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ROLE OF NASOPHARYNGEAL STATUS IN THE TREATMENT OF TYPE 2 PRIMARY DIFFUSE CHRONIC RHINOSINUSITIS IN ADULT PATIENTS

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The study was devoted to evaluating the role of the nasopharyngeal zone in the course and treatment of type 2 primary diffuse chronic rhinosinusitis in adults. A total of 339 patients were examined, of whom 68 (20.06 %) had concomitant chronic nasopharyngitis. At the second stage, 58 patients with chronic nasopharyngitis and 91 patients without it received standard therapy supplemented with the mucosal bacterial vaccine Lantigen B, whereas 36 control patients received standard treatment alone. Clinical, videoendoscopic, functional, microbiological, and immunological assessments were performed. Patients with chronic nasopharyngitis more frequently demonstrated grade I adenoid vegetations, greater clinical severity, pronounced nasopharyngeal dysbiosis, and middle-ear involvement. The addition of Lantigen B resulted in a significantly greater reduction in symptoms, normalization of the nasopharyngeal microbiome and secretory IgA levels in oropharyngeal secretions, and a lower incidence of acute otitis media and otitis media with effusion, particularly in patients with concomitant chronic nasopharyngitis.

Key words: chronic rhinosinusitis, chronic nasopharyngitis, otitis media, allergy, pharyngeal tonsil, bacterial complications, microbiome, dysbiosis, immunocorrection, mucosal vaccine.

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РОЛЬ СТАНУ НАЗОФАРИНГЕАЛЬНОЇ ЗОНИ ПРИ ЛІКУВАННІ ПЕРВИННОГО ДИФУЗНОГО ХРОНІЧНОГО РИНОСИНУСИТУ ТИПУ 2 У ПАЦІЄНТІВ ДОРОСЛОГО ВІКУ

Дослідження було присвячене оцінці ролі стану назофарингеальної зони у перебігу та лікуванні первинного дифузного хронічного риносинуситу типу 2 у дорослих. Обстежено 339 пацієнтів, серед яких у 68 (20,06 %) діагностовано супутній хронічний назофарингіт. На другому етапі 58 пацієнтів із хронічним назофарингітом та 91 пацієнт без нього отримували стандартну терапію з додаванням мукозальної бактеріальної вакцини Лантіген Б; 36 пацієнтів контрольної групи отримували лише стандартне лікування. Застосовували клінічне, відеоендоскопічне, функціональне, мікробіологічне та імунологічне дослідження. У пацієнтів із хронічним назофарингітом частіше виявляли аденоїдні вегетації I ступеня, тяжчі клінічні прояви, виражений дисбіоз та ураження середнього вуха. Додавання Лантігену Б забезпечувало достовірніше зменшення симптомів, нормалізацію мікробіому назофарингеальної зони і рівня секреторного IgA у ротоглотковому секреті та зниження частоти гострого середнього і секреторного отиту.

Ключові слова: хронічний риносинусит, хронічний назофарингіт, середній отит, алергія, глотковий мигдалик, бактеріальні ускладнення, мікробіом, дисбіоз, імунокорекція, мукозальна вакцина.

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From the perspective of the anatomical and functional characteristics of different parts of the respiratory tract, rhinosinusitis, nasopharyngitis, and so-called adenoiditis denote inflammatory diseases with different predominant localizations. However, these conditions have overlapping clinical manifestations due to the anatomical continuity and functional unity of the respiratory epithelium [2, 5]. At the same time, the nasopharynx has specific structural features: unlike the nasal cavity, where epithelial cells are located on a well-developed basement membrane with an underlying vascular layer, the epithelium covering the pharyngeal tonsil is in direct contact with lymphoid tissue. Therefore, damage to the ciliated epithelium during viral infection may involve not only the mucosal surface but also the pharyngeal tonsil, especially when a secondary bacterial component develops after acute respiratory infection.

