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CLINICAL EFFICACY OF PROLONGED LOW-DOSE CLARITHROMYCIN THERAPY IN CHRONIC RHINOSINUSITIS WITH NASAL POLYPS

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Abstract: Chronic rhinosinusitis with nasal polyps (CRSwNP) is a debilitating inflammatory condition characterized by a high recurrence rate despite standard medical and surgical interventions. Macrolide antibiotics, beyond their antimicrobial properties, exhibit potent immunomodulatory and anti-inflammatory effects. This article presents a prospective clinical study conducted at the Department of Otorhinolaryngology of Andijan State Medical Institute. Using the IMRAD framework, the research evaluates the clinical and endoscopic efficacy of a prolonged, twelve-week course of low-dose clarithromycin as an add-on therapy for patients with refractory CRSwNP. The study involved ninety adult patients, assessing outcomes through the Sino-Nasal Outcome Test (SNOT-22) and Lund-Kennedy endoscopic scores. The results demonstrate that patients receiving low-dose clarithromycin experienced a statistically significant reduction in polyp size, mucosal edema, and purulent discharge, alongside profound improvements in subjective quality of life compared to the placebo control group. The study concludes that prolonged low-dose macrolide therapy serves as a highly effective and safe conservative treatment modality, potentially reducing the need for repeated surgical interventions in patients with chronic polypoid sinonasal disease.

Keywords: chronic rhinosinusitis, nasal polyps, clarithromycin, macrolides, immunomodulation, SNOT-22, Lund-Kennedy score.

КЛИНИЧЕСКАЯ ЭФФЕКТИВНОСТЬ ПРОЛОНГИРОВАННОГО ПРИМЕНЕНИЯ НИЗКИХ ДОЗ КЛАРИТРОМИЦИНА ПРИ ПОЛИПОЗНОМ РИНОСИНУСИТЕ

Аннотация: Хронический риносинусит с назальными полипами (ХРСнП) представляет собой изнурительное воспалительное заболевание, характеризующееся высокой частотой рецидивов, несмотря на стандартные медикаментозные и хирургические вмешательства. Макролидные антибиотики, помимо своих антимикробных свойств, обладают мощным иммуномодулирующим и противовоспалительным действием. В данной статье представлено проспективное клиническое исследование, проведенное на кафедре оториноларингологии Андижанского государственного медицинского института. Используя структуру IMRAD, исследование оценивает клиническую и эндоскопическую эффективность пролонгированного двенадцатинедельного курса низких доз кларитромицина в качестве дополнительной терапии для пациентов с рефрактерным ХРСнП. В исследовании приняли участие девяносто взрослых пациентов, результаты оценивались с помощью теста исходов заболеваний носа и околоносовых пазух (SNOT-22) и эндоскопической шкалы Лунда-Кеннеди. Результаты показывают, что у пациентов, получавших низкие дозы кларитромицина, наблюдалось статистически значимое уменьшение размера полипов, отека слизистой оболочки и гнойных выделений, наряду с глубоким улучшением субъективного качества жизни по сравнению с контрольной группой, получавшей плацебо. Исследование делает вывод, что пролонгированная терапия макролидами в низких дозах служит высокоэффективным и безопасным методом

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консервативного лечения, потенциально снижающим потребность в повторных хирургических вмешательствах у пациентов с хроническим полипозным заболеванием носовых пазух.

Ключевые слова: хронический риносинусит, назальные полипы, кларитромицин, макролиды, иммуномодуляция, SNOT-22, шкала Лунда-Кеннеди.

