symptoms of ARS than antibiotic therapy alone.

Abbreviations

ARS	Acute rhinosinusitis
MF	Mometasone furoate
MFNS	Mometasone furoate nasal spray
NMCTH	Nepal Medical College and Teaching Hospital
PNS	Paranasal sinuses
URI	Upper respiratory infection

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Authors' contributions

SS has written all the articles under the guidance of RRJ. All data analysis, interpretation, and literature review were done by SS and SS under the guidance of RRJ. The authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Declarations

Ethics approval and consent to participate

The ethical approval was taken from the Institutional Review Committee (IRC) of Nepal Medical College and Teaching Hospital (NMCTH) before commencing the study. Consent to Participate: Informed written consent to participate in the study was provided by all the participants or parents/ guardians of patients under 16 years old.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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