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Assessing the Effect of Aqueous Lavender Extract Sprays on Gingivitis in Pediatric Patients with Type 1 Diabetes (Randomized Clinical Trial)

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Abstract:

Introduction: The prevalence of diabetes mellitus in children and adolescents has increased worldwide over the past three decades. High blood sugar levels in diabetic patients negatively affect the inflammatory response to dental plaque, leading to gingivitis and periodontitis, manifested by periodontal abscesses, and xerostomia, which leads to cervical caries and a high carious predisposition. Several studies have shown that plaque removal is not completely achieved using mechanical methods alone, so chemical control methods have emerged as an adjuvant and enhancing method.

The aim of the research: The current study aims to evaluate lavender sprays on gingivitis in pediatric patients with type 1 diabetes.

Materials and methods: The study was designed as a randomized controlled clinical study that included a sample of 30 children divided into two main groups (placebo spray, lavender spray). Children were given one of the sprays used in the research sample randomly and were taught how to use it, using it twice daily for one minute each time. The gingival index was assessed at baseline and after one week,
one month and three months. The data were collected and analyzed statistically using the SPSS V.25 software.

Results: There were no statistically significant differences in the mean gingival index before starting the study, and after the first week, inflammation improved in both groups, with significant differences between the effect of the two sprays after one week, one month and three months in favor of the lavender spray group more than in the placebo spray group.

Conclusions: Within the limitations of the current study, the lavender spray contributed to reducing gingivitis in children with type 1 diabetes when compared with the placebo spray.

Keywords: Oral Sprays; Lavender; Placebo Effect; Gingivitis; Type 1 Diabetes

تقييم تأثير بخاخات مستخلص الخزامى المائي على الالتهاب اللثوي عند المرضى الأطفال المصابين بداء السكري من النمط الأول (دراسة سريرية معشاة)

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الملخّص:

المقدمة: زاد انتشار داء السكري عند الأطفال والمراهقين في جميع أنحاء العالم خلال العقود الثلاثة الماضية، وإن مستويات السكر المرتفعة في الدم لدى مرضى السكري تؤثر سلباً على الاستجابة الالتهابية للويحة السنية مما يؤدي الى التهاب اللثة والتهاب النسج الداعمة، وتتظاهر بوجود التهاب اللثة والتهاب النسج حول السنية والخراجات اللثوية وجفاف الفم والذي يؤدى لنخور عنقية واستعداد نخري كبير. أظهرت العديد من الدراسات أن إزالة اللويحة لا تتم بكاملها باستخدام الوسائل الميكانيكية وحدها لذلك ظهرت وسائل السيطرة الكيميائية بوصفها وسيلةً مساعدة و معززة.

الهدف من البحث: تهدف الدراسة الحالية لتقييم بخاخات الخزامى على التهاب اللثة عند المرضى الأطفال المصابين بداء السكري من النمط الأول.

المواد والطرائق: صممت الدراسة على انها دراسة سريرية مضبوطة معشاة شملت عينتها

احدى البخاخات المستخدمة في عينة البحث وتم تعليمهم كيفية الاستخدام حيث يستخدم مرتين يومياً كل مرة لمدة دقيقة واحدة. تم تقييم مشعر التهاب اللثة قبل البدء وبعد أسبوع وشهر وثلاثة اشهر. ومن ثم جمعت البيانات وحُللت باستخدام برنامج SPSS v.25.

النتائج: لا يوجد فروقات ذات دلالة إحصائية في متوسط مشعر الالتهاب اللثوي قبل البدء بالدراسة، وبعد الأسبوع الأول تحسن الالتهاب عند المجموعتين مع وجود فروق ذات دلالة بين تأثير البخاخين بعد أسبوع وشهر وثلاثة أشهر لصالح مجموعة بخاخ الخزامى أكثر منه عند مجموعة مستخدمي البخاخ الوهمي

الاستنتاجات: ضمن محدوديات الدراسة الحالية فإن بخاخ الخزامى ساهم في خفض الالتهاب اللثوي عند الأطفال المصابين بداء السكري من النمط الأول عند مقارنته مع البخاخ الوهمي.

الكلمات المفتاحية: البخاخات الفموية؛ الخزامى؛ التأثير الوهمي؛ التهاب اللثة؛ داء السكري النمط الأول.

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Introduction

The World Health Organization (WHO) defined dental plaque as a specific and highly variable colony of microorganisms that grow on and inhabit the surfaces of teeth and restorations, consisting of different species and strains embedded within a cellular matrix composed of bacterial metabolic products, serum, saliva and blood (Jakubovics et al., 2021).

