

# EFFICACY AND SAFETY ASSESSMENT OF NASAL SPRAY CONTAINING N-ACETYLCYSTEINE AND HYPERTONIC SODIUM CHLORIDE SOLUTION IN CHRONIC RHINOSINUSITIS

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**Abstract.** *The aim:* to assess the efficacy and safety of nasal hypertonic saline solution with N-acetylcysteine in the treatment of patients with chronic rhinosinusitis (CRS).

**Methods.** The study was conducted in accordance with the principles of the 1975 Declaration of Helsinki and its revision in 2000. The study protocol was approved by the local Committee on Bioethics and Deontology. The authors declare that there is no conflict of interest. The study involved 30 patients with partially controlled or uncontrolled CRS without the presence of nasal polyps. Patients were prescribed the nasal spray “FLU-ACYL Rhino” three sprays in each nostril three times a day as monotherapy. The efficacy of treatment was assessed based on the analysis of subjective and objective signs of CRS, impact of CRS on the quality of patients’ life using the VAS scale and nasal cytology results before and after treatment.

**Results.** The study demonstrated regression of objective and subjective clinical signs of CRS. The dynamics of the reducing in the feeling of nasal congestion and the objective sign of “swelling of the nasal mucosa” correlated during the study. The score of the symptom “rhinorrhea/postnasal drip” was significantly lower on the 5<sup>th</sup> day, which was confirmed on the 10<sup>th</sup> day of treatment. This effect of treatment can be explained by the mucolytic properties of acetylcysteine, the content of which in the studied spray is 6 %. The average VAS quality of life score on the 10<sup>th</sup> day was significant higher compared to baseline.

After treatment, there was a certain changes in the rhinocytological picture, in particular, the ratio of ciliated and goblet cells, towards the characteristics inherent in the normal nasal mucosa. At the end of treatment microflora (bacteria, fungal spores and hyphae) had a lower abundance then baseline. Bacterial biofilms were not revealed on 10<sup>th</sup> day in two of the 6 patients in whom it was detected before treatment.

**Conclusions.** The nasal spray “FLU-ACYL rhino” use contributes to the decreasing of subjective and objective CRS signs score and improving the quality of patients’ life. The reduction in nasal mucosal inflammation was confirmed by semi-quantitative characteristics of nasal cytograms obtained before and after treatment. The tolerability of the nasal spray “FLU-ACYL rhino” in patients with CRS corresponds to a favorable safety profile. Therefore, “FLU-ACYL rhino” can be considered a rational choice for the treatment of patients with CRS. The encouraging clinical and rhinocytological results obtained with the nasal spreys containing acetylcysteine should be confirmed in further studies.

**Key words:** chronic rhinosinusitis, N-acetylcysteine, hypertonic sodium chloride solution, nasal cytology.