The pharyngeal tonsil is considered a peripheral organ of the immune system and participates in the regulation of mucosal immunity of the nasal cavity and paranasal sinuses [2]. In children, it is a large exophytic lymphoid formation covered with ciliated epithelium, which directly contacts the lymphoid follicles and resembles the respiratory epithelium of the nasal cavity and sinuses [3]. In adults, the pharyngeal tonsil usually undergoes physiological involution; however, under conditions of chronic infection, allergy, or anatomical predisposition, residual adenoid tissue may persist and remain clinically significant. Persistent adenoids in adults are reported in 2.5 % of the general adult population, while their frequency among adult patients with chronic nasal obstruction may be considerably higher [6]. Regardless of size, residual pharyngeal tonsil tissue may become inflamed, presenting with mucosal edema, hyperemia, mucopurulent deposits, postnasal drainage, and symptoms related to the auditory tube and middle ear [10].

The lymphoadenoid tissue of the pharynx participates in antibacterial and antiviral defense through the production of interferons, lysozyme, antibodies, and maintenance of the normal upper-airway microbiota [1]. Therefore, impairment of this local protective system may contribute to the

coexistence of rhinosinusitis and nasopharyngeal inflammation [13, 15]. Although the relationship between rhinosinusitis and adenoiditis has been studied mainly in pediatric patients, poorly controlled allergic rhinitis, recurrent respiratory infections, type 2 chronic rhinosinusitis with or without nasal polyps, and recurrent auditory tube or middle-ear disorders in adults may also be associated with chronic inflammation of the nasopharyngeal zone [13].

The concept of upper-airway mucosal dysbiosis is also important. Microbiome imbalance may lead to the predominance of opportunistic microorganisms over commensals and contribute to bacterial complications [12]. However, it remains unclear whether dysbiosis is a primary factor in chronic rhinosinusitis or develops secondarily due to inflammation-induced changes in the local environment [11]. Conventional treatment of chronic rhinosinusitis includes corticosteroids, sometimes antibiotics, and surgery in refractory cases; nevertheless, the effectiveness of antibiotics remains controversial, and surgery does not always provide stable remission [8, 14]. Microbiome studies before and after endoscopic sinus surgery have shown that microbial composition may return to the preoperative state within several weeks [9], indicating that microbiome correction may require more complex approaches than mechanical restoration of drainage or antibacterial therapy alone [4].

The purpose of the study was to improve the treatment outcomes of adult patients with type 2 primary diffuse chronic rhinosinusitis and bacterial complications by assessing the status of the nasopharyngeal zone.

Materials and methods. The study was conducted from September 2022 to November 2025 at the Otorhinolaryngology Department of Odesa Regional Clinical Hospital.

At the first stage, 339 patients with type 2 chronic rhinosinusitis (T2 CRS) were assessed using complaints and medical history, videoendoscopic examination, functional evaluation of the auditory tube, and microbiological and immunological investigations. The patients were divided into those with concomitant chronic nasopharyngitis (CNP; 68 patients) and those without nasopharyngeal inflammation (271 patients). The exclusion criteria for the subsequent study were age under 18 years, pronounced structural changes in the nasal cavity, systemic and neoplastic diseases of the nose and paranasal sinuses, grade III or IV nasal polyposis, and refusal to participate. The inclusion criteria were age over 18 years, type 2 CRS without nasal polyps (CRSsNP), type 2 CRS with grade I or II nasal polyps (CRSwNP), purulent inflammation during exacerbations, dysbiosis of the nasopharyngeal zone between exacerbations, and written consent to participate. At the second stage, 58 patients with T2 CRS and CNP (Group A; 35 men and 23 women; mean age, 34.25±4.8 years) and 91 patients with T2 CRS without CNP (Group B; 55 men and 36 women; mean age, 38.25±5.2 years) received the bacterial vaccine Lantigen B in addition to standard treatment. The control group (CG) comprised 36 patients with T2 CRS without CNP (21 men and 15 women; mean age, 36.31±5.3 years) who received standard treatment without Lantigen B. The overall mean age was 35.75±6.8 years and did not differ significantly among the groups ($p>0.05$).

