

ORIGINAL ARTICLE

Xylitol Containing Chewing Gums in the Management of Chronic Otitis Media with Effusion

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OBJECTIVE: To determine the efficacy of the xylitol in chewing gums in combination with the antibiotics for treatment of the chronic otitis media with effusion.

STUDY DESIGN: Prospective, randomized, single blinded.

METHODS: 29 patients with chronic otitis media with effusion were given xylitol or sorbitol containing chewing gums in a constant dosage with antibiotics. They were followed up monthly and at the end of 3 months, tympanometry was performed to all children whose ear condition were recorded according to otoscopic examinations and tympanograms.

RESULTS: In the xylitol group, the middle ear pressure for the right ear before the treatment was $-347,71 \pm 60,04$ daPa, whereas it was decreased to -230.00 ± 123.88 daPa ($p < .01$) after the treatment. In the sorbitol group the middle ear pressure for the right ear before the treatment was -351.57 ± 80.29 daPa, and it was decreased to -321.36 ± 62.90 daPa ($p < .05$) after the treatment. In the xylitol group, the middle ear pressure for the left ear before the treatment was -312.14 ± 87.38 daPa, whereas it was decreased to -154.4 ± 185.27 daPa ($p < .05$) after the treatment. In the sorbitol group the middle ear pressure decrease for the left ear after the treatment was not found statistically significant ($p > .05$). The patients who received xylitol containing chewing gums had more improvement in the pressure levels for the right and the left ears than those in the sorbitol group.

CONCLUSION: In the treatment of chronic otitis media with effusion, the chewing gums containing xylitol have been more effective than sorbitol containing gums.

Chronic otitis media with effusion is an inflammatory process in which there is collection of fluid behind an intact tympanic membrane without any sign of acute infection. It is one of the most common causes of "hearing loss in children". Although the etiology of effusion is not clear, bacteriae such as *H. Influenzae*, *S. Pneumoniae*, *B. Catarrhalis*, *S. Pyogenes* and *S. Epidermidis* are shown in the cultures taken from the effusions. These findings support the role of the bacteriae in the pathogenesis of the chronic otitis media with effusion.^[1,2] In most cases; after 3 months follow up, if the effusion is not still resolved and inspection of the tympanic membrane is not normal, the placement of a tympanostomy tube under general anesthesia is required. Nearly 600,000 tympanostomy procedures have been performed in the USA every year.^[3] Antibiotics^[4,5], antihistaminics, decongestants^[6] and corticosteroids^[7] have been used alone or in combination to treat the disease medically without any need of surgery. The antibiotics in excessive amounts for the treatment of the chronic effusion, unfortunately, leads to resistance and thus negatively effect the course of the disease.^[8] In recent years; Xylitol, a five-carbon sugar alcohol, that occurs naturally in certain fruits (plums, strawberries, raspberries, and rowanberries) and that has been widely used as a sweetener mainly in chewing gums, have been found to inhibit the growth of the *Streptococcus Pneumoniae*.^[9] Using this data; studies have been performed and xylitol sugar when given in a syrup or chewing gum was found to be effective in decreasing the acute otitis media incidence in about 30-40% of the day-care children.^[10,11] In these studies; the day-care children evaluated for acute otitis media, are given treatment but none of them have been followed for chronic otitis media with effusion.

In this study, since the treatment of chronic otitis media with effusion using antibiotics has not always been successful, we added xylitol containing chewing gums to the treatment protocol to see whether they are effective in clearing the effusion and normalizing the middle ear pressure. If our hypothesis were true, then we would be able to discard unnecessary antibiotics from the treatment protocol.

METHODS

Recruitment

This study is a randomised and a prospective trial performed in the Department of Otolaryngology, Head and Neck Surgery; Dr. Lutfi Kirdar Kartal Training and Research Hospital. The study was held between February 2004 and September 2004 with the approval of the hospital ethic committee. The informed consent forms were obtained from the families.

Only the children whose parents gave written informed consent were included in the trial.

Participants and screening

The participants (n=29) were recruited from the outpatient clinic of Dr. Lutfi Kirdar Kartal Training and Research Hospital; aged from 4 years to 10 years. All the children who were included in the trial had been followed up for 3 months and those whose effusion persisted were included in the trial. All the children who were receiving long term antimicrobial prophylaxis, who had acute otitis media recently and who had craniofacial abnormalities were excluded. Also the children who were unable to chew gums were not included. The history of the patients and the data on the risk factors for otitis media with effusion (OME) were collected from the parents by a questionnaire. Routine examination was performed to all children, including nasopharyngeal endoscopy and pneumatic otoscopy. At the beginning of the trial all the children were also screened with tympanometry and pure tone audiometry. Their ear condition, adenoid and tonsil sizes were recorded. Adenoid size was defined as the percentage rate of the obstruction of the choanal passage. Tonsilla palatina was defined as in size between grades 1 and 4. Those with abnormal tympanograms (other than an A-curve) were re-checked by the pneumatic otoscopy. All those who had middle ear effusion without any co-existing acute respiratory tract infection (ARI) were accepted.

