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COMPARATIVE EVALUATION OF CHLORHEXIDINE AND POMEGRANATE MOUTHWASH IN THE MANAGEMENT OF PLAQUE-INDUCED GINGIVITIS (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

Objective: Because mechanical plaque control is typically insufficient to fully manage plaque and preserve optimal oral health, using natural plant extracts has been demonstrated to be more effective in managing disorders mediated by dental plaque.

Aim: The purpose of this study is to evaluate the clinical efficacy of mouthwashes containing chlorhexidine, pomegranate and a placebo mouthwash in treating gingivitis .

Subjects and Methods: This clinical trial included 60 patients having plaque-induced gingivitis, the years old range was among eighteen to forty. Subjects were allocated into three groups: **Group A** receiving pomegranate peel extract mouthwash and **Group B** taking chlorhexidine mouthwash. **Group C** receiving a placebo mouthwash. Clinical indices, including the papillary bleeding index (PBI), gingival index (GI) and plaque index (PI) had been used to assess studied cases at baseline (before treatment) and four weeks later.

Results: After a four-week follow-up, there was a statistically significant decrease in the mean **PI**, **GI**, and **PBI** scores for all groups. Both pomegranate and chlorhexidine mouthwashes restricted plaque accumulation and gingival inflammation.

Conclusion: Given the known adverse consequences of using chemical formulations over an extended period, the mouthwash preparation with pomegranate peel extract shows potential as a useful self-care strategy.

KEYWORDS: Chlorhexidine, Dental plaque, Gingivitis, Pomegranate.

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INTRODUCTION

The main causative agent of periodontal disorders is dental plaque. The major goals of periodontal disease prevention and therapy are plaque reduction and the elimination of bacterial biofilms from tooth surfaces. [1][2]

Plaque-induced gingivitis is the most prevalent kind of periodontal disease, affecting fifty percent to ninety percent of individuals globally. Good dental care can restore gingivitis, but if left unchecked, it may develop into periodontitis, which is characterized by inflammation that destroys tissue, loses alveolar bone, and ultimately leads to tooth loss. [3]

Conventional mechanical plaque control aids such as manual tooth brushing, chewing sticks and dental flosses are getting advanced day by day, however, mechanical plaque management is typically insufficient to maintain a degree of control consistent with dental health for an extended length of time. Bacteria in the soft tissues may recolonize the tooth surfaces even after mechanical plaque management has been applied. [4]

Since chlorhexidine has a stronger antiplaque impact and substantivity for a duration of ten to twelve hours, it is the gold standard by which the efficacy of more recent anti- plaque medicines is measured. [5]

One of the earliest fruits known to science, the pomegranate (*Punica granatum)* is used extensively in traditional medicine across the globe to treat a variety of ailments, including skin conditions and cancer. Moreover, P. granatum was found to possess multiple antioxidant activities, such as the capacity to scavenge radicals, chelate ferrous ions and reduce the antioxidant power of ferric ions.[6,7]

Pomegranate mouthwash has an inhibitory effect against putative periodontal pathogens like *Aggregatibacter actinomycetemcomitans* and *Prevotella intermedia* in addition to its role in management of chronic inflammatory oral diseases as lichen planus and opportunistic fungal infection as oral candidiasis.[8 9]

SUBJECTS AND METHODS

Ethical approval

The current research followed the ethical standards set out by the World Medical Association (Declaration of Helsinki, 1978, as updated in 2008) for clinical trials involving human participants. Code number (11)/4-2024 indicates that the Future University in Egypt's Research Ethics Committee (FUE. REC) approved the protocol under consideration.

All participants provided an informed consent after receiving a thorough description of the study's procedures before participation began.

Study Population:

Sixty studied cases from the outpatient clinic of diagnosis and periodontology department of the Faculty of Oral and Dental Medicine (Future University in Egypt) have participated in this research.

Selection criteria:

a- Inclusion criteria

Sixty patients with plaque-induced gingivitis, aged between 18 and 40 years, possessing a minimum of thirty percent bleeding when probing at qualifying sites and at depths not exceeding 3mm. They were medically free and have at least twenty-four natural teeth in their mouth, excluding the third molars.

b- Exclusion criteria

Removable orthodontic appliances, smoking, pregnant and lactating women, studied cases who had taken antibiotic therapy in the month before the research began, studied cases who had received periodontal therapy in the six months prior to the research's start, syndromes or systemic diseases that may have contributed to inflammatory processes. [10]

Clinical evaluation

Clinical measures such as the papillary bleeding index (PBI)[11], gingival index (GI)[12] and plaque index (PI)[13] were evaluated. The primary investigator gathered data, which had been repeated on days; zero to four weeks later. Additionally, all the groups completed a self-reported measure that measured their subjective happiness on a scale from one to ten.

Oral and written instructions on dental hygiene were given to participants of the three groups. Every participant was instructed to abstain from using any additional undesignated oral hygiene products.

