

Efficacy Of Clarithromycin Versus Oral Steroids In Reducing The Grading Of Nasal Polyps In Pre-Operative Patients Of Functional Endoscopic Sinus Surgery

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Abstract

Objective: To compare the use of oral steroids and clarithromycin in the reduction of Nasal polyp score in pre-operative patients of FESS.

Methods: After the ethical approval from the institutional review board, this comparative study was conducted at the Department of Otorhinolaryngology, Head and Neck Surgery, Rawalpindi Teaching Hospital, Rawalpindi Medical University, Rawalpindi from December 2023 to May 2024. Through non-probability consecutive sampling, 60 patients aged between 18-60 years, with Bilateral Nasal polyps and clinically Grade 4, were included in the study.

Results: In terms of endoscopic scores, before treatment (Table 2), Group A had a mean score of 3.1 ± 0.6 , while Group B had a higher baseline score of 3.6 ± 0.7 , with a statistically significant difference between the two groups ($p = 0.009$). After treatment, the mean endoscopic score in Group A decreased to 2.3 ± 0.70 , while in Group B, it decreased more substantially to 1.5 ± 0.56 . This difference in post-treatment scores was highly significant ($p < 0.0001$) (Figure 1). The mean reduction in the endoscopic score was 0.8 ± 0.40 in Group A and 2.03 ± 0.9 in Group B, indicating a significantly greater decrease in Group B ($p < 0.0001$).

Conclusion: Clarithromycin has more anti-polyp effect in terms of size reduction than oral steroids, which provides a strong recommendation towards the management of FESS patients through pre-operative use of the drug.

Keywords: Oral steroids, Clarithromycin, nasal polyps, FESS, Steroids, Antibiotics, Endoscopy, Treatment Outcome.

Introduction

Nasal polyposis is one of the major presentations of chronic rhinosinusitis (CRS), which poses a considerable burden of disease.¹ The pathological changes are characterised by chronic inflammation, which is mostly mediated by eosinophils and cytokines such as interleukins (IL-4, IL-5, and IL-13).² Therefore, the medical treatment of nasal polyps is focused on controlling the inflammation taking place within the sinuses, as well as improving the drainage of the sinuses.³ Oral corticosteroids are commonly employed as the first such drugs for polyps reduction, but carry several systemic side effects which restrict chronic use, particularly in patients who could require several courses before surgery.⁴⁻⁶ Macrolide antibiotic clarithromycin has emerged in the recent past as a drug of interest in the treatment of nasal polyposis. In addition to the antibacterial activity, the drug used has inflammatory effects and, therefore, influences the synthesis of cytokines and immune response.⁷ In particular, a study by Peric et al. showed that long-term, low-dose macrolide therapy reduces nasal polyp size, increases nasal airflow, and decreases levels of pro-inflammatory cytokines. This anti-inflammatory effect of clarithromycin makes the drug more preferable to corticosteroids, especially in patients with known steroid hypersensitivity or those who are prone to developing steroid-related complications.^{8,9} Bezerra et al., have also shown that the immunomodulatory effects of clarithromycin result in a decrease in mucus secretion and eosinophilic inflammation in patients with CRS and nasal polyposis.¹⁰ Few studies have been conducted comparing clarithromycin with oral steroids in an attempt to downgrade nasal polyps. In a randomised controlled trial, Lin et al. have shown that an antibiotic clarithromycin was

Contributions:

AJ, SC, AB, SS, AU - Conception, Design
AJ, SC, SM - Acquisition, Analysis, Interpretation
AJ, SC, AB, SS, AU - Drafting
AJ, SC, SM - Critical Review

All authors approved the final version to be published & agreed to be accountable for all aspects of the work.

Conflicts of Interest: None

Financial Support: None to report

Potential Competing Interests: None to report

Institutional Review Board Approval

No. 4822/RTH,Rwp.

