Xylitol Nasal Irrigation in the Management of Chronic Rhinosinusitis

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Introduction

Xylitol is a five-carbon sugar alcohol which has gained relative prominence as a naturally occurring antibacterial agent. It is not believed to possess antibacterial properties; rather it appears to enhance the body’s own innate bactericidal mechanisms.1-2

We sought to explore the therapeutic potential of xylitol irrigations in treating chronic rhinosinusitis (CRS). Saline irrigation, which has been shown to be beneficial for patients with rhinosinusitis, served as an accepted standard treatment for comparison. We conducted a prospective, randomized, crossover study to compare the therapeutic value of saline versus xylitol irrigations in patients with CRS.

Methods

Study Design
Prospective, randomized, double-blinded, controlled crossover pilot study. Institutional Review Board approval was obtained for the protocol, and all patients gave their written informed consent.

Patients
Adults with CRS who had undergone bilateral endoscopic sinus surgery to include at a minimum maxillary antrostomy and anterior ethmoidectomy. Subjects were excluded if they had a history of immunocompromise, cystic fibrosis, primary ciliary dyskinesia, active smoking, treatment with antifungal medications, an active bacterial infection requiring antibiotics, history of head and neck irradiation, active pregnancy, or granulomatous disease.

Materials
Xylitol: Pharmaceutical grade xylitol (Acros Organics, Fair Lawn, New Jersey, USA) was packaged into unlabeled, sealed packets each containing 12mg. Subjects were given ten packets and instructed to dissolve the contents of one packet in 240mL of water (5% w/v) in a sinus irrigation bottle, followed by bilateral sinus irrigation once daily. One packet was to be used daily.

Saline: Standard buffered isotonic salt packets (NeilMed, Santa Rosa, CA, USA) were re-packaged into unlabeled, sealed packets. Each subject was given ten packets as well, and instructed to dissolve the contents into 240mL of water, with subsequent bilateral irrigation. One packet was to be used daily.

Subjects were instructed to begin the trial with three days of no irrigation to allow for an initial washout period from any prior saline irrigation use. Then they were instructed to perform ten days of once-daily irrigations with the first envelope’s irrigants, followed by another three-day washout period, and ending with ten days of once-daily irrigation with the other irrigant. The order of irrigation was randomized using a random-number generator, in a double-blinded fashion.

Outcomes Measures
SNOT-20: The Sino-Nasal Outcome Test 20 (SNOT-20) was given to all subjects to be completed on the first and final day of each irrigation course as the primary outcome measure.

Visual Analog Scale (VAS): Given at enrollment for self-completion on the first and final days of each irrigation course. It was measured as a mark made by the subject on a 100mm line to represent their overall sinonasal well-being, where the lowest extreme of the line (0) indicates the “worst” possible feeling, and the highest extreme end (10) represents “best” possible feeling.

Statistical Analysis
SAS Enterprise Guide 4.2 (SAS, Cary, NC, USA) was used for data analysis.

Results

There were ten subjects in each group. The average age was 44 years in both groups. The male to female ratio of the Saline then Xylitol group was 3:7, and 7:3 in the other. Fifteen (75%) subjects returned data for use in the analysis.

There was no significant effect of the order of irrigation with saline or xylitol (p=0.27). Of the subjects who completed both phases of irrigation (n=14), comparing each participant’s SNOT-20 scores to himself, nine had greater reduction of symptoms during the xylitol rinse phase versus the saline phase. Three subjects had greater reduction of symptoms with saline. Two subjects had no difference between the irrigation courses. [See Figure 2]. For an as-treated analysis the difference in SNOT-20 scores was still significantly more improved for the xylitol irrigations (p=0.049).

Utilizing the data collected from the fifteen subjects on an intent-to-treat basis, the mean change in summed SNOT-20 score from pre to post-irrigation was an increase of 3.93 points for the saline irrigations, from 15 to 18.93. The mean change in total SNOT-20 score from pre to post-irrigation was down 2.43 points for the xylitol irrigations, from 17.93 to 15.5. This difference in treatment effect was statistically significant (p=0.0437). [See Figure 1].

Using the same model to evaluate changes in the visual analog scale, the mean change for the saline irrigation from pre to post-treatment was a drop by 0.07 from 6.85 to 6.78, whereas the corresponding change for the xylitol irrigation was an increase of 0.56, from 6.91 to 7.47. There was no statistically significant difference in these treatments (p=0.35) nor their order (p=0.80). [See Figure 3]

One subject (7%) reported minor stinging in his nose with the xylitol that went away quickly the first time and did not recur. Three subjects (21%) made negative comments about the saline rinses. There were no reports of stinging with the saline rinses.

Regarding overall safety, there were no adverse events noted after irrigating with the xylitol.

Conclusion

Xylitol is a safe, natural five carbon sugar which is gaining interest in many fields for promising data showing efficacy against chronic bacterial infections. We have shown that it is a well-tolerated sinonasal irrigant when mixed with water in a 5% weight/volume formulation, with only few complaints regarding its inherently sweet taste and one isolated report of transient stinging. In our small randomized double-blinded controlled pilot, there were small but significant improvements in SNOT-20 scores with xylitol irrigation as compared to saline irrigation. Further studies with longer treatment courses and more subjects are merited to further delineate these findings and to determine their clinical significance.