Follow-up and treatment

During the 3 months follow up period, the children were examined monthly, and the parents were asked to

bring their children to our outpatient clinic whenever there was any evidence of acute respiratory tract infection (clear or purulent discharge from nose, cough, conjunctivitis, painful dysphagia, earache, or fever). Tympanometry and pure tone audiometry were both performed by the same audiologist; the tympanograms were classified by Jerger method.^[12] A course of (10 days) amoxicillin-clavulanate was prescribed for all children at the beginning of the trial followed by 1 month observation period as recommended by AHCPR^[13] for the medical treatment of OME. At the second visit, the children were examined by the pneumatic otoscope and the signs of improvement were noted. If there was an improvement, no medication was given and the third visit was scheduled within one month. If there was still no improvement, another course of amoxicilline-clavulanate was prescribed and the third visit was scheduled within one month. If the children had any ARI between the visits, they were treated with 7 days antibiotherapy after pediatrician's and authors examination and then examined weekly. At the end of 3 months, tympanometry was performed to all children, ear condition was recorded according to otoscopic examination and tympanograms. The children with persistent effusion underwent adenoidectomy or adenotonsillectomy operation in combination with myringotomy. The condition of the ear and the presence of glue were recorded peroperatively. If glue was present, the grommet tympanostomy tube was introduced.

Administration of the xylitol and patient compliance

The participating children were randomized to receive either xylitol (n=15) or sorbitol (n=14) containing chewing gums for 3 months. Xylitol has similar sweet taste as sorbitol. Each child was instructed to chew two pieces of standard gum five times (one box) a day after each meal which was equal to total dose of 8.4 g xylitol per day. The chewing process lasted until there was no taste left or for at least five minutes. Parents were advised not to give their children any other xylitol containing food (plums, strawberries, raspberries, and rowanberries) and preparations during the follow up period.

Compliance was monitored by asking the parents to list the doses on the daily symptom sheet and by counting the unchewed pieces of chewing gum returned at the last appointment.

Presence of allergic rhinitis, breast feeding history, birth weight, premature gestation, and family smoking history status were compared between the two groups. Also size of the tonsilla palatina and adenoid and presence of chronic tonsillitis were compared between the groups. Pressure levels in tympanograms were compared between the right and the left ear before and after the treatment. A comparison was also made between the two groups.

Study design

The study was single blinded in the xylitol and sorbitol groups. Randomization was performed using tables of random numbers and using a block randomization with block size of 4. We used random number table to make the proportion of participants in each study group approximately the same.

Sample size

The calculation of sample size was based on our earlier experience of the occurrence of OME during the respiratory tract infection and its resolution rate during the 3 months observation period under antibiotherapy. A group size of 29 was required for a power of 95 %, a .05 type 1 error (p value).

Statistical analysis

Analysis was done using a SPSS (Statistical Package for Social Sciences) for Windows 10.0 program. Analysis of the parametric nonrepeated measures was performed with student t test and Mann-Whitney test, analysis of nonparametric nonrepeated and repeated measures were performed with Fisher exact test and χ^2 test.

RESULTS

Twenty-nine children were included in this study. Fifteen children used xylitol containing chewing gums (xylitol group) and fourteen used sorbitol containing

chewing gums (control group). Ages ranged between 4 and 10 (mean±SD= 6.20±1.80).

While the mean age of the xylitol group was 7.0±1.64, it was 5.35±1.59 in the sorbitol group. The difference between the mean ages of the two groups was found statistically significant ($p<.05$). The groups were similar with respect to sex, allergic rhinitis history, breast feeding, birthweight, premature birth and the smoking history of the family ($p>.05$.) (Table 1).

The size of the tonsil tissue in the sorbitol group was larger than those in the xylitol group and this difference was found statistically significant ($p<.05$). There were no significant difference between the groups in terms of the size of adenoid tissues ($p>.05$) and incidence of chronic tonsillitis ($p>.05$) (Table 2).

Before the treatment, there was no statistically significant difference in terms of the middle ear pressure for the right and left ear in both groups ($p>.05$).

In the xylitol group, the middle ear pressure for the right ear before the treatment was -347.71 ± 60.04 daPa, whereas it was decreased to -230.00 ± 123.88 daPa, and this decrease was statistically highly significant ($p<.01$). In the sorbitol group the middle ear pressure for the right ear before the treatment was -351.57 ± 80.29 daPa, and it was decreased to -321.36 ± 62.90 daPa, and also this decrease was found statistically significant ($p<.05$). When the middle ear pressure difference for the right ear before and after the treatment was compared, no difference was detected ($p>.05$) (Table 3).