19-09-2023

Rawalpindi Teaching Hospital

Review began 01/01/2025

Review ended 01/09/2025

Published 29/09/2025

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How to cite this article: Javaid A, Chaudhry S, Masood S, Bushra A, Sahar S, Umara A. Efficacy Of Clarithromycin Versus Oral Steroids In Reducing The Grading Of Nasal Polyps In Pre-Operative Patients Of Functional Endoscopic Sinus Surgery. JRM. 2025 Sep. 29;29(3). <https://doi.org/10.37939/jrmc.v29i3.2805>

superior to oral steroids in the reduction in the size of nasal polyps before Functional Endoscopic Sinus Surgery (FESS).¹¹ Similarly, in another clinical trial by Tetik et al., it was discovered that clarithromycin with saline nasal irrigation has a comparable effect as oral steroids in polyp size reduction and symptom relief without the systemic side effects.¹² Nevertheless, such findings are optimistic; thus, it is crucial to use the existing body of evidence more intensively and conduct large-scale studies to confirm these outcomes, along with the development of specific guidelines for the use of clarithromycin as a steroid-sparing agent in nasal polyposis. The present study aims to compare the use of oral steroids and clarithromycin in the reduction of the Nasal polyp score in pre-operative patients of FESS.

Materials And Methods

After the ethical approval from the institutional review board, this comparative study was conducted at the Department of Otorhinolaryngology, Head and Neck Surgery, Rawalpindi Teaching Hospital, Rawalpindi Medical University, Rawalpindi, from December 2023 to May 2024. Through non-probability consecutive sampling, 60 patients aged between 18-60 years, with Bilateral Nasal polyps and clinically Grade 4, were included in the study. Patients with any history of Hypertension, Type I or II diabetes, head trauma, Pregnancy or lactation, Systemic infection, Aspirin intolerance, peptic ulcer, liver diseases or taking any concomitant medications that would interact with prednisolone or clarithromycin were excluded from the study. Patients were randomly divided into two groups: Group A (Oral steroids) or Group B (Clarithromycin), with 30 patients in each group. After initial assessment and ethical approval, and consent, patients in group A were administered Prednisolone 60 mg and tapered on the 7th day total of 2 weeks. Patients in group B were administered Clarithromycin 250mg, 8 hourly for 2 weeks. On completion, Nasal Endoscopy was done with a 0 nasal endoscope under Local anaesthesia, and the Endoscopic score was calculated for comparison. The data were analysed using descriptive statistics to compare the mean reduction in endoscopic score between the two groups. A paired t-test was used to compare pre- and post-treatment endoscopic scores within each group, while an independent t-test was applied to compare the two groups. Statistical significance was set at a p-value of < 0.05. SPSS version 26 was used for data analysis.

Results

The demographic characteristics of the study participants in both treatment groups were comparable. The mean age of patients in Group A (oral steroids) was 44.26 ± 12.2 years, while in Group B (clarithromycin), it was 45.3 ± 11.5 years, with no statistically significant difference between the groups ($p = 0.813$). The gender distribution was also similar, with 50% male and 50% female participants in Group A, compared to 53% male and 47% female in Group B, showing no significant difference ($p = 0.731$) (Table 1).

Table 1: Demographic parameters of the study participants

Parameters	Group A-Oral Steroids (n=30)	Group B Clarithromycin (n=30)	P value
Age	44.26±12.2	45.3±11.5	0.813
Gender			0.731
Male	15 (50%)	16 (53%)	
Female	15 (50%)	14 (47%)	

In terms of endoscopic scores, before treatment (Table 2), Group A had a mean score of 3.1 ± 0.6 , while Group B had a higher baseline score of 3.6 ± 0.7 , with a statistically significant difference between the two groups ($p = 0.009$).

Table 2: Endoscopic score of the study participants before and after treatment in both study groups

Endoscopic Score	Group A-Oral Steroids (n=30)	Group B Clarithromycin (n=30)	P value
Before treatment	3.1±0.6	3.6±0.7	0.009
After treatment	2.3±0.70	1.5±0.56	<0.0001
Mean Decrease	0.8±0.40	2.03±0.9	<0.0001
P Value	<0.0001	<0.0001	

After treatment, the mean endoscopic score in Group A decreased to 2.3 ± 0.70 , while in Group B, it decreased more substantially to 1.5 ± 0.56 . This difference in post-treatment scores was highly significant ($p < 0.0001$) (Figure 1). The mean reduction in the endoscopic score was 0.8 ± 0.40 in Group A and 2.03 ± 0.9 in Group B, indicating a significantly greater decrease in Group B ($p < 0.0001$) (Figure 2). Both groups demonstrated significant improvement from baseline within their respective treatments, with a p-value of < 0.0001 for both groups.