Dental plaque consists of 80% water, 20% organic and inorganic materials, and an intercellular matrix (20-30%), with bacteria constituting about 70-80% of the plaque (Jakubovics et al., 2021).

Each milligram of plaque contains about (150-200 million) bacteria, and microorganisms include fungi, mycoplasma, and some viruses (La Rosa et al., 2023).

The organic material consists of a polysaccharide protein as a basic component, while calcium and phosphorus form the main inorganic components (Jakubovics et al., 2021).

Diabetes is a disease that affects the body's metabolism at many levels. It is characterized by increased levels of glucose in the blood and abnormalities in the metabolism of both proteins and fats. This disorder results from a defect in insulin secretion or a defect in its function or both. It is a chronic disease that leads to disorders in various functions in the body (Subramanian et al., 2024).

Diabetes is a disease that exacerbates periodontal diseases, and uncontrolled patients show greater responses than normal people to any local gingival irritation. several studies have shown that the incidence of gingivitis in diabetic patients is greater than in normal people when the plaque index is equal between the two groups (Reddy et al., 2022).

Studies have also confirmed the presence of intimate association between diabetes and periodontal disease. Periodontal disease has been classified as the sixth complication of diabetes. Epidemiological studies have shown that both types 1 and 2 are a risk factor for periodontal diseases, especially in the presence of poor blood sugar control (Chakraborty et al., 2021).

Uncontrolled diabetes patients are more likely to develop oral infections, gingivitis and periodontitis than controlled diabetes patients. It is noted that the possibility of developing periodontitis was greater when the diabetes incidence was earlier (Costa et al., 2023).

Gingivitis is an inflammatory process that occurs on the parts of the gingiva and is curable, caused by microorganisms that form colonies that later form what is called dental plaque that adheres to the gingiva's surface, but the epidermal attachment remains attached to the dental tissues (Kaneyasu et al., 2024).

Gingivitis is manifested by redness and swelling of the gingival tissue, a tendency to bleeding when probing, an increase in gingival fluid and a change in the consistency of the gingiva (Pandiyan et al., 2022).

Bacteria present in dental plaque and calculus are the causative agent of most types of gingivitis, which usually develops within (10-21) days in the absence of plaque control, and can be removed mechanically by toothbrushing, chemically by toothpaste and mouthwash, or by scaling and root planing, or by a combination of the three methods (Pandiyan et al., 2022).

Phytochemical analysis shows that lavender essential oils contain linalool, linalyl acetate, 8-cineole-ocimene, terpene-4-ol, and camphor as major components. The mechanism of action of their various properties depends on this composition (Kozuharova et al., 2023).

Lavender essential oils have been used in medicine since the Middle Ages, and the bactericidal properties of essential oils were first tested by De La Croix (Speranza et al., 2023).

Lavender oil has a significant anti-inflammatory effect, and has been used in the treatment of dermatitis and eczema. In an animal study, lavender oil showed anti-inflammatory activity compared to dexamethasone. It was suggested that the mechanism involved is related to a G protein-coupled receptor or involves a secondary messenger system between cells (Ao et al., 2023).

Study (Kandaswamy et al., 2018) aimed to compare the effectiveness of chlorhexidine and sesame oil mouthwashes on children aged 10-12 years. The study sample consisted of 45 healthy children aged 10-12 years in a school in India. They were randomly divided into three groups. After giving the children oral care instructions, they were given mouthwashes to use once daily. The plaque index and gingivitis index were measured before, after two weeks, and after four weeks to assess their plaque control. The results showed that the chlorhexidine group outperformed the other groups by a statistically significant difference. The study concluded that

the used mouthwashes led to a significant reduction in plaque for the chlorhexidine group after two and four weeks.

Study (Salem et al., 2023) aimed to evaluate the effectiveness of anise and aloe vera mouthwashes at different concentrations against mutans bacteria compared to fluoride mouthwashes. The study sample included 70 children between the ages of 6 and 13 years randomly, and they were randomly distributed into 7 groups according to the applied intervention. Saliva samples were studied before and after applying the mouthwashes using bacterial culture. The study concluded that all herbal groups are effective in reducing bacteria at certain concentrations; compared to fluoride, and anise concentration of 15% was the most effective.

