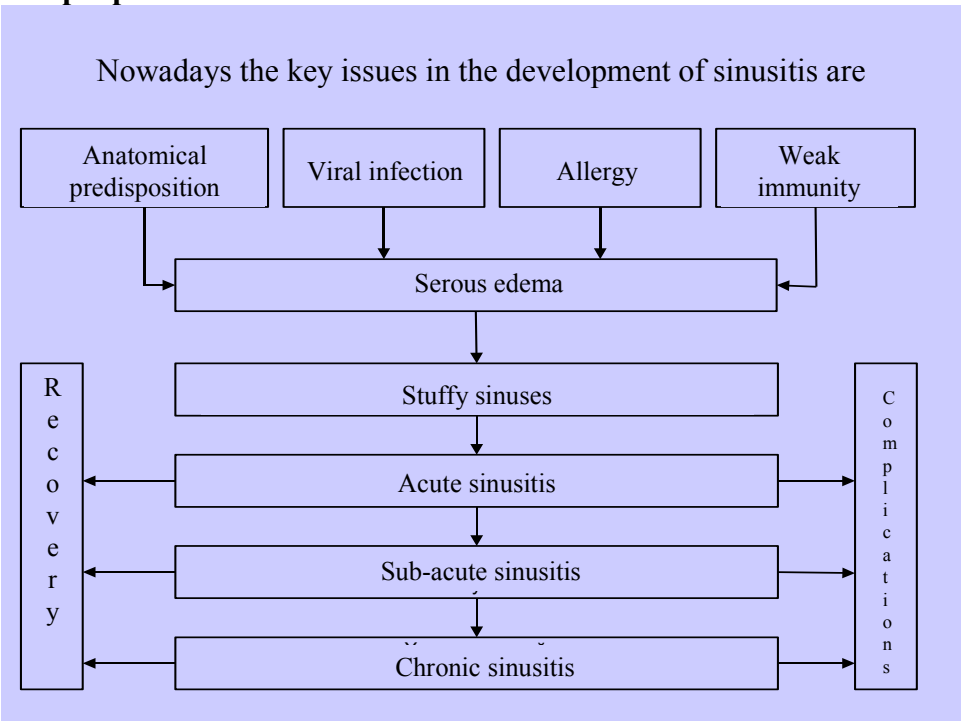
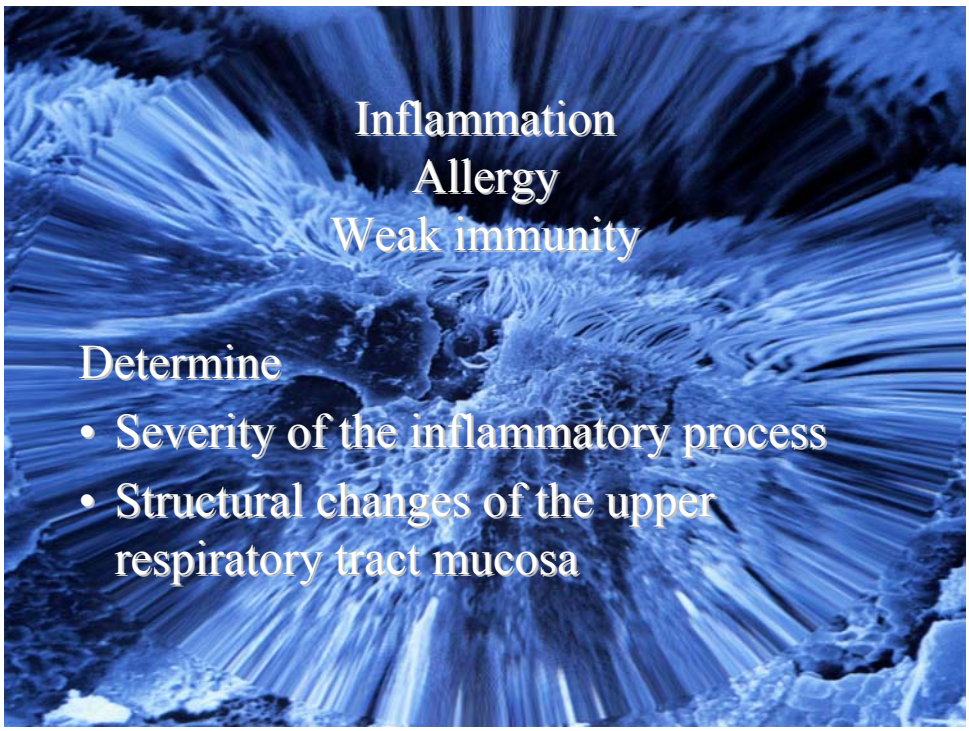