In the xylitol group, the middle ear pressure for the left ear before the treatment was -312.14 ± 87.38 daPa, whereas it was decreased to -154.4 ± 185.27 daPa, and this decrease was found statistically significant ($p<.05$). In the sorbitol group the middle ear pressure for the left ear before the treatment was -330.86 ± 80.06 daPa, and it was decreased to -319.00 ± 68.64 daPa.

Table- 1: Demographic properties of groups.

		Xylitol Group		Sorbitol Group		p
		Mean	SD	Mean	SD	0.011*
+Age (year)		7.00	1.64	5.35	1.59	
		n	%	n	%	
++Gender	Male	11	73.3	9	64.3	0.700
	Female	4	26.7	5	35.7	
++A.rhinitis		6	40.0	4	28.6	0.518
+++Breast Feeding (month)		14	93.3	11	78.6	0.330
+++Birth Weight		11	73.3	9	64.3	0.434
+++Prematurity		3	20.0	5	35.7	0.427
++Parental Smoking		7	46.7	9	64.3	0.340

* $p<0.05$, SD: Standart Deviation.

+ Student t test

++ Chi-Square test

+++Fisher's Exact test

Table-2: Tonsilla palatina and adenoid size, incidence of chronic tonsillitis between groups.

		Xylitol Group		Sorbitol Group		p
		Mean	SD	Mean	SD	Value
+Age (year)		7.00	1.64	5.35	1.59	
+Tonsil size		2.80	0.67	2.14	0.77	0.017*
+Adenoid size (%)		63.83	22.25	59.28	14.91	0.715
		n	%	n	%	
++History of Chronic tonsillitis		6	40.0	8	57.1	0.356

* $p<0.05$, SD: Standart Deviation.

+ Student t test

++ Chi-Square test

This decrease was not statistically significant ($p > .05$). There was highly statistically significant difference between the groups in terms of the middle ear pressure for the left ear after the treatment ($p < .01$). However the middle ear pressure difference for the left ear before and after the treatment was statistically significant ($p < .05$). After treatment with xylitol the decrease in the pressure was statistically higher than the sorbitol group (Table 3).

Analysis of the pure tone audiometry, the number of patients who had glue secretion after myringotomy and the incidence of acute otitis media attack during the follow up period revealed no significant difference ($p > .05$) (Table 4).

DISCUSSION

In this trial, we evaluated whether chewing gum including xylitol was effective in the treatment of effusion when given together with antibiotics for 3 months or not. We found that the middle ear pressure improved in the xylitol group than it did in the sorbitol group.

If new drugs or substances which are effective in the treatment of chronic effusion when used in combination with the antibiotics are found, the appropriate dosage of the antibiotics can be reduced. This decreases the incidence of the effusion and also

Table-3: Comparison of the pressure levels for the right and left ears before and after the treatment.

		Xylitol Group		Sorbitol Group		p Value
		Mean	SD	Mean	SD	
Pressure R	+BT	-347.71	60.04	-351.57	80.29	0.747
	+AT	-230.00	123.88	-312.36	62.90	0.059
<i>p</i> *		0.006**	0.023*			
Difference (BT-AT)		-117.71	107.93	-39.21	107.05	0.135
Pressure L	+BT	-312.14	87.38	-330.86	80.06	0.872
	+AT	-154.14	185.27	-319.00	68.64	0.004**
<i>p</i> *		0.013*	0.443			
+Difference (BT-AT)		-167.00	222.72	-11.85	71.63	0.046*

* $p < 0.05$ ** $p < 0.01$ p : values in the groups BT: before treatment AT: After treatment
SD: Standart Deviation. L. Left R. Right
+ Mann Whitney U test *p*°:Wilcoxon sign test

Table- 4: Comparison of the pure tone audiometric results and the presence of glue after the treatment

		Xylitol Group		Sorbitol Group		p
		Mean	SD	Mean	SD	
+Pure tone R		26.93	10.64	28.28	8.91	0.715
+Pure tone L		26.80	11.88	28.28	11.33	0.733
		n	%	n	%	
++GLUE R		8	53.3	8	57.1	0.837
++GLUE L		8	53.3	6	42.9	0.573
+++ AOM		3	20.0	4	28.6	0.682

SD: Standart Deviation,
AOM: Acute Otitis Media
+ Student t test ++Chi-Square test +++Fisher's Exact test

reduces the incidence of bacterial resistance to antibiotics.^[8]