A study (Vanishree et al., 2021) was conducted to compare the effects of alum and herbal mouthwashes in controlling and preventing plaque formation. The study sample consisted of 60 children divided into three groups (alum mouthwash, herbal mouthwash, and physiological serum). It was applied once daily for 30 days and the plaque index was measured on the first, fifteenth, and thirtieth day. The results showed a significant decrease in plaque on the first, fifteenth, and thirtieth day in the alum group when compared to the herbal group and the physiological serum group. The study concluded that alum mouthwashes were more effective in controlling plaque than the other groups in the study.

The current study aims to evaluate the effect of lavender sprays on gingival inflammation in pediatric patients with type 1 diabetes.

Material & Methods

Study Design

This study is a controlled, and randomized clinical trial to evaluate gingival inflammation in pediatric patients with type 1 diabetes when using lavender spray compared to placebo spray.

The allocation ratio was 1:1.

Sample size was estimated based on a previous similar study using G*power v3.1, which used herbal mouthwashes) Bagchi et al., 2015(Based on this, the sample size was 13 children in each group. The sample size was increased to 15 children in each group in case of any dropouts.

The study groups included:

Group 1: Using a placebo spray containing no active ingredient.

Group 2: Using a spray containing lavender.

Inclusion Criteria

- Children's aged from 8 to 12 years.
- Presence of permanent first molars and maxillary incisors.
- Absence of any caries on the buccal and palatal surfaces of the teeth studied.
- Children were cooperative (positive or absolutely positive behavior according to the Frankel scale).
- Parental consent for the child's enrollment in the study.

Exclusion Criteria

- Children who had taken antibiotics, anti-inflammatory medications, or mouthwashes at least four weeks prior to this study.
- Children who had been on a preventive program within the last three months prior to the start of the study.
- Children undergoing orthodontic treatment.
- Allergy to any of the components of the spray used.

Gingival Index

This index is measured on the four permanent incisors and four permanent molars, and classifies gingivitis as follows:

- Grade 0: No inflammation.
- Grade 1: (Mild gingivitis) Minor discoloration, no bleeding on probing.
- Grade 2: (Moderate gingivitis) Redness, edema, surface gloss, bleeding on probing.
- Grade 3: (Severe gingivitis) Severe, obvious redness, edema, ulceration, spontaneous bleeding.

Materials

A. Personal protective equipment for the examining physician (gloves, mask, headgear).

B. Plastic lip retractor (for clear viewing of the work area and appropriate clinical documentation).

C. Diagnostic kit:

- Oral mirror.
- Dental probe.
- Forceps.

D. Periodontal probe (UNC 15).

E. Sterile cotton swabs.

F. Placebo spray containing water without any added active ingredient.

G. Lavender spray from Cham Company (Syria).

H. Children's toothbrush from Vinsa Company

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Figure(1): materials of study

Figure(2): mouth sprays

Methodology

The research was conducted using the following methodology:

- Initially, the patient's compliance with the inclusion criteria was confirmed.
- Initial informed consent to participate in the research and a commitment to follow-up were obtained from the child's guardian.
- Initial measurements of periodontal health indicators were performed, and mechanical and educational treatment was performed for the patient, if required.
- The patient's diagnostic information was recorded on a designated form.
- The child was then randomly assigned one of the sprays according to a sequence previously determined using the Randomizer software.
- The child was taught how to use the sprays using the tell-show-do method, and the patient was given appropriate instructions for applying the sprays, which is to apply the spray twice daily and leave it for one minute before spitting out the substance.
- Children were taught the rotary brushing technique using the tell-show-do method.
- The child was given the same toothbrush and toothpaste to standardize the procedure.
- The patient is followed up one week, one month, and three months after the initial session.

Case(1): Placebo spray

Case(2): Lavender Spray

Results

The sample ranged in age from 8 to 12 years, with a mean age of 9.86 years. The percentage of females in the study sample was 43.3%, and the percentage of males in the study sample was 56.7%.

- Gingival Index (GI) Table 1

Table(1): Descriptive statistics of GI

Gingival Index	Basline	1 Week	1 Month	3 Months
Mean	1.65	1.16	0.57	0.47
Median	1.66	1.22	0.31	0.19
SD	0.42	0.33	0.53	0.58
Minimum	0.66	0.41	0.03	0.00
Maximum	2.44	2.03	2.13	2.03

A clear decrease in the gingival index (GI) is noted throughout the study period among the sample members, starting from the first week of treatment. Despite this decrease, the upper limits of the GI decreased slightly compared to the averages. While the medians remained high throughout the study, they were far below the median. This indicates a weak response to treatment in some sample members.