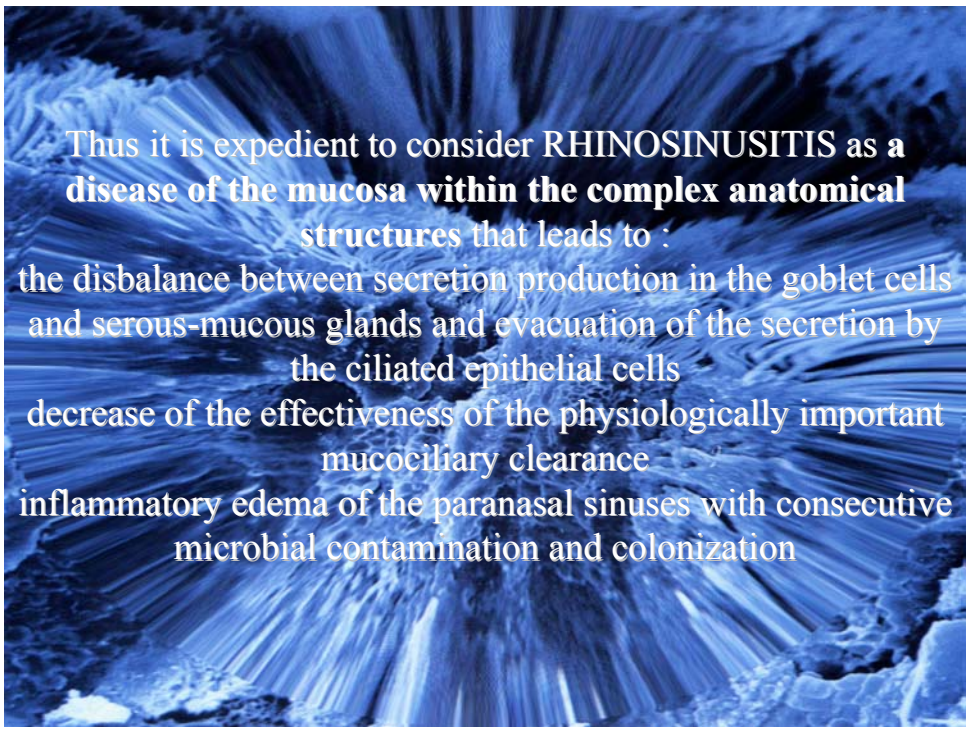
T. I. Garaschenko, M. R. Bogomilsky, E. Yu. Radtzig