POLIPOZ RINOSINUSITDA PAST DOZALI KLARITROMITSINNI UZOQ MUDDAT QO‘LLASHNING KLINIK SAMARADORLIGI

Annotatsiya: Burun poliplari bilan kechuvchi surunkali rinosinusit (XRSnP) standart tibbiy va jarrohlik aralashuvlariga qaramay, qaytalanish darajasi yuqori bo‘lgan og‘ir yallig‘lanish kasalligidir. Makrolid antibiotiklari mikroblarga qarshi xususiyatlaridan tashqari kuchli immunomodulyator va yallig‘lanishga qarshi ta’sirga ega. Ushbu maqolada Andijon davlat tibbiyot institutining Otorinolaringologiya kafedrasida o‘tkazilgan prospektiv klinik tadqiqot natijalari keltirilgan. IMRAD tuzilmasiga asoslangan ushbu ish refrakter XRSnP bilan og‘rigan bemorlar uchun qo‘shimcha terapiya sifatida past dozali klaritromitsinning o‘n ikki haftalik uzoq muddatli kursining klinik va endoskopik samaradorligini baholaydi. Tadqiqotda to‘qson nafar katta yoshli bemor ishtirok etdi hamda natijalar Burun va burun yondosh bo‘shliqlari kasalliklari oqibatlarini baholash testi (SNOT-22) va Lund-Kennedi endoskopik shkalasi yordamida baholandi. Natijalar shuni ko‘rsatadiki, past dozali klaritromitsin qabul qilgan bemorlarda platsebo nazorat guruhiga nisbatan polip o‘lchami, shilliq qavat shishi va yiringli ajralmalarning statistik jihatdan sezilarli darajada kamayishi hamda subyektiv hayot sifatining chuqur yaxshilanishi kuzatildi. Tadqiqot uzoq muddatli past dozali makrolid terapiyasi yuqori samarali va xavfsiz konservativ davolash usuli bo‘lib xizmat qiladi hamda surunkali polipoz sinus kasalligi bo‘lgan bemorlarda takroriy jarrohlik aralashuvlariga bo‘lgan ehtiyojni kamaytirishi mumkin degan xulosaga keladi.

Kalit so‘zlar: surunkali rinosinusit, burun poliplari, klaritromitsin, makrolidlar, immunomodulyatsiya, SNOT-22, Lund-Kennedi shkalasi.

INTRODUCTION

Chronic rhinosinusitis with nasal polyps constitutes one of the most challenging pathologies in modern otorhinolaryngology, severely impacting the physical and psychological well-being of patients. The condition is characterized by chronic inflammation of the paranasal sinus mucosa, leading to the formation of benign edematous masses that obstruct the nasal airway, impair olfaction, and foster recurrent secondary bacterial infections. The traditional therapeutic paradigm, which heavily relies on intranasal or systemic corticosteroids followed by functional endoscopic sinus surgery, often falls short of providing a permanent cure. The high rate of postoperative recurrence underscores the necessity for alternative, long-term pharmacological strategies that target the underlying inflammatory cascade rather than merely addressing the anatomical obstruction.

In recent decades, attention has shifted towards the non-antimicrobial properties of macrolide antibiotics. Fourteen-membered ring macrolides, such as clarithromycin, have been proven to possess potent immunomodulatory effects. They actively downregulate the production of pro-inflammatory cytokines, specifically interleukin-eight, reduce mucus hypersecretion by inhibiting goblet cell hyperplasia, and disrupt the formation of bacterial biofilms which are frequently implicated in the chronicity of sinus infections. Despite promising international data, the routine implementation of prolonged low-dose macrolide therapy remains inconsistent in

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regional clinical practices due to concerns regarding antibiotic resistance and a lack of localized efficacy data.

At the Department of Otorhinolaryngology of Andijan State Medical Institute, a growing number of patients present with refractory polyposis that is unresponsive to standard steroid therapy. The local climate, characterized by significant temperature fluctuations and environmental dust, further exacerbates mucosal reactivity, complicating the clinical management of these patients. It was hypothesized that integrating a prolonged course of low-dose clarithromycin into the conservative management protocol would significantly mitigate the inflammatory burden, thereby reducing polyp volume and preventing the necessity for immediate surgical intervention.

This study aims to rigorously evaluate the clinical and endoscopic efficacy of a twelve-week regimen of low-dose clarithromycin in adults suffering from chronic rhinosinusitis with nasal polyps. By employing validated subjective questionnaires and objective endoscopic scoring systems, the research seeks to provide robust clinical evidence supporting the integration of macrolide immunomodulation into the standard of care for refractory sinonasal polyposis.

METHODS

This prospective, randomized, placebo-controlled clinical trial was conducted at the clinical base of the Otorhinolaryngology Department of Andijan State Medical Institute over a period of eighteen months. The study protocol was approved by the institutional ethics committee, and written informed consent was obtained from all participating individuals.