A 10-point visual analogue scale (VAS) was used before and after treatment to assess the overall severity of symptoms according to patient self-evaluation. After the patient had rated their condition, the physician interpreted the severity as mild (0–3 cm), moderate (3–7 cm), or severe (7–10 cm). During endoscopic examination, the physician assessed the severity of signs and symptoms before and after treatment using a 4-point MMS scale ranging from 0 to 3 points: 0, absent; 1, mild; 2, moderate; and 3, severe or very severe.

Standard bacteriological and microscopic methods were used for the qualitative and quantitative assessment of the nasopharyngeal microbiome. The study procedure involved endoscopically guided collection of material from the nasopharynx through the nasal cavity before and after treatment. The obtained material was inoculated onto a set of standard culture media. Because the nasopharynx contains abundant resident flora, the degree of dysbiosis was evaluated by direct inoculation onto differential diagnostic media using a calibrated loop. Cultivation was performed under aerobic, anaerobic, and reduced-oxygen conditions. Microbiological examination included identification of all microorganism species persisting on the nasopharyngeal mucosa. Microbial population levels were expressed as colony-forming units per milliliter of washings (CFU/mL).

Treatment was conducted in accordance with the current adapted clinical guidelines of the Ministry of Health of Ukraine: Order No. 499 of July 16, 2014 (acute respiratory infections), Order No. 1793 of October 13, 2023 (chronic rhinosinusitis), Order No. 181 of March 24, 2009 (chronic pharyngitis), and Clinical Guideline No. 00864 of November 30, 2017 (allergic rhinitis).

In addition to standard conservative basic therapy, patients in the main groups received a suspension of bacterial antigens obtained by controlled autolysis of microorganisms that are among the most frequent causative agents of respiratory tract infections (S. pneumoniae, S. pyogenes, B. catarrhalis, S. aureus, H. influenzae, and K. pneumoniae). Local immune processes were stimulated through absorption of bacterial antigens by the oral and pharyngeal mucosa. The simulation of foreign-agent entry through the oral mucosa enhances the production of circulating IgM and IgG, mucosal IL-1 and neutrophils, and secretory immunoglobulin A (sIgA) by submucosal plasma cells, which plays an

important role in protecting the respiratory mucosa. Therefore, to evaluate the effectiveness of immunocorrection as part of the comprehensive treatment of patients with type 2 primary diffuse CRS, we determined sIgA levels in oropharyngeal secretion (OPS) before and after treatment.

The product is registered in Ukraine under the trade name Lantigen B (UA/1857/01/01) and is available without a prescription. Lantigen B (Bruschettini S.r.l., Italy) was administered at a dose of 15 drops sublingually twice daily, in the morning and evening, for 3 weeks, followed by a 14-day interval and a second 2-week treatment course. The principal indication for the product is the prevention of recurrent upper respiratory tract infections; in some patients, it may reduce the number and severity of infectious episodes [7].

The study was performed in accordance with the principles of the Declaration of Helsinki. All examinations included in the study are generally accepted and approved for clinical use. Each patient was informed of the study purpose and objectives and provided written informed consent to participate. All medicinal products and medical devices used in the study were registered by the relevant authorities of the Ministry of Health of Ukraine and approved for use in medical practice. The Biomedical Ethics Commission of Odesa National Medical University (Protocol No. 9 dated November 12, 2025) established that this scientific study complied with ethical and moral-legal requirements in accordance with Order of the Ministry of Health of Ukraine No. 281 dated November 1, 2000.

Statistical processing of the results was performed using parametric and nonparametric methods. Numerical variables were summarized as the arithmetic mean (M) and standard error of the mean (m), and Student's t-test was used for independent and paired samples. The Shapiro–Wilk test was applied to assess the distribution of quantitative data.

Results of the study. The results were analyzed sequentially according to the status of the nasopharyngeal zone, the presence and size of the pharyngeal tonsil, the severity of clinical manifestations, middle-ear involvement, microbiological changes, and mucosal immune parameters. Particular attention was paid to differences between patients with type 2 CRS and concomitant chronic nasopharyngitis and those without signs of nasopharyngeal inflammation. This approach made it possible to assess whether nasopharyngeal involvement was associated with a more severe clinical course and a different response to treatment.

