Comparative clinical efficacy of propolis mouthrinse in the management patients with chronic generalized gingivitis: a randomized clinical trial

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Aim: The aim of the present study was to evaluate the clinical efficacy of propolis and chlorhexidine digluconate containing mouthrinse on a plaque accumulation and gingival inflammation in 14-day period in patients with generalized chronic gingivitis. Materials & Methods: Thirty subjects were randomly divided into three groups of ten subjects each, which received a propolis-containing mouthrinse, or Saline (a negative control) or Chlorhexidine (a positive control). Plaque and gingival indexes were recorded at baseline and at the end of the 14th days. Results: Chlorhexidine was the most effective in reducing gingival index compared to the other groups and no significant differences were observed between propolis and saline groups (P<0.05). There were no significant differences among groups for plaque index at the end of the 14th days (P>0.05). Conclusion: Propolis mouthrinse is promising agent as an alternative to other antimicrobial agents in the mechanical plaque control and gingivitis treatment, but further randomized controlled trials are needed with increased number of individuals. Clinical Significance: Mechanical plaque control mechanism plays an essential role in reducing microbial burden among patients with gingivitis. However, microorganisms present at many areas of the oral cavity are not mechanically reachable. Therefore, a chemical mechanism; in conjunction with mechanical procedures can play an important role the management of gingival diseases.

Keywords: Propolis, Chlorhexidine gluconate, Gingivitis, Mouthwashes, Saline
Introduction

The most effective method for the prevention of periodontal disease is mechanical supragingival plaque control [1] with toothbrushes (manual or electric), dental floss and interdental brushes. The patient required having sufficient skills and motivation for the use of these oral hygiene tools [2].

The use of mechanical devices which remove plaque effectively by the patients, is dependent on compliance with the oral hygiene instruction by dental professionals. There are many reasons for not complied; among them education, income level, beliefs and personal habits, oral care, stressful life circumstances, psychomotor skills, age and frequency of dental visits can be said [3,4]. In addition, provision of adequate oral hygiene is an insurmountable problem for a group of people, such as people with disabilities [5]. Therefore, patients need to convenient to use, easy and inexpensive methods in addition to mechanical plaque removal [6]. Several related substances were investigated. The major problems associated with these substances are a short interact time of the active agent with teeth and some side effects [7].

Antibacterial agents containing chemical plaque inhibitors have been used successfully in providing supragingival cleaning at mechanical oral hygiene procedures. However, side effects such as tooth discoloration, bad taste are available in the long-term use of antibacterial chemicals such as benzethonium chloride and chlorhexidine [8].

Therefore, an antiplaque agent is still needed that can be used per day with minimal side-effects. Some natural products containing antibacterial agents and medical compounds are used in alternative medicine as therapeutic agents. Some substances isolated from these products have many potential effects beside the antimicrobial activity in the treatment and prevention of periodontal diseases.

Propolis is the most promising product among the natural products that used in the prevention of oral diseases [9, 10]. It is strong antimicrobial and anti-inflammatory agent that produced by honeybees. Honeybees collect the resin from the cracks of tree bark and leaf buds. Bees chew the resin and salivary enzymes are added in the meantime.

This partially digested material is mixed with bees wax used for plastering of the holes in the hive. The coating material makes the wall softer and provides protection against intruders [11].

Also, propolis, helps to protect the hive against viruses, bacteria and other organism's harmful effects with antibiotic activity [12]. It is used as anti-inflammatory, antymycotic, antiscar and antimicrobial agents at the homeopathic and herbal healthcare applications. It doesn't have any side effects [13].


Pharmacologically, most important components of propolis are flavonoids, phenolic and aromatics [20]. Flavonoids are well-known plant compounds with antioxidant, antibacterial, antifungal, antiviral and anti-inflammatory properties.

Propolis has effects on prostaglandin synthesis inhibition, thymus gland activation, support the immune system by increasing phagocytic activity, stimulating cellular immunity and increasing the healing potential of epithelial tissues as an anti-inflammatory agent [21-23]. Also, propolis contains elements which important for collagen synthesis such as zinc, iron [20, 24].

Many cases and a clinical pilot study have been shown that the use of propolis is useful in treating gingivitis and oral ulcers.

Propolis extract has antimicrobial effectiveness against Streptococcus mutans, Gr (+) cocci and facultative anaerobes located in the human oral cavity [25]. Besides, it has been shown in a study that evaluating the activity of propolis against the periodontal pathogens, that propolis has a clinical value [26].