There is an increasing concern in the medical community about inappropriate oral antibiotic usage. In pediatrics, the increasing resistance of *Streptococcus Pneumoniae* to penicillins causes great problems, because *S. Pneumoniae* is the leading bacterial cause of acute otitis media (AOM), sinusitis, pneumonia, bacteremia, and meningitis^[14]. Xylitol is a sugar alcohol which reduces the growth of *Streptococcus Pneumoniae* and the adherence of pneumococci and *Haemophilus Influenzae* to nasopharyngeal cells. Xylitol prevents acute otitis media but does not decrease the nasopharyngeal carriage of the pneumococci. The observed changes in the polysaccharide capsule and the cell wall of pneumococci can affect the adherence and virulence of the bacteria which explains the good clinical efficacy of xylitol in the prevention of acute otitis media^[15]

In a double blind study by Uhari et al., 306 children (day-care) were divided into two groups and were given sucrose containing chewing gums or xylitol containing (8.4g/day) chewing gums for two months. During this time, the incidence of at least one attack of AOM and the amount of prescribed antibiotics were found statistically less in the xylitol group when compared to the control group. They reported that when given to the children with recurrent otitis media, xylitol containing chewing gums reduced the occurrence of otitis media with the overall success rate of 40%. As a result, authors suggested that xylitol had protective effect against acute otitis media.^[10]

In another study, Uhari et al. distributed 857 healthy children into five groups randomly. Groups received syrup, gum or lozenge with xylitol and syrup or gum with sucrose during 3 months period. The incidence of AOM attacks and the need for antibiotics were decreased in children who received xylitol containing chewing gums and syrups.^[11] However, if xylitol was only given during the acute phase of the respiratory tract infections, its preventive effect on acute otitis media could not be seen.^[16]

In those previous studies, the preventive effect of xylitol on AOM attacks has been shown clearly. Depending on these results; we planned this study to evaluate the effect of the same sweetener (xylitol) in the treatment of the chronic otitis media with effusion. Our groups were settled by selecting the patients who were diagnosed as chronic otitis media with effusion. All the children who were included in the trial have been followed up for 3 months and those whose effusion persisted were included in the trial. These patients were followed up with tympanometry and pure tone audiometry for 3 months in addition to the standart clinical examination which made the difference of our study when compared to the previous studies. We also designed a control group in which sorbitol containing chewing gums were given to evaluate whether the curative effect of xylitol containing chewing gums depend on mechanical factors or not.

Although no significant difference has been found in demographic variables between the two groups in our study, the mean age of xylitol users was higher than those using sorbitol. This might be the only handicap for the similarity of the two groups. Size of adenoid tissue which was important for the pathogenesis of chronic effusion has been found to be similar in both groups. Size of tonsilla palatina that was not as important as adenoids in the pathogenesis of chronic effusion was found larger in the xylitol group. No significant difference was detected in the incidence of chronic tonsillitis between the two groups.

At the beginning of the study; no significant difference in pressure levels were detected in both the right and the left ears between the two groups. At the end of the treatment; despite the statistically significant improvement of the middle ear pressure in the left ears in the xylitol group, there was no significant improvement in the sorbitol group. For the right ear; at the end of the treatment, there was highly statistically significant improvement in the xylitol group, also significant improvement was present in the sorbitol group. When we evaluated the difference of

the pressure levels at the pre and post treatment periods for each ear and for the particular groups; difference of pressure levels in the xylitol group was more for both ears than the control group, but only in the left ears the difference was statistically significant. For the right ear the pressure difference was 117.71 daPa in xylitol group, 39.21 daPa in sorbitol group, for the left ear the pressure difference was 167.00 daPa in xylitol group, 11.85 daPa in sorbitol group. There was no statistically significant difference between the groups in terms of the presence of glue in the middle ear and the pure tone audiometric results for right and left ears respectively after the treatment. In the context of these results we could say that the improvement of middle ear negative pressure in the xylitol group better than the sorbitol group for both ears.

Xylitol is slowly absorbed from the gastrointestinal tract; if it is taken in large amounts, it can cause osmotic diarrhea. No such a side effect has been seen in our patients.

In the study of Uhari et al, most of the patients in the xylitol group had adenoidectomy performed previously.^[10] This might be the cause of the success in preventing the AOM. In our study none of our patients had adenoidectomy previously. If our patients were performed adenoidectomy before the study, our treatment results could be expected to be better. The mean age of children in our trial was 6.20(1.80 years old. This age is older than that of most patients with acute otitis media as the peak incidence occurs at the age of 6-15 months.^[17-18] The children participating in our trial had to be able to chew gums without swallowing it. This forced us to select older children. To be able to include the younger children who can not chew gums to the study, studies with xylitol syrup or xylitol lozenges should be planned in future.

CONCLUSION

We concluded that xylitol containing chewing gums, when used in combination with the antibiotics is

an effective, well tolerated and inexpensive way in the management of the chronic otitis media with effusion.

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