

PRACTICAL PAEDIATRICS

Use of Stérimar® solution enriched with copper during treatment of infectious rhinitis in children

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Owing to its ventilation function, a child's nose is the body's initial "filter" and therefore the first organ exposed to irritant and infectious agents from the outside environment. Children, who are in the midst of developing their immune system, are extremely sensitive to these attacks. This is indicated by inflammation and obstruction of the nasal fossae, followed by often superinfected rhinorrhoea. The infection remains local in the majority of cases, but may subsequently develop into the rhinopharynx and result in rhinopharyngitis accompanied by fever.

We wished to assess the effects of the use of a Stérimar® solution enriched with copper on uncomplicated infectious rhinitis in children. Copper is indeed a trace element recognised as playing a role in the formation of inflammation mediators and also possessing antimicrobial activity⁽¹⁾. This study was conducted in our paediatric ENT department, during the winter season 2000-2001.

■ PATIENTS AND METHODS

Patients

The prospective study, conducted between 1st November 2000 and 1st April 2001 in the paediatric ENT department of Clocheville teaching hospital in Tours, allowed inclusion of 41 children. The inclusion criteria were an age of less than 15 years, presence of simple infectious rhinitis (inflammatory mucosa and purulent rhinorrhoea with no fever) and acceptance of treatment by the family. Prescription of concomitant treatment, by

antibiotics or corticosteroids via the local or systemic route, represented an exclusion criterion and likewise the existence of clear rhinitis within an atopic context; in the latter case, the children received Stérimar® enriched with manganese (only 6 children received this product, since this study was performed during the winter season, which seldom provides this type of disorder).

Methods

Stérimar Cu® was prescribed according to the methods mentioned on the product characteristic sheet: one spray in each nostril in the morning and evening. The duration of use involved a minimum period of 1 month and a maximum of 3 months. According to the child's age and compliance, a parent or the child him/herself administered the product. All the children were seen again during a consultation at the end of treatment. The following data were recorded in an Excel 97® sheet: age, sex, duration of use, good or poor compliance with administration, good or poor safety in use, presence or absence of adverse events, disappearance, improvement or absence of improvement in rhinorrhoea, mucosal inflammation and nasal obstruction. Nasal obstruction was assessed subjectively by questioning the child or the parents. The appearance of the mucosa and improvement of rhinorrhoea were evaluated objectively by examination by anterior rhinoscopy performed by a paediatric otorhinolaryngologist.

■ RESULTS

The 41 children included in the study (25 boys and 16 girls, sex ratio: 1,5) were of an average

age of 5.35 years (extreme values: 0.5-14 years). All presented with purulent rhinitis with inflammatory mucosa; 12 of the children also had nasal obstruction.

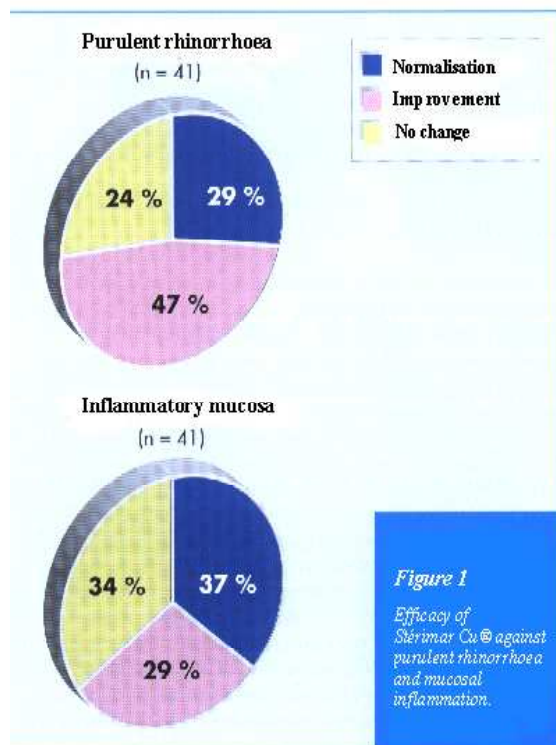
Compliance and safety

Compliance with administration was excellent in 93% of cases. Only 3 children had difficulty in accepting care, requiring restraint for administration of the solution. Safety in use was very satisfactory and only one minimal nosebleed was recorded as an adverse event in an older child of 14 years of age.

Efficacy

From the point of view of efficacy, disappearance or reduction in purulent rhinitis on completion of treatment was observed in 75% of the children and 66% presented normalisation or improvement of the appearance of the pituitary mucosa (figure 1). Improvement was observed in 61% of the 13 children who complained of nasal obstruction (figure 2).

For the 6 children presenting with allergic rhinitis and having used Stérimar Mn®, compliance was good in 5 cases, with an improvement in the symptoms (nasal obstruction, rhinorrhoea and normalisation of the mucosa) for three of the children.



DISCUSSION

Agents responsible for infectious rhinitis in children

The nasal mucosa is exposed to multiple types of aggression, including infection, allergy and toxic agents. The response of the mucosa to these attacks involves inflammation, with vasodilatation, rhinorrhoea and often nasal obstruction. Since most of the infectious agents involved are present in the air, the nasal inflammatory reaction often represents the body's first line of defence.

Viruses are the most frequent cause of infectious rhinitis in children (2): rhinoviruses, adenoviruses, coxsackie A and B viruses, myxoviruses and syncytial respiratory viruses. The discharge, which is initially clear, may become puriform without however bacterial superinfection being involved: the viruses result in major epithelial cytolysis and the secretions become puriform, containing by necessity bacteria which proliferate easily in this moist and confined environment. Bacterial superinfection frequently occurs; however, the diagnosis cannot be made based on the clinical appearance of the discharge, but on the duration of evolution (more than 15 days). The germs generally responsible are the usual inhabitants of the nasal fossae: *Haemophilus influenzae*, *Streptococcus pneumoniae* and other streptococci, staphylococci and *Branhemeila catarrhalis*(²).

