



EVALUATION OF XYLITOL WIPES AS AN ORAL HYGIENE PROTOCOL FOR HEMOPHILIC CHILDREN: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Objectives: The purpose of this study was to evaluate the efficacy of xylitol wipes in reducing the dental plaque and as an oral hygiene protocol for hemophilic children. **Subjects and methods:** Thirty patients participated in this study. **Group A** (xylitol group): the patients who received xylitol dental wipes. **Group B** (control placebo group): the patients who received plain dental wipes without therapeutic ingredients. All children were instructed to use them twice a day for one week. Simplified Plaque index was recorded at baseline, and after one week. The obtained data were tabulated and analyzed. **Results:** A noteworthy reduction in dental plaque was noted in the group A using xylitol wipes compared to the group using placebo wipes. The results of the intergroup comparison were deemed statistically insignificant. **Conclusion:** Although both the tooth wipes are effective in reducing dental plaque, but the xylitol wipes were higher in reducing dental plaque than placebo wipes.

KEYWORDS: Xylitol, hemophilia, tooth wipes, oral hygiene, dental plaque.

INTRODUCTION

Haemophilia, a prevalent sex-linked bleeding disorder on a global scale, exhibits an incidence of approximately 5000–10000 male births ^(1,2). In Egypt, as per the 2022 annual global survey by the World Federation of Hemophilia (WFH) and Egyptian Society of Hemophilia, the number of individuals diagnosed with hemophilia was 7,486. Among them, hemophilia A accounted for 5,521 cases, hemophilia B for 1,278 cases, and von Willebrand disease (vWD) for 687 cases ⁽³⁾.

Patients suffering from congenital bleeding disorders often experience significant apprehension regarding the likelihood of bleeding episodes

occurring during or after treatment, along with concerns about the level of comprehension dentists have about their bleeding disorder and its management ⁽⁴⁾. Furthermore, many patients tend to become anxious when their gums bleed while brushing, leading them to avoid proper oral hygiene practices, thereby exacerbating the issue ⁽⁵⁾. Consequently, addressing the needs of such individuals necessitates heightened awareness, accommodation, and focused attention, coupled with specialized expertise. Emphasizing the implementation of preventive strategies to mitigate undesired oral health complications in this demographic represents the optimal approach to managing this condition.

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The utilization of tooth-wipes has been recognized as a suitable supplementary tool for mechanical plaque removal and the maintenance of oral hygiene in children. The adoption of xylitol-wipes has demonstrated both safety and high acceptability among parents and infants alike ^(6,7). For some individuals with hemophilia, there exists a fear that the act of brushing and flossing may trigger oral bleeding episodes.

This study aimed to assess the effectiveness of xylitol wipes as part of an oral hygiene regimen for children with hemophilia.

SUBJECTS AND METHODS

Selection of patients

The sample population was selected from hemophilic children who attend to outpatient dental clinic of Egyptian society of hemophilia, ranging from 6 to 12 years old.

Inclusion criteria:

“Hemophilic children A or B with No other systemic diseases”.

Exclusion criteria:

Uncooperative child. “Children whom parents refused to participate in the study Children”.

Patients consent:

Upon completion of the initial assessment and approval, parental consent was obtained in written form subsequent to a comprehensive elucidation of the procedure entailed, the duration of the treatment, and a particular focus on the potential results.

Grouping of patients:

Thirty patients participated in the study. This study was designed as a randomized controlled clinical study up to one week follow-up and the protocol approved by the ethics committee of faculty of Dental Medicine Azhar University, Boys, Cairo. (EC Ref No. 687/3906/02/10/2021). and Permission from the hemophilia society was obtained.

Randomization Was done using randomization website, (<https://www.randomizer.org/>) and participants will randomly divide into two Groups: by applying number of set 2 and numbers per set 15 and the range from 1 to 30 the website will randomize the numbers into 2 sets or groups. *Group A*: xylitol group: the patients received xylitol dental wipes. *Group B*: placebo group: the patients received plain dental wipes without therapeutic ingredients.

Treatment protocol for both groups

Xylitol Wipes Allocation

At the initial appointment, mothers were provided with comprehensive information regarding the research study and its duration. The process of obtaining informed consent was followed by the assignment of a unique patient study ID number.