It is used to prevent tooth decay, treat gingivitis and stomatitis in addition to mouthwash and toothpaste [27]. Recently, some studies have shown that propolis toothpaste has very good plaque removal, plaque inhibition and anti-inflammatory effects, [28] propolis mouthwash may an alternative to the chemical mouthwash 10 and compared with conventional treatment better results can be obtained at microbiological and clinical parameters when used in the subgingival irrigation [29]. Based on this information, propolis mouthwash might be considered as a good tool with low side effects for
Preventing the accumulation of plaque and gingival inflammation in addition to mechanical oral hygiene practices.

The purpose of this study was to evaluate the clinical efficacy of propolis & chlorhexidine mouthwash and saline solution on the plaque accumulation and gingival inflammation in 14-day period in patients with generalized chronic gingivitis in addition to oral hygiene procedures and scaling [30].

Materials & Methods

**Study settings:** The individuals included in the study were selected from the patients that coming to the Department of Public Health Dentistry, People’s Dental Academy for treatment.

**Duration:** This study was designed as randomized, single-blind, and parallel design, 14-days clinical trial. Three mouthwashes were compared: Propolis mouthwash prepared with propolis extracts (test), saline as placebo (negative control) and chlorhexidine mouthwash (positive control).

**Inclusion criteria**

Participants included in the study were selected according to the following criteria:
- 18-60-year-old, systemically healthy individuals;
- Without any medical history;
- With chronic generalized gingivitis;
- Who have not taken any antibiotics in the last 2 weeks;
- Who have at least 20 permanent teeth;
- Who don’t smoke;
- Who are not allergic to honey and honey products.

**Exclusion criteria**

Individuals in the following criteria were excluded from the study:
- A patient is excluded from the study in case of leaving the operation or interrupt the follow-up.
- Patients have systemic diseases that may affect the study results during the study and in case of taking any medication.

**Random allocation:** Participants were randomly divided into 3 groups, baseline plaque [31] and gingival index [32] scores have been recorded.

**Data collection:** After baseline records a professional dental cleaning that contain scaling and polishing has applied to the patients. After baseline treatment, the plaque elimination was made in all patients and oral hygiene procedures were described.

After treatment, propolis mouthwash, chlorhexidine mouthwash and saline solution were given to the first, the second and the third groups, respectively. The clinician was blind Patients continued their oral hygiene procedures, and additionally all subjects were instructed to rinse two times a day with the mouthwash of their group half an hour after brushing for one minute. After a week, participants called again for assessment of oral hygiene and second session periodontal treatment. At the end of 14 days, participants came to the clinic, plaque index (PI) and gingival index (GI) measurements were recorded again. Then the collected data was statistically analyzed.

**Statistical analysis:** The normality of the data's distribution was examined using the Shapiro-Wilk test. Non-normally distributed data were expressed as median (interquartile range-IQR). The differences among three groups were investigated with the Friedman test. Mann-Whitney U test was also made to determine the groups leading to significant differences.

In intragroup comparison, the alteration of variables before and after treatment at the 14th day was carried out by Wilcoxon Signed Rank test. SPSS for Windows Ver. 15.0 (SPSS Inc., Chicago, ILL, USA) and MS-Excel 2007 programs were used for statistical analysis. Statistical significance level p<0.05 was significant considered.

**Results**

Demographic characteristics of the study groups and controls were displayed in Table 1. There were no significant differences between men and women among the groups. The age of the subjects ranged between 19 and 25 years, and no statistically differences were observed among the groups.
Table-2: Comparison of clinical parameters among three groups

<table>
<thead>
<tr>
<th></th>
<th>Propolis Med (IQR)</th>
<th>Chlorhexidine Med (IQR)</th>
<th>Saline Med (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plaque Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.29 (0.32)</td>
<td>1.33 (0.20)</td>
<td>1.51 (0.13)</td>
</tr>
<tr>
<td>14th days</td>
<td>0.11 (0.68)*</td>
<td>0.27 (0.24)*</td>
<td>0.36 (0.30)*</td>
</tr>
<tr>
<td><strong>Gingival Score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.56 (0.11)</td>
<td>1.67 (0.18)</td>
<td>1.59 (0.19)</td>
</tr>
<tr>
<td>14th days</td>
<td>1.06 (0.30)*</td>
<td>0.64 (0.65)*, Ɨ</td>
<td>1.13 (0.30)*</td>
</tr>
</tbody>
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Med: Median; IQR: Interquartile Range
*Significant differences compared to baseline
Ɨ Significant differences compared with propolis and saline groups.