Nonparametric tests (K-independent samples) were used to test for differences between the studied groups regarding GI values and their changes during the study periods (before the treatment, after one week, after one month, and after three months)(Table 2).

Table(2): Comparison of gingival index in study groups

	Group	N	Mean Rank
GI - Baseline	Placebo	15	22.20
	Lavender	15	32.67
	Total	30	
GI – 1 week	Placebo	15	21.90
	Lavender	15	23.80
	Total	30	
GI – 1 Month	Placebo	15	11.40
	Lavender	15	21.60
	Total	30	
GI – 3 Months	Placebo	15	9.20
	Lavender	15	23.57
	Total	30	

The Kruskal-Wallis test revealed no statistically significant differences in GI measurements between the two groups before the start of the study. This result indicates that the oral health of diabetic patients was similar before the start of the study. GI measurements differed between groups one and three months after the study, and the groups responsible for these differences (the source of the differences) need to be identified. Therefore, the Mann-Whitney test is used to determine the significance of pairwise differences between each group (Table 3).

Table(3): Mann-Whitney Test between study groups

Time	Group	Mean	Ranks Mean	U Mann-Whitney	P-Value
Baseline	Placebo	1.4	11.50	52.5	0.112
	Lavender	1.6	19.50		
1 Week	Placebo	0.94	15.0	105.0	0.002
	Lavender	1.06	16.0		
1 Months	Placebo	1.7	11.40	51.0	0.010
	Lavender	0.4	19.60		
3 Months	Placebo	1.6	9.10	16.5	0.000
	Lavender	0.25	21.9		

The previous table shows that among diabetics, there were no statistically significant differences in the average gingival index before the treatment, as the average gingival index was 1.6 in the placebo spray group and 1.4 in the lavender spray group. After the first week, inflammation decreased in both groups, with significant differences between the effect of the two sprays after one week, one month, and three months, in favor of the lavender spray group.

Discussion

With the increasing prevalence of type 1 diabetes, it was necessary to increase attention to those affected and treat the complications caused by this disease, which manifest in various body organs, including the oral cavity, especially tissues with dense perfusion, as this disease affects the blood vessels and causes their fragility, which disrupts the organs' function, such as the kidney, retina, and gingiva in the oral cavity (Herold et al., 2024).

It manifests orally with dry mouth and halitosis in addition to cervical caries, and it also contributes to the inability to control dental plaque. The combination of dental plaque with fragility of blood vessels and weak immunity, which in turn leads to increased susceptibility to infection, leads to gingivitis, which may develop into periodontitis (Alqadi, 2024).

Children face difficulties in controlling dental plaque, which is represented by their inability of applying brushing methods effectively, in addition to the inability to use mouthwashes due to the immaturity of their swallowing reflex and the long-term negative effects of mouthwashes. Therefore, it has been suggested to use sprays as a safe alternative to mouthwashes for children (Salem et al., 2023).

The ideal substance that helps control dental plaque and reduces levels of gingivitis and that does not have any side effects is still not available, and herbal materials are considered the safest.

Previous studies (Bagchi et al., 2015; Kandaswamy et al., 2018; Salem et al., 2023; Vanishree et al., 2021) have shown that herbal mouthwashes such as lavender and peppermint have a significant effect in controlling dental plaque and reducing levels of gingivitis.

Hence, it was necessary to conduct a controlled clinical study to compare the effectiveness of lavender extract in reducing gingivitis in children with type 1 diabetes compared to healthy children.

The Gingival Index (GI) was chosen as it measures color and morphological changes in the gingiva, which are clinical signs of inflammation that decrease within 72 hours of treatment. It is therefore a rapid tool for assessing gingival improvement.

The mean Gingival Index (GI) was similar across all groups before the start of the awareness and spray interventions, indicating no bias toward one group over another.

The mean Gingival Index (GI) decreased significantly within each study group compared to the pre-treatment measurement, possibly due to the oral hygiene instructions and the use of sprays.

Regarding the diabetic children's groups, gingivitis levels were similar before the treatment among the diabetic groups, while the response after one week of the study differed between the diabetic groups. The response after one month of the study differed between the diabetic groups, and the response after three months of the study differed between the diabetic groups. The placebo spray had no statistically significant effect on gingivitis in the diabetic groups, while the lavender spray had a statistically significant effect on gingivitis levels in the diabetic groups.

Conclusion

Within the limitations of the current study, lavender spray reduced gingivitis in children with type 1 diabetes when compared to a placebo spray.

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