Russian State Medical University, ENT department of pediatric faculty, Moscow

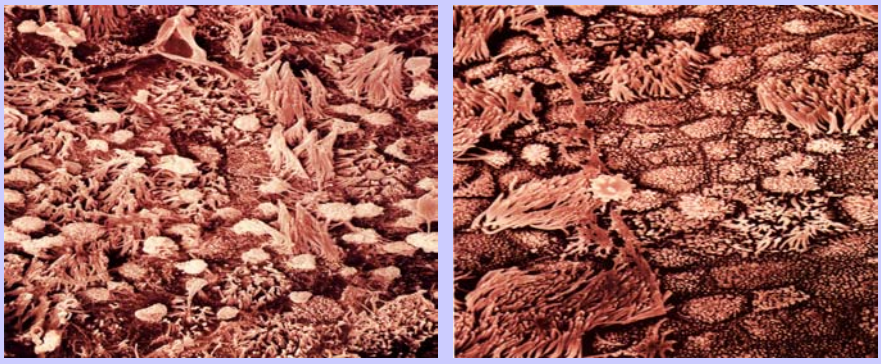
The purpose:




Inflammation
Allergy
Weak immunity
Determine
• Severity of the inflammatory process
• Structural changes of the upper respiratory tract mucosa


Thus it is expedient to consider RHINOSINUSITIS as **a disease of the mucosa within the complex anatomical structures** that leads to :
the disbalance between secretion production in the goblet cells and serous-mucous glands and evacuation of the secretion by the ciliated epithelial cells
decrease of the effectiveness of the physiologically important mucociliary clearance
inflammatory edema of the paranasal sinuses with consecutive microbial contamination and colonization

Further damage of the mucosa results into more prominent changes:



- Cilia disappear almost totally. Only separate cilia groups remain. Short cilia can be seen on the surface of some cells (an attempt of cellular regeneration) but the completion of the process requires 2 to 6 weeks.
- When the secretion gets to the sites with almost no cilia **the mucociliary transporting mechanism is blocked.**

Thus in the context of the above-stated data **pathogenically the main strategy of treatment** of acute and chronic rhinosinusitis should be aimed at

- \- improvement of ventilation and drainage of the paranasal sinuses and tympanic cavity (successfully fulfilled by means of perfect endoscopic surgical technologies)
- \- achievement of the adequate mucociliary transporting function, i.e. providing a normal work of the ciliary epithelium and normalization of the compound of the secretion
- This has just recently become possible since mucoactive drugs have got into a physician's practice

Methods:

In the ENT Clinic of the pediatric faculty of the RSMU in 1996 a large study of efficacy of inclusion of mucoactive drugs in the standard treatment protocols, in particular for acute and chronic sinusitis, was initiated.

We conducted a clinical trial of the clinical efficacy of Sinupret in children (n=30, 100%) with acute sinusitis.

Sinupret (BIONORICA AG, Germany) is phytosecretolytic with the anti-inflammatory, antiviral and immunostimulating effects. The dosages for children are as recommended: from 2 to 6 years old – 15 oral drops 3 times p.d., for schoolchildren – 25 drops 3 times p.d.

The age of the children varied from 2 years and 6 months to 12 years, the average age was 7 years and 3 months. 18 boys (60%) and 12 girls (40%) were enrolled. In 9 children (30%) adenoid vegetations of the 1-2 degree were observed. For assessment of clinical efficacy of the drug a control group of children with the same pathology (n=30, 100%) - 16 boys (53%) and 14 girls (47%) - was formed.

Besides the efficacy of MAD of the carbocysteine group compared with the standard treatment protocols, which include antibiotics of different groups (cefuroxim acsetil, josamycin), was evaluated.

All the patents underwent:

- General assessment of the patient's state
- ENT-examination including rhino-pharyngo-oto-endoscopy
- Registration of time of the mucociliary transport (carbon powder test)

The assessment of the mucociliary transport function (MCT) was based on the carbon powder test results. For evaluation of the MCT function we used the classification suggested by Prof. B.V.Shevrygin in 1985:

Normal – under 15-20 min,
1 degree – 20-30 min,
2 degree – 31-60 min,
3 degree – more than 60 min.

Results

The dynamics of the MCT parameters in children with acute sinusitis treated with Sinupret is presented in the Figure 1.