Among the 339 patients with T2 CRS, 68 had signs of CNP, accounting for 20.06 %. We analyzed the presence and size of the PT in patients with T2 CRS and CNP and in those with T2 CRS without CNP, including 91 patients in Group B and 36 patients in the CG (Fig. 1).

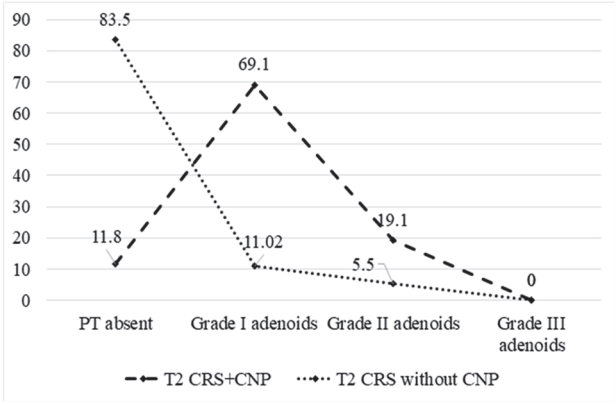

Fig. 1. Pharyngeal tonsil size in adult patients with type 2 CRS by study group (%).

Grade I adenoid vegetations (AVs) were detected in 69.1 % of adult patients with T2 CRS and CNP, grade II AVs in 19.1 %, and absence of the PT in 11.8 %. In contrast, among patients with T2 CRS without CNP, the corresponding values were 11.02 %, 5.5 %, and 83.5 %, respectively, with $p<0.01$ for grade I AVs and absence of the PT. This pattern may be explained by the fact that chronic infection and allergy are major causes of delayed PT involution and may also reflect an association between uncontrolled allergy and persistence of lymphoid tissue in adulthood.

According to the inclusion and exclusion criteria, 58 patients with T2 CRS and CNP were included in the subsequent study. To reliably evaluate complaints and symptoms characterizing both the nasal cavity and nasopharynx, we assessed colored nasal discharge, nasal obstruction, hyposmia, postnasal drainage, aural fullness, and ear pain. The physician-rated endoscopic signs included purulent discharge in the middle and/or superior nasal meatus, purulent deposits on the nasopharyngeal mucosa and/or residual pharyngeal tonsil tissue, edema and abnormal coloration of the nasal mucosa, edema and abnormal coloration of the nasopharyngeal mucosa, signs of acute otitis media, and signs of otitis media with effusion.

The aggravation of clinical manifestations when adjacent anatomical regions were involved in the inflammatory process was confirmed by higher total VAS (>7 points) and MMS (>2 points) scores in Group A (T2 CRS+CNP) than in Group B and the CG (T2 CRS without CNP), in which VAS scores were <7 points and MMS scores were <2 points.

The condition of the auditory tube and, consequently, the tympanic cavity is an important indicator of nasopharyngeal involvement in the inflammatory process. Therefore, we evaluated the frequency of middle-ear involvement in the study groups by considering the occurrence of otitis media with effusion (OME) and acute otitis media (AOM) before and after treatment (Fig. 2).

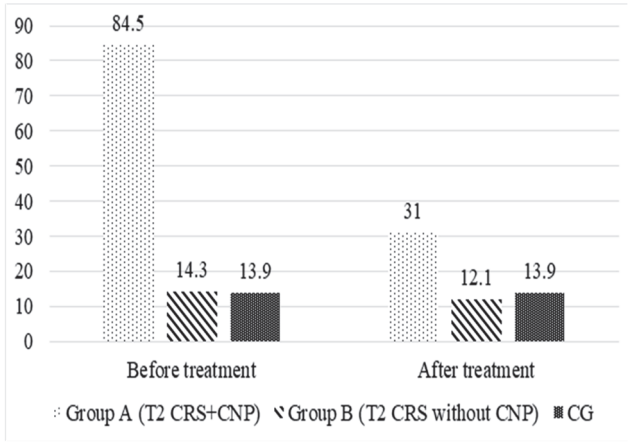

Fig. 2. Middle-ear involvement in the study groups before and after immunocorrection (%).