Study design and patient grouping:

Following the selection based on inclusion and exclusion criteria ,Allocation Concealment technique was applied for randomization ,the sixty patients were asked to choose any of the sixty envelopes (20 of envelopes have letter **A** inside, 20 of envelopes have letter **B** inside and 20 of the envelopes have letter **C** inside).

In **Group A,** 20 patients were given pomegranate peel extract mouthwash and had been instructed to rinse with 15ml of the solution for 30 seconds two times a day while in **Group B,** 20 patients were given CHX hydrochloride 125mg/100ml (Hexitol; Arab Drug Company for Pharmaceutical and Chemical Industries, Cairo, Egypt) mouthwash and had been instructed to rinse with 15ml of the solution for 30 seconds two times a day and in **Group C,** 20 patients were given a placebo mouthwash which contains glycerin 40 ml, peppermint water 0.5 ml, distilled water about 50 ml and ethylene blue 0.4 ml and had been instructed to rinse with the solution for 30 seconds two times a day.

Steps of pomegranate peel extract mouthwash preparation:

The peel of pomegranate was mixed in the mixer with a minimal amount of water and filtered by distillation flask then heated to one-third of its original volume under reduced pressure to gain a dry powder. The 5% pomegranate mouthwash had been prepared (0.5g of the powder extract in 100ml distilled water) and poured into bottles each containing 250ml of the solution. [14]

STATISTICAL ANALYSIS:

Data had been gathered at baseline and four weeks later, and SPSS Version 28.0-the statistical package for social sciences-was used to analyze the results. For intragroup comparison, the paired t-test was employed, and for intergroup comparison, the independent t-test was used. One-way ANOVA test used to determine differences between three groups.

RESULTS

Sixty studied cases in all gave their permission to participate in the trial. Every studied case adhered to the follow-up schedule, and the outcomes had been documented.

i-Demographic Data:

A-Sex:

There were twelve males and eight females studied cases in group A, fourteen males and six females studied cases in group B and eleven males, nine females in group C.

B-Age:

Participants in groups A, B and C had average ages of 33.91, 34.04 and 34.17 years, respectively

-There had been no discernible variation in the distribution of sexes or ages among the three groups.

ii-Clinical parameters:

1-Papillary bleeding index (PBI) [11]:

At baseline the mean and standard deviation (SD) values of papillary bleeding index (BPI) were (1.61±0.75) for group A, (1.79 ±0.79) for group B, (1.61±0.71) for group C. One-way ANOVA test

showed that there was no statistically significant difference between the groups with (P value=0.983) table (1).

TABLE (1) (PBI) at baseline.

Group	Range	Mean± SD	F.test	P.value
A	1-3	1.61 ±0.75		
B	1-3	1.79 ±0.79	0.058	0.983^{NS}
C	1-3	1.61 ±0.71		

After 4 weeks the mean and standard deviation values of (PBI) were (0.52±0.77) for group A, (0.35±0.71) for group B, (0.27±0.48) for group C. One-way ANOVA test showed that there was no statistically significant difference between the groups (P value=0.829) ^{ns} table (2).

Paired (t-test) showed statistically significant decrease in the mean and standard deviation (SD) values of papillary bleeding index (PBI) for all groups compared with baseline (P value<0.05)* table (3).

TABLE (2) (PBI) after four weeks.

Group	Range	Mean± SD	F.test	P.value
A	0-2	0.52 ±0.77		
B	0-2	1.35 ±0.71	0.294	0.829^{NS}
C	0-1	0.27 ±0.48		

2-Gingival index (GI) [12]:

At baseline the mean and standard deviation (SD) values of (GI) were (1.61± 0.31) for group A, (1.61±0.21) for group B , (1.61± 0.31) for group C. One-way ANOVA test showed that there was no statistically significant difference between the groups with (P value =0.892)^{NS} table (4) .

After 4 weeks the mean and standard deviation (SD) values of (GI) were (1.25±0.75) for group A, (1±0.52) for group B, (0.32±0.52) for group C. Paired (t-test) showed that all groups except group A recorded statistically significant decrease in the mean values of (GI) compared with baseline records (P value <0.05)* table (5).

TABLE (3) (PBI) for all groups over the study follow up period.

Group	Parameter	Range	Mean± S.D	T.test	P-value
A	(PBI) Baseline	1 - 3	1.61 ± 0.75	9.000	0.010*
	(PBI) 4 weeks	0 - 2	0.52 ± 0.77		
B	(PBI) Baseline	1 - 3	1.79 ± 0.79	14.355	
	(PBI) 4 weeks	0 - 2	0.35 ± 0.71		0.002*
C	(PBI) Baseline	1 - 3	1.61 ± 0.71	19.696	0.001*
	(PBI) 4 weeks	0 - 1	0.27 ± 0.48		

TABLE (4) (GI) at baseline.

Group	Range	Mean ± S.D	F.test	P.value
A	1 - 2	1.61 ± 0.31		
B	1.5 - 2	1.61 ± 0.21	0.205	0.892^{NS}
C	1 - 2	1.61 ± 0.31		

TABLE (5) (GI) value for all groups over the study follow up period.