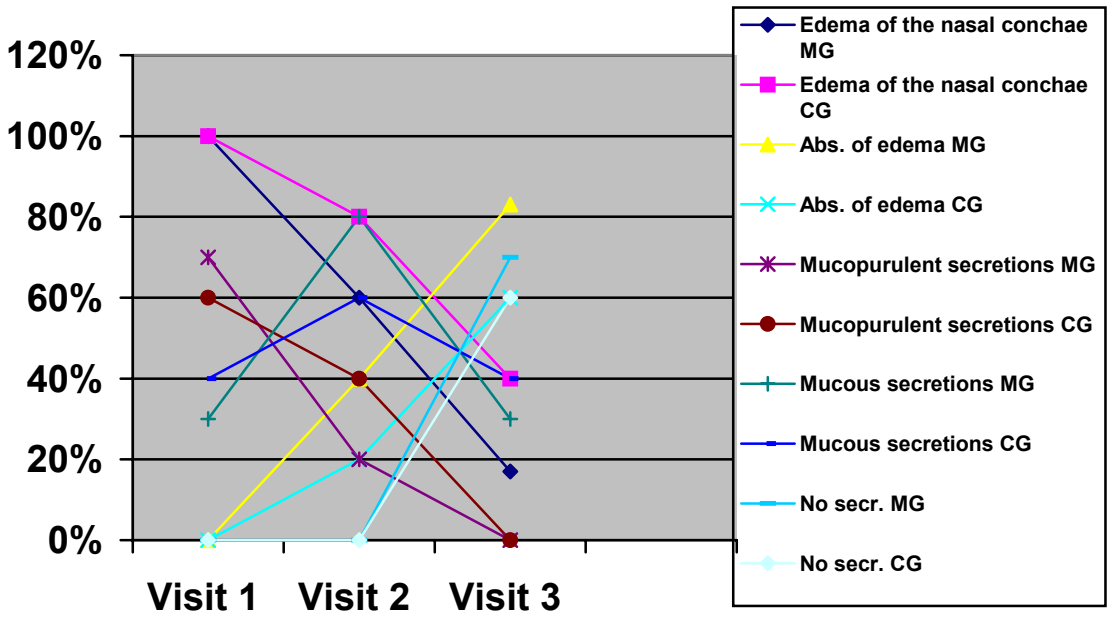


Figure 1. Dynamics of the rhinoscopic picture in treatment with Sinupret

The dynamics of the rhinoscopic picture

Visit 1

Edema of the nasal conchae was observed in 30 children (100%) of the MG and CG, mucopurulent secretions in the nasal cavity – in 21 patients (70%) of the MG and 18 patients (60%) of the CG, mucous secretions – in 9 patients (30%) of the MG and 12 patients (40%) of the CG.

Visit 2:

Edema of the nasal conchae was observed in 18 children (60%) of the MG and 24 children (80%) of the CG. In 12 children (40%) of the MG (and in only 6 children (20%) of the CG) the edema of the nasal conchae was not diagnosed. Mucopurulent secretions in the nasal cavity were observed in 6 patients (20%) of the MG and 12 patients (40%) of the CG, mucous secretions – in 24 patients (80%) of the MG and 24 patients (60%) of the CG.

Visit 3:

Edema of the nasal conchae was observed in 5 children (17%) of the MG and 12 children (40%) of the CG. In 25 children (83%) of the MG and in 18 children (60%) of the CG the edema of the nasal conchae was not diagnosed. Mucopurulent secretions in the nasal cavity were not observed in 100% of cases (30 children) in the MG and CG. Mucous secretions were observed in 9 patients (30%) of the MG and 12 patients (40%) of the CG. The examination revealed no secretions in 21 patients (70%) of the MG and 18 patients (60%) of the CG.

Our studies proved that 2-week treatment with secretolytics with mucoregulating effect showed excellent and good results in 95% of children with acute sinusitis, whereas the standard therapy showed positive results, mostly at the expense of good results, in 78% of children (Fig. 3). Clinical recovery period was shorter by 5-7 days. Time of the mucociliary transport normalized by the 5-7th day (in the control group – by the 14-23rd day).

In spite of the long duration of the disease a positive tendency to normalization of the transporting function in exacerbations of chronic rhinitis, serous and purulent rhinosinusitis, polypoid-purulent processes was observed after 3-week treatment courses with carbocisteine, Sinupret in 70% of the patients. Normalization of the parameters was observed in 30% of the patients.