Xylitol wipe: manufactured by: My Dentist's choice TM Rocky Hill, Connecticut, USA.

Placebo wipe: manufactured by: Elnakhla Tex for Industry Belbeis, Al Sharqia Governorate, Egypt.

Both the xylitol wipe and placebo wipe were indistinguishable in appearance and were identified as wipes for either Group A or Group B. Each xylitol wipe contained 0.7 grams of xylitol, along with additional components such as purified water, glycerin, hydroxyl ethyl cellulose, sodium benzoate, natural flavor, and citric acid. Conversely, the placebo wipes mirrored the ingredients of the xylitol wipes except for the absence of xylitol. Detailed instructions on usage were provided alongside a practical demonstration for the mothers. Subsequent visits involved the monitoring and documentation of any potential side effects on a designated tracking form.

Procedures:

Steps will follow the manufacturing instructions as following:

Step 1. The wipe was Extended around the index finger.

Step 2. The patients instructed to Lightly scrub tooth surfaces (buccal, lingual and occlusal) with the tooth wipe.

Step 3. The wipe was removed from finger and dispose of properly and each tooth should be wiped two to three at a time.

Step 4. Instruct the child to do the previous steps to ensure effective understanding of oral hygiene measure.



FIG (1) Photograph showing xylitol wipes bag.

Timing

The children were instructed to use the allotted wipes one hour after their meals, two times a day for one week consecutively.

Observation:

Children were evaluated and record the Plaque index for two groups before using wipes at baseline and after one week.

Plaque index:

Measure for estimating status of oral hygiene by measuring dental plaque that occurs in areas adjacent to gingival margin.

0= "No staining".

1= "Film at gingival margin".

2= "Moderate accumulation".

3= "Abundance of plaque".

Data management and statistical analysis were conducted utilizing the Statistical Package for Social Sciences (SPSS) version 27. Summary statistics for numerical data included means, standard deviations, and ranges. Assessment for normality of the data involved the Kolmogorov-Smirnov test and Shapiro-Wilk test. Categorical data were presented as percentages. Group comparisons were carried out using the independent t-test, while the paired t-test was employed for analyzing differences among repeated measures. All statistical tests were two-sided, with significance level set at $p < 0.05$.

RESULTS

Age

In accordance with Table (1), the average age of individuals within the Xylitol cohort was determined to be 9.8 years, exhibiting a SD of 1.7 years. Conversely, the mean age within the Placebo cohort was 9.3 years, accompanied by a SD of 2.1 years. Notably, there existed no statistically significant distinction in age between the Xylitol cohort and the Placebo cohort ($P > 0.05$).

TABLE (1) Comparison of Age between the Xylitol Group and Placebo Group

	Xylitol group	Placebo group	P value
Age(years)	9.8±1.7	9.3±2.1	0.453

SD: standard deviation, $p < 0.05$ "is statistically significant, analysis was done by independent t test"

Plaque Index:

In Table (2), it is illustrated that prior to the intervention, the mean plaque index in the Xylitol group was 1.9 with a SD of 0.5, while in the

Placebo group, it was also 1.9 with a SD of 0.3. The resulting P-value of 0.811 indicates the absence of a statistically significant distinction in plaque index between the two groups at baseline ($P > 0.05$).

Subsequent to the intervention, the mean plaque index in the Xylitol group diminished to 0.9 with a SD of 0.2, whereas in the Placebo group, it decreased to 1.1 with a SD of 0.2. The P-value obtained for this comparison was 0.039, implying a statistically significant divergence in plaque index post-intervention between the two groups ($P < 0.05$).

Moreover, the computation of percentage reduction in plaque entailed a comparison between pre- and post-intervention plaque indices. In the Xylitol group, the average percentage reduction stood at 52.6% with a SD of 13.2%, while in the Placebo group, it was 44.8% with a SD of 8.6%. Despite the P-value of 0.071 denoting the absence of a statistically significant variance in percentage reduction between the two groups ($P > 0.05$).