history of AOM and OME in patients with T2 CRS is an important differential diagnostic criterion when evaluating associated nasopharyngeal conditions. Before immunocorrection, 49 of 58 (84.5 %) patients in Group A had inflammatory or non-inflammatory middle-ear changes, compared with 13 of 91 (14.3 %) patients in Group B and 5 of 36 (13.9 %) patients in the CG. Immunocorrection with the mucosal vaccine Lantigen B significantly reduced the frequency of AOM and OME in patients with T2 CRS ($p<0.01$), whereas the frequency of these complications remained almost unchanged in Group B and the CG. The dynamics of complaints and symptoms in all study groups before and after treatment are presented in Fig. 3.

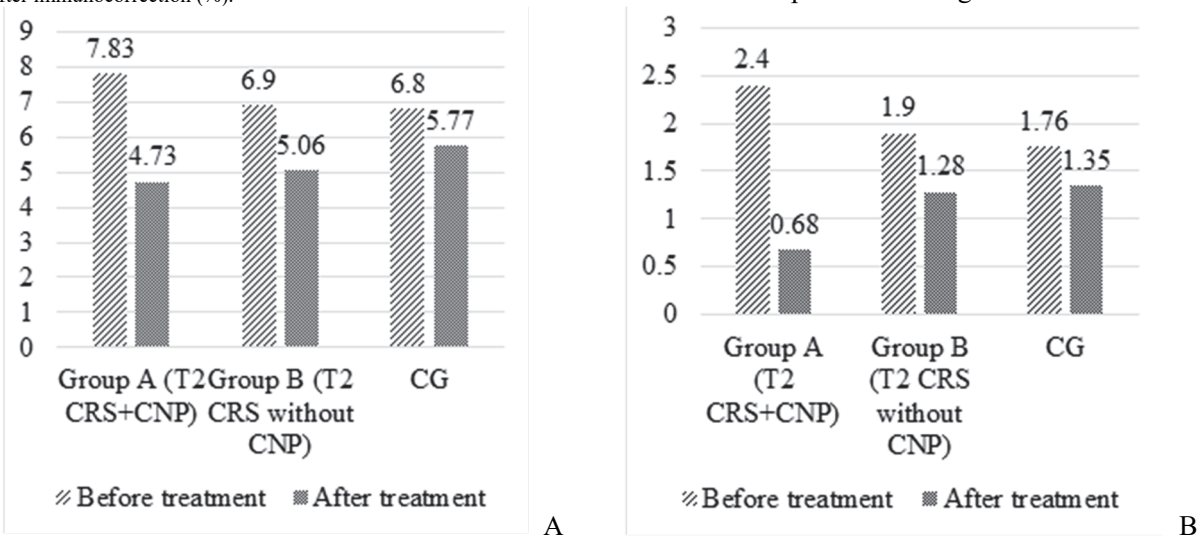

Fig. 3. Dynamics of complaints and symptoms in all study groups before and after treatment: a, patient-rated VAS scores; b, physician-rated MMS scores.

The regression of patient-reported complaints and symptoms after treatment was significant in Group B ($p<0.05$) and particularly pronounced in Group A ($p<0.01$) compared with the CG.

The regression of physician-rated complaints and symptoms after treatment was significant in Group B ($p<0.05$) and particularly pronounced in Group A ($p<0.01$) compared with the CG.

Before treatment, microbiome alterations in 48 (82.8 %) patients in Group A, 55 (60.4 %) patients in Group B, and 14 (38.9 %) patients in the CG were characterized by excessive nasopharyngeal colonization with opportunistic microorganisms, including pyogenic streptococci (7.58±0.22 CFU/mL) and epidermal staphylococci (6.22±0.11 CFU/mL), and pathogenic bacteria, including pneumococci (3.54±0.12 CFU/mL), Haemophilus species (3.85±0.08 CFU/mL), and Pseudomonas aeruginosa (4.35±0.19 CFU/mL), in association with Candida species (2.95±0.21 CFU/mL). This excessive colonization with opportunistic and pathogenic flora was accompanied by an almost complete absence of symbiotic microorganisms, including lactobacilli, bifidobacteria, and salivary streptococci. Clinical manifestations of nasopharyngitis were pronounced in these patients. These findings corresponded to grade III dysbiosis, the prevalence of which was significantly higher in Group A than in the CG ($p<0.01$) and Group B ($p<0.05$).