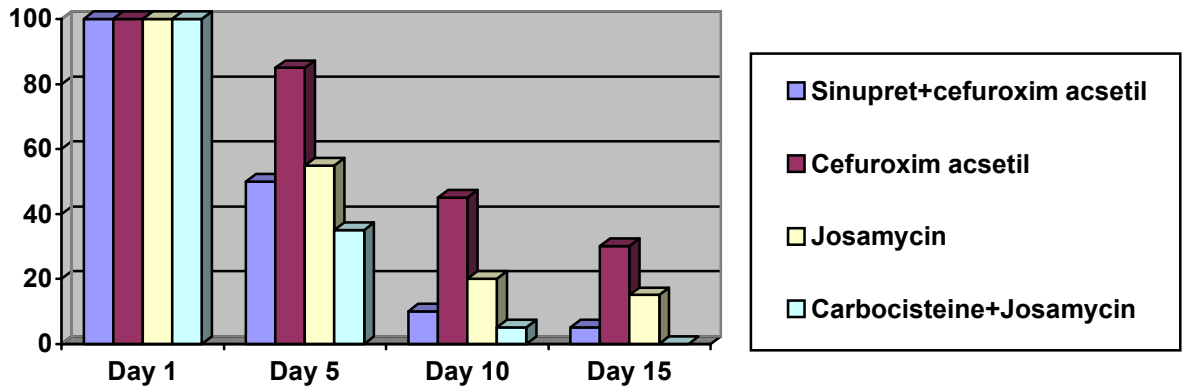


Fig. 2. **The state of the mucociliary transport in children with acute sinusitis during the treatment, which includes mucoactive drugs**

The ordinate axis shows percentage of patents with increased time of the mucociliary transport.

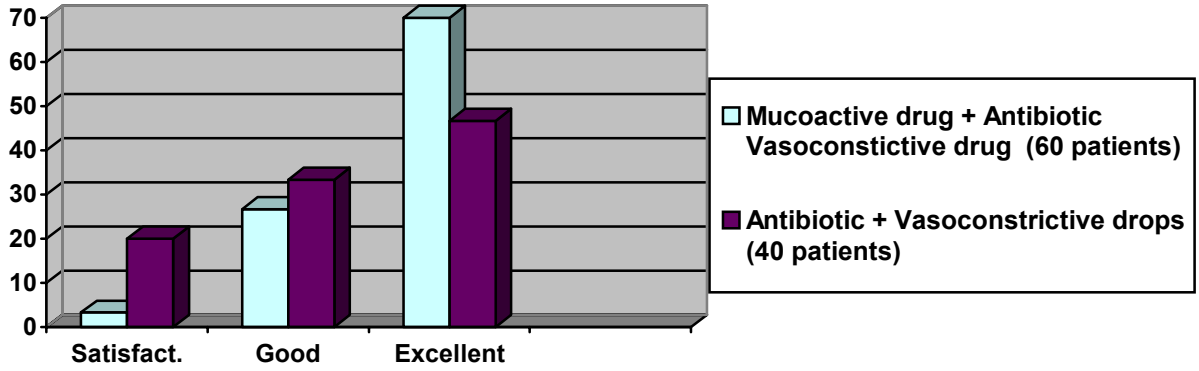


Fig. 3. **Results of treatment, which included mucoactive drugs (Sinupret, carbocisteine), in children with acute sinusitis**

The ordinate axis shows percentage of patients

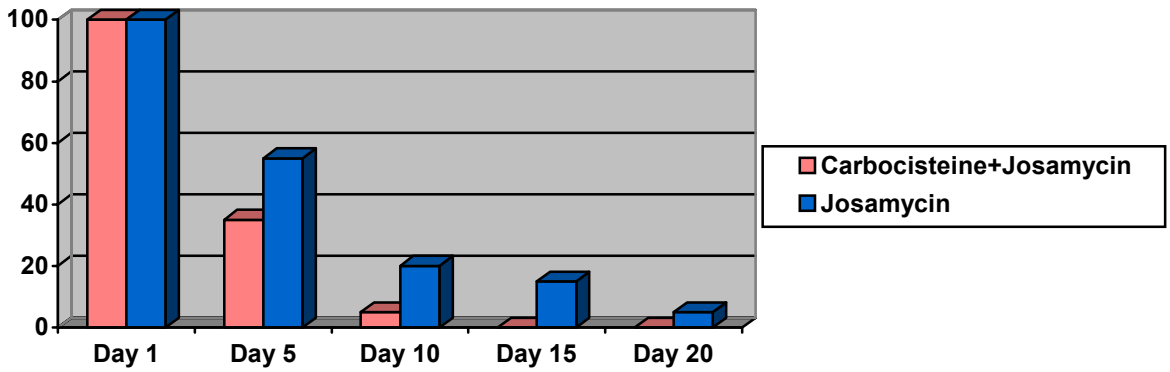


Fig. 4 **The state of the mucociliary transport in children with acute sinusitis during the treatment with carbocisteine**