In conclusion, these observations indicate that the utilization of Xylitol might result in a more pronounced decrease in plaque index in contrast to the placebo.

TABLE (2) Comparison of Plaque Index and Percentage Reduction in the Xylitol Group and Placebo Group

Plaque Index	Xylitol group	Placebo group	P value
	Mean \pm SD	Mean \pm SD	
Before	1.9 \pm 0.5	1.9 \pm 0.3	0.811
After	0.9 \pm 0.2	1.1 \pm 0.2	0.039
PI % reduction	52.6 \pm 13.2	44.8 \pm 8.6	0.071

PI: Plaque index, SD: standard deviation, $p < 0.05$ is statistically significant, analysis was done by independent t test

Overtime

In Xylitol group

As shown table (3) Before the intervention, the mean plaque index was 1.9 with a SD of 0.5. After the intervention, the mean plaque index significantly decreased to 0.9 with a SD of 0.2. This reduction was statistically significant, as indicated by a P-value of less than 0.001.

In placebo group

As shown table (3) Before the intervention, the mean plaque index was 1.9 with a SD of 0.3. After the intervention, the mean plaque index decreased to 1.1 with a SD of 0.2. The reduction in plaque index was statistically significant, as indicated by a P-value of less than 0.001.

Although both decreased by time but the xylitol group was higher than placebo.

TABLE(3) Plaque index change overtime in the studied groups

Plaque Index	Before	After	% Reduction	P value
	Mean \pm SD	Mean \pm SD		
Xylitol group	1.9 \pm 0.5	0.9 \pm 0.2	52.5 \pm 13.2	<0.001
Placebo group	1.9 \pm 0.3	1.1 \pm 0.2	44.8 \pm 8.6	<0.001

PI: Plaque index, SD: standard deviation, $p < 0.05$ is statistically significant, analysis was done by paired t test

DISCUSSION

There has been scarce literature focusing on the oral health status and requirements of haemophilic children in Egypt. The current investigation aims to address this gap by conducting a needs assessment specifically targeting these children.

Mutans streptococci are commonly present in dental plaque, and the mechanical elimination

of these bacteria is believed to lower mutans streptococci levels and reduce susceptibility to dental caries⁽⁸⁾.

Disclosing agents serve various purposes, ranging from assessing the efficacy of oral hygiene⁽⁹⁾, maintenance to preparing plaque indices⁽¹⁰⁾. In the present research, disclosing agents were utilized to measure plaque index instead of employing a dental probe to minimize the risk of bleeding in certain haemophilic children⁽¹¹⁾.

Tooth wipes were selected for this study due to their disposable nature and lack of necessity for washing or storage. The use of individually packed tooth wipes substantially reduces the risk of microbial transmission. These wipes, designed without bristles, minimize irritation and are suitable for individuals with sensitive oral tissues, such as hemophilic patients, as they do not require any dentifrice or water for usage.

Children exhibited a more favorable response to xylitol-wipes compared to placebo-wipes. These results align with previous findings by Galganny-Almedia et al.,⁽¹²⁾ who observed improved acceptance of xylitol-wipes among infants during nighttime and equal satisfaction during the daytime compared to tooth brushing. The study also revealed that sweetening tooth wipes with xylitol significantly enhanced children's acceptance of them.

The analysis of our study involved calculating the percentage reduction in plaque by comparing the plaque index before and after the intervention. The Xylitol group showed a mean reduction of 52.6% with a SD of 13.2%, while the Placebo group exhibited a reduction of 44.8% with a SD of 8.6%. Despite a non-statistically significant P-value of 0.071, signifying no significant difference in the reduction percentage between the two groups ($P > 0.05$).

These results are consistent with the study by Deshpande MA et al.,⁽¹³⁾ which reported a substantial decrease in plaque scores in both the

Triphala tooth wipes group and the placebo group after 7 days. Upon intergroup comparison, no statistically significant difference was observed at any stage ($P > 0.05$).

CONCLUSION

Although both tooth wipes are effective in reducing dental plaque but the xylitol wipes were higher in reducing dental plaque than placebo wipes. Thus, xylitol tooth wipes can be used as oral hygiene practices in children with special health care needs like haemophilic children.

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