Before treatment, 5 (8.6 %) patients in Group A, 32 (35.2 %) patients in Group B, and 12 (33.3 %) patients in the CG demonstrated a reduced proportion of symbiotic microbiota, particularly lactobacilli and bifidobacteria, accompanied by two or three opportunistic species (Staphylococcus aureus, Staphylococcus epidermidis, and Streptococcus pyogenes) at levels exceeding threshold values. Thus, both the quantitative and qualitative composition of the nasopharyngeal microbiota was significantly altered. In contrast, lactobacilli, salivary streptococci, and bifidobacteria, which occupy a leading position in the normal nasopharyngeal microbiocenosis, were detected at low population levels. These changes corresponded to grade II dysbiosis, which was significantly more prevalent in Group B and the CG than in Group A ($p<0.05$).

Before treatment, minor changes in the nasopharyngeal microbiocenosis were observed in 5 (8.6 %) patients in Group A, 4 (4.4 %) patients in Group B, and 8 (22.2 %) patients in the CG. These changes reflected a subthreshold but statistically

significant increase in one or more opportunistic microorganisms, including staphylococci, streptococci, and enterobacteria. Candida species and pathogenic microorganisms, including pneumococci, Haemophilus species, and pseudomonads, were absent. The major representatives of the normal nasopharyngeal microbiota were preserved, although their abundance was significantly reduced. These changes corresponded to latent or grade I dysbiosis and were significantly more prevalent in the CG than in Groups A and B ($p<0.05$). Although statistically significant, the low number of patients with latent dysbiosis in all groups before treatment indicated substantial microbiome alterations in the entire study population, particularly given the absence of normobiosis in every patient. The regression of pathological grades of nasopharyngeal dysbiosis before and after treatment in the study groups is shown in Fig. 4.

Eight weeks after the initiation of immunization with Lantigen B, 42 of 48 patients in Group A and 44 of 55 patients in Group B no longer had grade III nasopharyngeal dysbiosis and shifted to less severe grades. Complete microbiome normalization was achieved in 23 (39.7 %) patients in Group A and 5 (5.5 %) patients in Group B. The opposite tendency was observed in the CG, in which the numbers of patients with grade III and grade II dysbiosis increased slightly after standard treatment, involving three additional patients, while the nasopharyngeal microbiome did not normalize in any control patient.

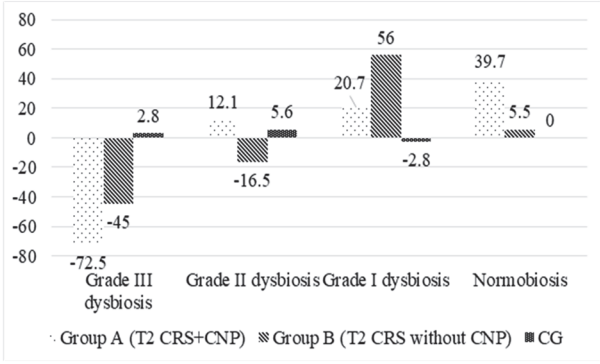

Fig. 4. Changes in the grades of nasopharyngeal dysbiosis after treatment in the study groups (%).

Before treatment, sIgA levels were below the reference range (<40 μg/mL) in 28 of 58 (48.5 %) patients in Group A, 45 of 91 (49.5 %) patients in Group B, and 22 of 36 (61.1 %) patients in the CG (Table 1).

Table 1

sIgA content in OPS in all study groups before and after immunocorrection, Me (25–75 %)

Parameter	Treatment	Group A (T2 CRS+CNP), n=58	Group B (T2 CRS without CNP), n=91	CG, n=36
sIgA, μg/mL	Before	42.7 (22–58)	44.5 (15–52)	47.6 (24–48)
	After	94 (68–125)*	86 (71–128)*	55.2 (28–51)

Note: * statistically significant difference between the values before and after treatment. Statistical significance was established at $p<0.05$.