The ordinate axis shows percentage of children with increased time of the mucociliary transport

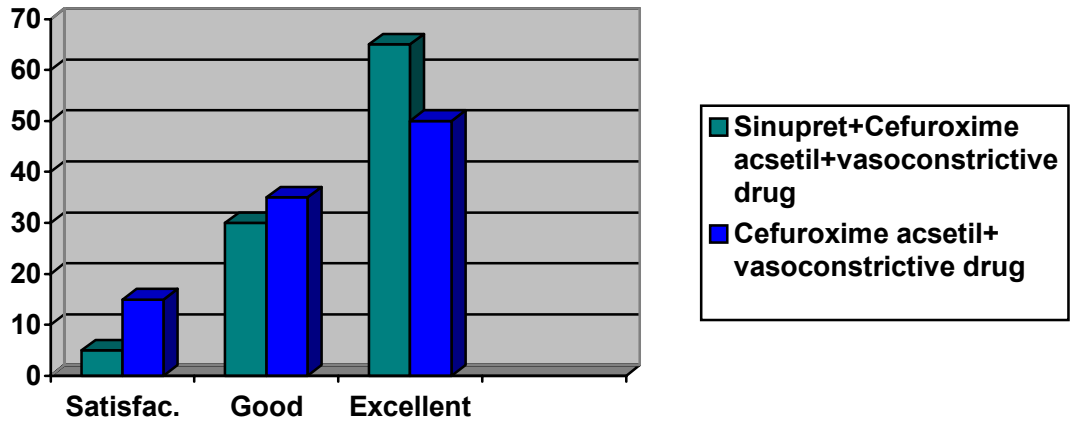


Fig. 5. **Results of treatment, which included Sinupret, in patients with acute sinusitis**
The ordinate axis shows percentage of patients

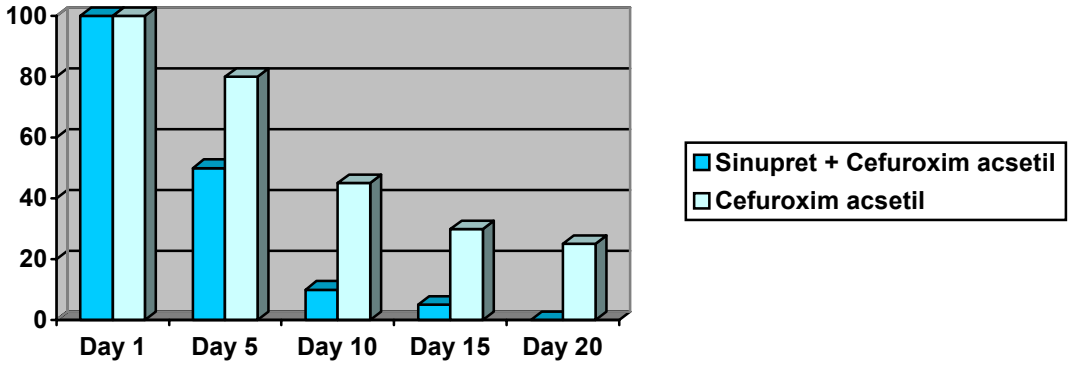


Fig. 6. The state of the mucociliary transport of the nasal cavity in patients with acute sinusitis during the treatment with Sinupret
The ordinate axis shows percentage of children with increased time of the mucociliary transport.

Conclusion

Thus in the context of the obtained results mucoactive drugs, especially should be included in the therapy of inflammatory diseases of the nose and paranasal cavity with mucociliary dysfunction. The choice of a drug influencing on the ciliary activity is in many respects determined by the phase of the disease, nature of the changed secretion, as well as by understanding of the pathogenesis of the disease and mechanisms of the drug action.