When intragroup comparisons were performed, the values of PI significantly decreased from baseline to the 14th day in all groups, however no statistically significant differences were observed among groups after the treatment protocol.

In chlorhexidine group, the values of GI significantly decreased from 1.67 (0.18) to 0.64 (0.65) and this reduction was significantly greater compared to propolis and saline groups (p<0.05). The GI values significantly decreased from 1.56 (0.11) to 1.06 (0.30) and from 1.59 (0.19) to 1.13 (0.30) in propolis group and saline group, respectively.

However, there was no significant differences between propolis and saline groups (p>0.05) (Table 2).

Discussion

In the present study investigated to compare the efficiency of propolis mouthwash with chlorhexidine and saline solution on the generalized gingivitis patients and it was observed that there was no significant differences among groups for PI; however, chlorhexidine was the most effective in reducing GI compared to the other groups and no significant differences were observed between propolis and saline groups.

The most common infectious oral diseases are tooth decay and periodontal disease associated with dental plaque in humans. Removal of bacterial biofilm is a major component of the treatment and prevention of disease. The use of mechanic agents in controlling gingivitis is a simple and cost-effective method [6, 7, 8, 33]. The effectiveness of this method may be affected by the individual's ability.

For such reasons, when the adequate plaque removal cannot be provided, the use of antimicrobial agents in addition to the mechanical application is interested [1, 2, 34].

Chlorhexidine mouthwash is an important antimicrobial agent that has a history of safe and effective on oral health [36]. In addition, chlorhexidine gluconate is regarded as the gold standard for the prevention of dental plaque in dentistry [36]. According to the results of a study, in gingivitis patients, chlorhexidine mouthwashes together with oral hygiene provide significant reductions in plaque and gingivitis scores [37, 38].

Similarly, in this study observed a significant decrease at gingival bleeding scores in chlorhexidine group compared with the other two groups, on the other hand plaque scores were not significantly different among the three groups. It was explained that plaque elimination was made at the beginning of the study and the patients were motivated. Furthermore, the study time was a short period of 14 days.

Medical use of propolis in the modern era is almost forgotten with the active use of antibiotics. Today, some pathogens to develop resistance to antibiotics and as a result some side effects on humans has increased the need for new antimicrobial agents [39].

This study is planned on the basis of the hypothesis that propolis mouthwash may be an alternatively means that having low side effects for prevent both gingival inflammation and plaque accumulation in addition to mechanical oral hygiene practices.

The aim of the study was to compare the effects of the propolis mouthwash with positive control chlorhexidine mouthwash and negative control saline solution on plaque accumulation and gingival inflammation over 14-days period [30].

In a recent study, the effects of propolis, chlorhexidine and saline solution were assessed on plaque accumulation and gingival scores. In this study, patients leave the mechanical cleaning and have used only mouthwashes for five days. Eventually, chlorhexidine yielded the most effective result on plaque scores and propolis on gingival scores [40].

In the present study, whilst there were no differences between patients in terms of plaque, chlorhexidine gave the most effective result for the gingival scores.
It can be explained that this state depends on the mechanical cleaning of patients in all groups. In the results of the study; there were no significant differences between test group propolis mouthwash and negative control saline in terms of plaque scores. As a reason of this condition might be continuing the mechanical cleaning by the patients. There were no statistically significant differences between the two groups for gingival scores.

The same results were seen between test group propolis mouthwash and positive control chlorhexidine mouthwash in terms of plaque scores. However, chlorhexidine group showed a statistically greater reduction compared to propolis group for gingival scores.

**Limitations**

The indices used in the study have inherent drawbacks which might affect the overall results. Only verbal instructions are given to the patients regarding treatment protocol. Strict, Vigorous monitoring may not be possible in all cases.

**Conclusion**

Propolis mouthwash is promising in use an alternative to other antimicrobial agents in the mechanical plaque control and gingivitis treatment, but further randomized controlled trials are needed with increased number of subjects.

**What the study adds to the existing knowledge**

Mechanical plaque control mechanism plays an essential role in reducing microbial burden among patients with gingivitis. However, microorganisms present at many areas of the oral cavity are not mechanically reachable. Therefore, a chemical mechanism; in conjunction with mechanical procedures can play an important role the management of gingival diseases.

**Author’s contribution**

**Dr. Sudheer Hongal:** Designed the study protocol and material procurement and designed the manuscript.

**Dr. Nilesh:** Collected the data, compiled and analysed.

**Dr. Vinay:** Guided in designing the manuscript.

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