Group	Parameter	Range	Mean± S.D	T. test	P- value
A	(GI) Baseline	1 - 2	1.61 ± 0.31	1.800	0.201^{NS}
	(GI) 4 weeks	0 - 2	1.25 ± 0.75		
B	(GI) Baseline	1.5 - 2	1.61 ± 0.21	10.722	0.006*
	(GI) 4 weeks	0 - 2	1.00 ± 0.52		
C	(GI) Baseline	1 - 2	1.61 ± 0.31	33.923	0.001*
	(GI) 4 weeks	0 - 1	0.32 ± 0.52		

3-Plaque index (PI) [13]

At baseline the mean and standard deviation values of (PI) were (3.73± 0.62) for group A , (3.63±0.65) for group B ,(3.73±0.63) for group C .One–way ANOVA test showed that there was no statistically significant difference between groups with (P value=0.954)^{NS} table (6) .

TABLE (6) (PI) for all groups at baseline.

Group	Range	Mean± SD	F.test	P.value
A	3 – 5	3.73 ± 0.62		
B	3 – 5	3.63 ± 0.65	0.112	0.954^{NS}
C	3 – 5	3.73 ± 0.63		

After 4 weeks the mean and standard deviation (SD values of (PI) were (3.55±0.42) for group A, (2.69±0.26) for group B , (3.63±0.35) for group C. Paired(t-test) showed that only group B recorded statistically significant decrease in the mean values of (PI) compared with baseline (P=0.001) table (7).

TABLE (7) (PI) value for all groups over the study follow up period .

Group	Parameter	Range	Mean± S.D	T.test	P-value
A	(PI) Baseline	3 - 5	3.73± 0.62	0.467	0.504^{NS}
	(PI) 4 weeks	3 - 4	3.55± 0.42		
B	(PI) Baseline	3 - 5	3.63 ± 0.65	0.000	0.001*
	(PI) 4 weeks	3 - 4	2.69 ± 0.26		
C	(PI) Baseline	3 - 5	3.73 ± 0.63	18.225	1.000^{NS}
	(PI) 4 weeks	2.5 - 3	3.63 ± 0.35		

DISCUSSION

Plaque bacteria are the cause of periodontal disease and research on oral health has focused on the potential to improve oral hygiene by adding chemotherapeutic drugs to mouthwash formulations. [15,16]

Many of human and animal studies have showed that pomegranate and its extract could be considered a natural alternative to chemical antimicrobial agents due to their potency against a wide range of viral, fungal and bacterial pathogens. [17][18]

Even with good tooth cleaning, bacteria will still colonize the tooth surface and produce a variety of

biologically active byproducts that will eventually diffuse into the gingival epithelium and trigger the host response that leads to gingivitis. Daily home care is an important part of oral hygiene which can limit these bacterial invasions.[19,20,21]

The results of the current study showed marked reduction of PBI, GI and PI from baseline to one month after using pomegranate mouthwash which was similar to results obtained by ***kiany et al., 2016***.[22] They declared that use of natural and organic non chemical detergents could be so beneficial to low socioeconomic societies. This may be attributed to the active ingredients of pomegranate as ellagic acid and punicalagins which are supposed to reduce liability to periodontal diseases due to their action to reduce oxidative stress beside their antibacterial and anti-inflammatory properties. Pomegranate extact can also prevent adherence and colonization of the plaque bacteria on the tooth surface. [23], [24], [25]

In the current clinical study, following the 4 weeks follow-up assessment there was a significant decrease in PBI, GI and PI scores in the three groups and those results go in harmony with ***Ghazi et al., 2020*** who reported the anti-inflammatory effect of pomegranate peel extract as a mouthwash and approved that it was effective for lowering all the clinical and the biochemical markers related to gingivitis. [26]

The findings of the current research were also in agreement with results by ***Malaiappan and Abraham, 2020*** who proved that pomegranate peel extract mouthwash was effective in the treatment of gingival disease as it inhibits prostaglandin and leukotriene formation. [27]

The improvement in the placebo group may be due to the Hawthorne effect which is a form of reactivity through which patients improve their behavior in response to the fact that they are under study, not in response to the experimental maneuver. [28]

In the present study after the follow-up period no adverse reactions has been reported in group A and these results agreed with **Eltay et al.,2021** who stated that pomegranate mouthwash can serve as a promising alternative in the management of gingivitis. [29]

Bearing in mind the adverse effects of chlorhexidine as staining of teeth, change in taste sensation and dry mouth, 5% pomegranate mouthwash may be considered as a first choice adjunctive aid for gingivitis. [30, 31]

Truthful achievement of this article will transform pomegranate mouthwash from a compound with potential into a vital player in management of gingivitis and periodontitis.

CONCLUSION

Comparable results have been observed between 5% pomegranate peel extract mouthwash and chlorhexidine mouthwash in the treatment of plaque-induced gingivitis which suggests it as a good alternative to chlorhexidine mouthwash without the undesirable side effects that may occur with the chlorhexidine mouthwash especially if used for long periods.

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