Efficacy of nasal lavages with isotonic saline solution

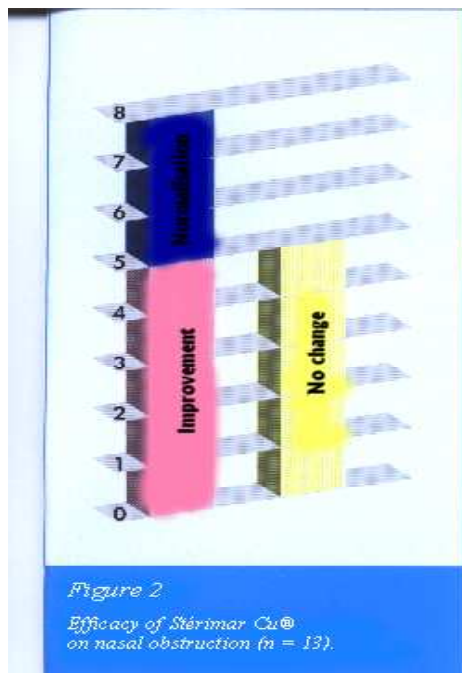
The necessity for nasal lavages in children as soon as congestion appears no longer needs to be demonstrated. Stérimar® fulfils this role of washing the nasal fossa, thereby limiting stagnation of the secretions and therefore superinfection.

Furthermore, Stérimar® is a physiological saline solution, since seawater is involved with a saline content of sodium chloride adjusted to 9 per 1 000. It is comparable to the freshwater Parsons solution (10 per 1 000) which has a decongestant effect on the nasal mucosa and increases mucocilliary clearance and frequency of stereocilium beating(³). Furthermore, sodium chloride in high concentrations is antiseptic. Our study also shows that this physiological

solution is well tolerated and free of irritation, which allows good treatment compliance, also observed in a study conducted by P. Contencin in 1999⁽⁴⁾.

Value and roles of copper and magnesium

Copper is a trace element that acts as a cofactor in a large number of enzymatic reactions, such as cell respiration, DNA and RNA duplication, maintenance of the integrity of the cell membrane and capture of free radicals⁽⁵⁾. Furthermore, it plays a role in preventing infections, since it is involved in the formation of certain inflammation mediators. Consequently, in certain animals, a lack results in lymphocyte B deficiency with cessation of the production of interleukin 2⁽⁵⁾



In children suffering from malnutrition and with recurrent infections, F. Kaldhi⁽⁶⁾ showed that copper and zinc levels were particularly low, justifying trace element supplementation during correction of malnutrition in these children.

Furthermore, the bactericidal activity of copper is recognised, since 1mg of copper is capable of destroying up to 5 g of colibacillus or staphylococcus aureus⁽¹⁾.

A study by J.-F. Coze⁽⁷⁾ demonstrated the effect of a manganese-copper solution in treatment of chronic pharyngitis: 46.5% of the patients showed an improvement in symptoms and in the appearance of the mucosa. To our knowledge, only Laboratoires Fumouze, the manufacturers of Stérimar®, use this trace element in a solution for lavage of the nasal fossae, in the form of copper sulphate pentahydrate at a concentration of 4 ppm.

Our study does not provide scientific proof of the efficacy of this nasal solution, but permits assessment of the acceptability, safety and comfort which its use may bring to the families who accepted to reply to our survey. The results are fully satisfactory for the cases of simple purulent rhinitis.

In our series, the number of cases is insufficient in order to be able to demonstrate the effects of Stérimar Mn® on allergic rhinitis in children. Nevertheless, P. Contencin⁽⁴⁾ had shown an improvement in symptoms in 60% of the treated children in his study. Indeed, manganese is reported to inhibit the release of certain mediators, such as histamine, may play a role in stimulating the chemotaxis of polynuclear cells and may capture free radicals of mitochondrial origin⁽⁸⁾. The manganese combined with this decongestant saline solution can only be a useful addition in improving the symptoms of allergic rhinitis. This product may be prescribed in combination with antihistamines and often local corticosteroids after performing an allergological survey with a test for the responsible allergen(s).

The pharmaceutical form of Stérimar®

Stérimar® nasal spray allows microdiffusion of the saline solution containing copper within the nasal fossa, ensuring a wide contact surface of the product throughout the entire pituitary mucosa, thereby representing a plus in comparison to use of the pipettes of physiological saline. Furthermore, the aerosol pressure remains moderate, which is essential for use in children and infants. In addition, the plastic nozzle on the aerosol is ergonomic and perfectly adapted to the shape and size of the nasal orifice, without causing injury. In children who sometimes move suddenly, this avoids injury and nosebleeds, which are sources of treatment rejection.

■ CONCLUSIONS

The copper-enriched form of Stérimar® may be readily recommended in children presenting with infectious rhinitis. This product provides respiratory comfort with a reduction in rhinorrhoea. The acceptability of treatment by children between 0 and 15 years of age renders it inevitable as first-line treatment, all the more so since the product is devoid of undesirable effects. The addition of copper to this solution of physiological saline confirms the previous publications showing the value of this trace element in treatment of infectious processes.

A study performed in the spring period and focusing on a larger patient cohort ought to allow confirmation of the efficacy of Stérimar Mn® in allergic rhinitis and thereby corroborate the good results obtained by other authors.

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