With an upper reference limit for sIgA of 170 mg/mL, the concentrations did not exceed 58 mg/mL, 52 mg/mL, and 48 mg/mL in Groups A, B, and the CG, respectively. After immunocorrection with the mucosal vaccine, sIgA levels in OPS normalized in Groups A and B ($p<0.05$), reaching maximum values of 125 mg/mL and 128 mg/mL, respectively. In contrast, the CG demonstrated only a statistically non-significant tendency toward increased sIgA levels.

Discussion. The findings indicate that the nasopharyngeal zone is clinically significant in type 2 primary diffuse chronic rhinosinusitis in adults. Chronic nasopharyngitis was identified in 20.06 % of patients with T2 CRS, supporting targeted nasopharyngeal examination even when the pharyngeal tonsil is expected to involute. This agrees with Bidaye et al., who noted that adult adenoid hypertrophy may remain undiagnosed [6].

In patients with concomitant T2 CRS and CNP, grade I adenoid vegetations were detected in 69.1 % of cases. Thus, limited residual lymphoid tissue may support inflammation under chronic antigenic stimulation, dysbiosis, and impaired mucosal immunity. Pharyngeal tonsil size should not be the only marker of active nasopharyngitis; endoscopic signs and auditory tube function are more informative. Higher VAS and MMS scores in Group A confirmed greater severity, while symptom overlap described by Purnell et al. supports combined clinical and endoscopic assessment [13].

AOM or OME was detected in 84.5 % of Group A patients, compared with 14.3 % in Group B and 13.9 % in the CG, reflecting tubal involvement and epithelial immune dysfunction [15]. Grade III dysbiosis was also most frequent in Group A, consistent with data linking CRS to reduced microbial diversity and increased pathogen prevalence [4]. Lack of microbiome normalization in the CG agrees with reports on bacterial repopulation and limited antibiotic efficacy in CRS [9, 11, 14].

Adding Lantigen B was associated with greater clinical regression, reduced dysbiosis, and increased sIgA levels in OPS. These results correspond to Braido et al. and suggest that CNP in patients with T2 CRS requires targeted diagnosis and consideration during treatment planning [7].

Limitations. The study was conducted at a single clinical center and included a limited follow-up period; therefore, the findings require further confirmation in multicenter studies with longer-term observation.

Conclusions

1. Approximately one-fifth (20.06 %) of patients with type 2 primary diffuse rhinosinusitis had chronic nasopharyngitis as an associated condition of the nasopharyngeal zone, most commonly (69.1 %) related to residual grade I adenoid vegetations.

2. The presence of chronic nasopharyngitis in patients with type 2 primary diffuse rhinosinusitis significantly increased disease severity according to patient- and physician-rated complaints and symptoms and was associated with a higher frequency of middle-ear complications.

3. Acute otitis media and otitis media with effusion were among the leading complications of type 2 primary diffuse rhinosinusitis associated with chronic nasopharyngitis and were identified in 84.5 % of patients ($p<0.05$ compared with patients without chronic nasopharyngitis).

4. The most pronounced changes in the nasopharyngeal microbiome were observed in patients with type 2 primary diffuse rhinosinusitis and chronic nasopharyngitis, which may be mutually associated with incomplete involution or secondary enlargement of the pharyngeal tonsil in adulthood.

5. Immunocorrection with the mucosal vaccine Lantigen B in patients with type 2 primary diffuse rhinosinusitis with or without chronic nasopharyngitis and chronic bacterial inflammation provided more effective disease control. This was confirmed by significant improvements in patient self-assessment, physician assessment, the grade of nasopharyngeal dysbiosis, and sIgA levels in OPS, as well as by a reduced frequency of acute otitis media and otitis media with effusion in patients with chronic nasopharyngitis compared with the control group.

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Conflict of interest. The authors have no conflicts of interest to declare.

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