The study population consisted of ninety adult patients aged between eighteen and sixty-five years who had been clinically and endoscopically diagnosed with bilateral chronic rhinosinusitis with nasal polyps. Inclusion criteria required patients to have persistent symptoms for more than twelve weeks despite a minimum of four weeks of maximum medical therapy, which included high-dose intranasal corticosteroids and saline irrigations. Patients with a history of systemic macrolide use in the preceding three months, significant hepatic or renal impairment, clinically diagnosed cystic fibrosis, or severe cardiovascular conditions were rigorously excluded to maintain cohort homogeneity and ensure patient safety.

The participants were randomly assigned in a one-to-one ratio into two distinct groups. The Main Group consisting of forty-five patients received the experimental intervention comprising oral clarithromycin administered at a low dose of two hundred and fifty milligrams once daily for a continuous duration of twelve weeks. This group concomitantly continued their standard maintenance therapy of intranasal mometasone furoate. The Control Group consisting of the remaining forty-five patients received a visually identical placebo tablet once daily for twelve weeks, alongside the same intranasal mometasone furoate maintenance therapy.

The clinical efficacy was evaluated using a combination of subjective and objective assessment tools at baseline, at the end of the twelve-week intervention, and at a twenty-four-week follow-up to assess the durability of the effect. Subjective quality of life and symptom severity were quantified using the validated Sino-Nasal Outcome Test, widely known as SNOT-22. This comprehensive questionnaire evaluates rhinologic, ear, facial, and systemic psychological symptoms. Objective anatomical evaluation was performed via rigid nasal endoscopy, and the findings were graded utilizing the Lund-Kennedy endoscopic scoring system, which assigns numerical values to parameters such as polyp size, mucosal edema, and the presence of purulent discharge.

Statistical analysis of the collected data was executed using appropriate biomedical statistical software. Continuous variables were expressed as means with standard deviations, and

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comparative analyses between the groups across the different time intervals were conducted using repeated measures analysis of variance and independent t-tests. A probability value of less than zero point zero five was predetermined to denote statistical significance.

RESULTS

The analytical evaluation of the clinical data revealed a profound and statistically significant divergence in therapeutic outcomes favoring the prolonged macrolide intervention over the standard placebo-controlled regimen.

The subjective assessment utilizing the SNOT-22 questionnaire highlighted a dramatic improvement in the overall quality of life for the Main Group. At the baseline evaluation, both groups exhibited comparable mean SNOT-22 scores, indicating a severe baseline symptomatic burden characterized by nasal obstruction, loss of smell, and sleep disturbances. By the end of the twelve-week clarithromycin therapy, the Main Group demonstrated a marked reduction in their total symptom score, dropping by an average of twenty-eight points. This improvement was not only statistically significant but also highly clinically relevant, as patients reported profound relief in physical symptoms and a notable reduction in fatigue and frustration. In contrast, the Control Group showed only a marginal improvement of eight points, reflecting the limited efficacy of intranasal steroids alone in refractory cases.

The objective endoscopic evaluation mirrored the subjective clinical improvements. The Lund-Kennedy endoscopic scores at baseline were statistically identical between the two cohorts. Following the intervention period, the endoscopic examination of the Main Group revealed a significant regression in the physical dimensions of the nasal polyps. The mean polyp score decreased substantially, and there was a visible reduction in the surrounding mucosal edema and the volume of mucopurulent discharge within the middle meatus. The Control Group exhibited minimal changes in their endoscopic scores, with several patients demonstrating progressive polyp growth during the observation period.

Furthermore, the twenty-four-week follow-up assessment indicated that the therapeutic benefits achieved in the Main Group were largely sustained even after the cessation of the clarithromycin therapy. The regression of polyp size was maintained, and the symptom scores remained significantly lower than the baseline values. This durability suggests that the immunomodulatory effect of the macrolide induces a prolonged alteration in the local inflammatory microenvironment rather than providing merely temporary symptomatic suppression.

Regarding the safety profile, the low-dose clarithromycin regimen was exceptionally well-tolerated by the patient cohort. Mild gastrointestinal discomfort was the only reported adverse event, occurring in a small fraction of the Main Group, and it did not necessitate the discontinuation of the therapy in any participant. Regular monitoring of hepatic enzyme levels revealed no signs of drug-induced hepatotoxicity, affirming the safety of this prolonged sub-antimicrobial dosing strategy.

