XYLITOL DELIVERY

CROSS REFERENCE TO RELATED APPLICATION

This application claims priority to a Provisional Application 60/079,184 filed Mar. 24, 1998, 60/079,184. Specific reference is made to that document.

BACKGROUND OF THE INVENTION

(1) Field of the Invention

This invention relates to cleaning the nasopharynx and thereby reducing the number of bacteria resident there. This reduction translates into less problems with upper respiratory infections (specifically otitis and sinusitis) and reduction in the severity of asthma when the asthma is triggered by upper respiratory irritants. General practice physicians have ordinary skill in this art.

(2) Description of the Related Art

Xylitol is the alcohol form of xylose, a pentose wood sugar. Since both forms are readily interchangeable, the term "xylitol/xylose" is used herein to mean "xylitol" or "xylose" or "xylitol and xylose". Xylitol, xylose, and mixtures of xylitol and xylose are equivalent and all equally effective in equal amounts in all therapeutic uses described herein. Xylitol is present in natural chemical cycles in the body (see Touster, 1974). It has about the same safety and toxicity as table sugar (Jori, 1984). Based on measuring the amount of xylitol in the urine of a group of southern European people who are deficient in an enzyme that assists in its metabolism Touster points out that the human body uses between 5 and 15 grams of xylitol daily. Xylitol is approved by the FDA as a food additive and is widely used as a sweetener especially in chewing gums. Xylitol is available at most health food stores. When ingested by mouth xylitol is about 90% absorbed, mostly in the jejunum, and rapidly metabolized; Asano and his group could find no detectable xylitol in the serum one and two hours after oral doses of 5 to 30 grams (Asano, 1973). Xylose is found in the body on the glycoprotein ligands that extend from cells and that are thought to participate in intercellular communication (Murray, 1996). Xylitol/xylose has been studied extensively for reducing dental caries through its effect on strep mutans, one of the bacteria responsible for cariogenic plaque. These studies have demonstrated that the action of xylitol/xylose that produces the cariogenic protection is by making this bacteria weaker and less adherent to dental plaque (Trahan, 1995). Paul Naaber found a similar decrease in adherence when he looked at Clostridium difficile in the gut in the presence of xylitol/xylose (Naaber, 1996). In 1998 Kontiokari found that a 2.5 percent solution of xylitol/xylose decreased the adherence of this bacteria when present either in the nasal mucosal cell or in the bacteria. When a five percent solution was present in both the bacteria and the mucosal cell, adherence of strep pneumonia, the major pathogen, was reduced by two-thirds; from an average of 41 bacteria per cell to 13 (Kontiokari, 1998). His article concludes by stating:

"These observations are consistent with the fact that monosaccharides are able to inhibit adherence only at the high concentrations, that are easily achieved in the oral cavity. The worldwide spread of penicillin-resistant strains of pneumocci substantiates the need for new approaches to preventing bacterial infections. Xylitol seems to be a promising agent for this purpose."

Matti Uhari, one of Kontiokari's colleagues in Finland has been studying the effects of oral xylitol/xylose in reducing the incidence of recurrent otitis as disclosed in U.S. Pat. No. 5,719,196 (Uhari, 1996; Uhari, 1998). Uhari's original study looked at the effect of xylitol chewing gum in reducing the incidence of otitis. The highest incidence of otitis is in infants less than two who cannot chew gum. Uhari subsequently studied the incidence of otitis in children getting an oral solution of xylitol. He found between a thirty and forty-percent reduction in the incidence of otitis using these supplements.

SUMMARY OF THE INVENTION

(1) Progressive Contribution to the Art

The first level of response of the immune system is to try and wash out the irritated area. In upper respiratory infections this usually translates into nasal congestion because the immune system gets the fluid it needs for this washing by dilating blood vessels in the area. The traditional response to these symptoms is to turn off the immune response by a decongestant or antihistamine. A treatment much more respectful of the wisdom of the immune system is to facilitate it in the attempt to wash the irritated area.

I have discovered that the use of xylitol in a saline solution as a nasal spray is a beneficial means for delivering xylitol more efficiently to the nasopharynx. It avoids the dilution associated with ingestion, absorption, metabolism and circulation to the nose where it is active, that is present with oral delivery. Xylitol's effect, even when given orally, is in the nasopharynx. Because of this it is possible to deliver a pleasant nasal spray containing almost three orders of magnitude less than that given orally to accomplish similar results. Use of this spray results in cleaning of the nasopharynx, reduction of the bacteria count in the nasopharynx and a reduction in infections associated with those bacteria. Because the bacteria are not killed, resistance is not as big a problem. The use of this spray as adjunctive treatment of appropriate infections reduces the need for second and third generation antibiotics. "Resistant" strains of strep mutans that can metabolize xylitol have been isolated in the mouth, but they are more friendly and less cariogenic (Trahan, 1995). Use of this cleansing solution translates into less otitis and sinusitis. Where asthma is triggered by upper respiratory inflammation, an amelioration of the severity of the asthma is accomplished. The addition of xylitol/xylose to conventional nasal sprays is an efficient method of administration. It is particularly useful with infants younger than two years who cannot chew gum.

(2) Objects of this Invention

An object of this invention is to reduce infections of the nasopharynx and symptoms associated with these infections.

Another object of this invention is to provide a means to clean the nasopharynx and reduce the population of the pathogenic bacteria resident there.

A further object of this invention is to reduce otitis, sinusitis and, where asthma is triggered by inflammation of the upper airway, a reduction in the severity of asthma.

Another object of this invention is to efficiently deliver xylitol/xylose for the adjunctive treatment of nasopharyngeal infections.

Other objects are to achieve the above with a method that is rapid, effective, efficient, natural, safe, and inexpensive, and does not require highly skilled people to formulate and administer.

Further objects are to achieve the above with a product that has a long storage life, is safe, versatile, efficient, stable and reliable, yet is inexpensive and easy to formulate and administer.