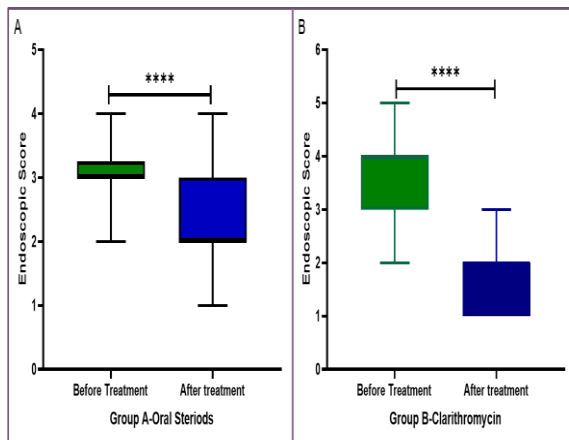


Figure 1: Difference in endoscopic score before and after treatment. A: Difference in Group A, B: Difference in Group B

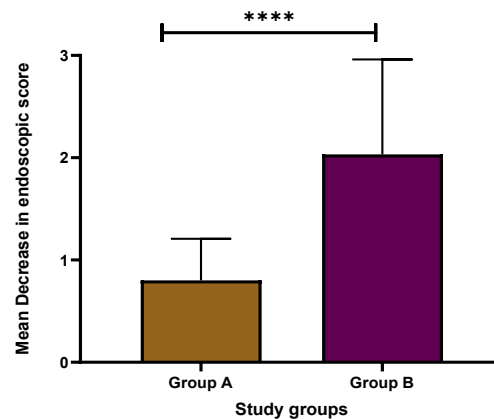


Figure 2: Comparison of mean decrease in the endoscopic score in both study groups

Discussion

The result of this study indicates that clarithromycin was statistically more effective than oral steroids at reducing the grading of the nasal polyps in pre-operative FESS patients. The endoscopic improvement, evaluated through the endoscopic activity index (EAI), showed a mean reduction value 2.03 ± 0.9 for the subjects that received clarithromycin and a mean reduction value of 0.8 ± 0.40 for oral steroid, $p < 0.0001$. These results are consistent with several other studies conducted in the previous year that looked at the effectiveness of clarithromycin and oral steroids for nasal polyps.

The previous study has revealed the beneficial impacts of clarithromycin in relation to its anti-inflammatory and immunomodulatory activity in patients with CRS with NP.¹³ For example, Zhang et al, have shown in their cross-sectional study of patients with chronic sinusitis treated with low-dose macrolide therapy, including clarithromycin, that the latter helps to reduce the size of the nasal polyps and improve symptoms by altering the pro-inflammatory cytokine balance and preventing epithelial cell proliferation.¹⁴ This is in support of the current study, whereby clarithromycin exhibited a higher reduction in polyp size and endoscopic scores as compared to oral steroids.

On the other hand, oral CS, particularly prednisolone, has continued to be commonly attributed as a treatment for nasal polyps based on their strong anti-inflammatory properties.¹⁵ Though Fokkens and colleagues' work has supported the need for oral steroids in the short-term use for polyp size reduction and amelioration of nasal obstruction.¹⁶ But it is pertinent to note that this study's findings are in harmony with other findings that suggest that the advantage of steroids is not steady in the long run and is comparatively less enduring than that of macrolides. The oral steroid group did improve significantly ($p < 0.0001$), but this result was not quite as dramatic as in the clarithromycin group, which would suggest that macrolides may have some benefits for more protracted pre-surgery interventions for nasal polyps.¹⁷

The superior efficacy of clarithromycin observed in this study may be attributed to its dual role: apart from the antimicrobial activity of the compound, it has a more potent anti-inflammatory activity because it prevents neutrophil activation and mucus formation in the sinuses. This is quite different from the actions of steroids, wherein the after effects are short-term and normally handle the initial inflammation.¹⁸

The higher initial endoscopic polyp scores in Group B (clarithromycin) also exhibited that this did not seem to have influenced the outcome of the results; the clarithromycin group yielded greater reductions in polyp size than the group without the antibiotic. This implies that clarithromycin should be more effective in patients with the most severe form of polyposis.¹⁹

Conclusions

Therefore, it can be concluded from the results of this study that clarithromycin has a more anti-polyp effect in terms of size reduction than oral steroids, which provides a strong recommendation towards the management of FESS patients through pre-operative use of the drug. Future research that includes a larger number of participants should be conducted to validate these findings and report on other follow-up effects.

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