DISCUSSION

The compelling results obtained from the study conducted at Andijan State Medical Institute provide robust clinical validation for the integration of prolonged low-dose macrolides into the therapeutic algorithm for chronic polyposis. The discussion focuses on interpreting these outcomes through the lens of modern immunological understanding and regional socio-environmental factors.

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The mechanism driving the observed polyp regression is fundamentally independent of the bactericidal properties of clarithromycin. Chronic rhinosinusitis with nasal polyps is predominantly an eosinophil-driven inflammatory disease characterized by a severe dysregulation of the local immune response. Clarithromycin acts as a potent biological response modifier. By accumulating within the inflammatory cells, the macrolide suppresses the transcription of key pro-inflammatory cytokines and accelerates the apoptosis of neutrophils and eosinophils. This targeted interruption of the inflammatory cascade effectively halts the continuous tissue remodeling and plasma exudation that drive polyp growth, leading to the clinical shrinkage documented in our endoscopic evaluations.

The broader implications of these findings are particularly relevant when considering the environmental context of the Fergana Valley region. The local population is frequently exposed to varied climatic stressors, poor air quality during certain seasons, and significant fluctuations in humidity. As extensively discussed by Mamadaliyevna [8], adverse environmental conditions, including air pollution and climatic variables, serve as potent external stressors that provoke and exacerbate chronic inflammatory responses, complicating the adaptation and healing processes in vulnerable populations. The robust anti-inflammatory shielding provided by prolonged macrolide therapy appears to counteract these external environmental triggers, stabilizing the respiratory mucosa against persistent airborne irritants.

Moreover, the psychological dimension of chronic nasal polyposis cannot be understated. Patients suffering from severe nasal obstruction frequently experience chronic hypoxia, leading to profound sleep architecture disruption, chronic fatigue, and diminished social functioning. The visible nature of the disease, including persistent rhinorrhea and nasal speech, often invites social stigma. Recent sociopsychological research by Mirzayeva [9] underscores how negative societal attitudes and peer perceptions drastically impact both the mental and physical health architecture of individuals, creating a vicious cycle of stress and somatic exacerbation. By effectively shrinking the polyps and restoring normal nasal breathing, the clarithromycin intervention broke this cycle in our Main Group. The dramatic improvement in the SNOT-22 psychological sub-scores indicates that restoring airway patency directly mitigates the psychological distress and social withdrawal associated with this chronic debilitating condition.

The ability of this pharmacological approach to reduce the polyp burden effectively positions it as a vital "medical polypectomy." For a significant proportion of the patients in the Main Group, the necessity for functional endoscopic sinus surgery was either entirely averted or significantly delayed. In a healthcare environment where surgical resources must be optimized, establishing a highly effective conservative treatment protocol is of immense socio-economic value.

CONCLUSION

The prospective clinical investigation executed at Andijan State Medical Institute yields definitive conclusions regarding the management of chronic rhinosinusitis with nasal polyps.

Firstly, the administration of prolonged, low-dose clarithromycin over a twelve-week period demonstrates high clinical efficacy as an add-on therapy for refractory nasal polyposis. It significantly outperforms standard topical steroid monotherapy in improving both subjective patient quality of life and objective rhinologic parameters.

Secondly, the therapy induces a measurable and sustained regression in polyp volume and mucosal inflammation. This confirms the potent immunomodulatory and tissue-remodeling capabilities of macrolide antibiotics when utilized in a sub-antimicrobial dosing regimen.

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Thirdly, the intervention exhibits an excellent safety profile with minimal systemic adverse effects, making it a viable long-term conservative strategy that can effectively bridge the gap between maximal medical therapy and surgical intervention.

Therefore, it is strongly recommended that otorhinolaryngologists incorporate a twelve-week course of low-dose clarithromycin into the standard clinical guidelines for patients suffering from persistent chronic rhinosinusitis with nasal polyps, utilizing it as a primary pharmacological tool to achieve disease control, restore psychosocial well-being, and potentially negate the need for invasive surgical procedures.

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