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Research Article

Evaluation of Clinical Efficacy of Propolis in Patients with Gingivitis: A Randomized Clinical Crossover Study

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Abstract

Aim and Objectives: To evaluate and compare the clinical efficacy of 20% propolis and 0.2% chlorhexidine gluconate mouthwashes in patients with gingivitis.

Materials and Methods: A total number of 40 subjects were randomly divided into two groups i.e. Group 1 and Group 2 including 20 subjects in each group. Group 1 was prescribed with 20% Propolis mouth wash and Group 2 was prescribed with 0.2% chlorhexidine gluconate mouthwash for 2 weeks. Subjects were assessed for clinical parameters such as plaque and gingival index at baseline and after 2 weeks followed by a wash out period of 30 days and further the mouth washes were exchanged between the two groups and the same clinical parameters were re-recorded at baseline and after 2 weeks follow up.

Statistical Analysis: Paired and unpaired 't' test were used for intragroup and intergroup comparison between the two groups. Statistically significant results were observed at the baseline and after 2 weeks in both the groups.

Results: Based on the present data, 20% propolis containing mouthwash and 0.2% chlorhexidine gluconate were equally effective in the treatment of gingivitis.

Conclusion: 20% propolis containing mouthwash has a promising plaque inhibitory potential and as effective as 0.2% chlorohexidine gluconate in preventing gingivitis as well as plaque control.

Keywords: Gingival Index; Plaque Index; Propolis; Chlorhexidine

Introduction

Dental plaque is the major etiological agent for the initiation of gingivitis [1]. Gingival disease can progress to periodontitis which if untreated may eventually compromise the entire periodontium [2]. The focus of any attempt to prevent and control periodontal disease is the maintenance of an effective level of plaque control by the individual through his or her oral hygiene. Even though mechanical cleaning by tooth brushing has been the cornerstone of oral hygiene and health, insufficient and inadequate brushing due to lack of dexterity skills can lead to plaque build-up, due to which the incidence and prevalence of gingivitis is still high in both the developed and developing countries. To achieve optimum results, a common strategy is to supplement mechanical plaque removal with a chemotherapeutic agent as supported by International Association for Dental Research (IADR) [2].

Various synthetic chemical agents have been evaluated over the years with respect to their antimicrobial activity in the oral cavity, but they do exhibit some limitations. Chlorhexidine digluconate (0.2%), currently recognized as gold standard chemotherapeutic agent has its duration of use limited to just a few weeks because of undesirable side effects [3,4] such as tooth discoloration, altered taste, and less commonly desquamation of oral mucosa [5] and thus search for alternative agents continues. Propolis is a naturally occurring bee product which is a hard resinous substance consisting chiefly of wax and plant extracts. Propolis apart from its antimicrobial and anti-inflammatory properties, also possess to have antifungal, antiviral, antioxidant action, immune enhancing properties [6,7]. Wound repair accelerating effects are also appreciated in the treatment of gingivitis, periodontal abscess, denture ulceration, stomatitis, candidal infections, dentinal hypersensitivity [8,9]. It is also used as an intracanal medicament in endodontic

procedures [10]. Hence to evaluate the clinical efficacy of propolis over plaque this randomized cross over study was designed and conducted to evaluate the clinical efficacy of 20% propolis containing mouthwash in comparison to 0.2% chlorhexidine mouthwash.

Aim and Objectives

The objective of this randomized controlled cross over study was

1. To evaluate the clinical efficacy of 20% propolis and 0.2% chlorhexidine gluconate.
2. To compare the clinical efficacy of the 20% pro polis mouthwash in comparison with 0.2% Chlorhe xidine gluconate.

Materials and Methods

This study was conducted in the Department of Periodontics, Dayananda Sagar College of Dental Sciences, Bangalore. The study design was randomized controlled clinical trial including 40 subjects. The study was approved by the ethical committee of the institution and all the subjects were informed about the procedures and an informed consent was obtained. The patient selection was done based on the following criterias.

Inclusion criteria

1. Subjects with moderate to severe gingivitis.
2. Not participated in similar investigations in past 4 weeks.
3. Subjects systemically healthy.
4. No history of periodontal treatment in past 6 months.
5. Subjects willing to follow the protocols.

Exclusion criteria

1. History of systemic diseases.
2. Pregnant or lactating females.
3. History of antibiotic therapy in past 30 days.
4. Subjects with deleterious habits like smoking, tobacco chewing.
5. History of allergy in usage of any mouthwash.
6. Patients with any periodontal diseases other than gingivitis.

Experimental material

The test agent used in this study was 20% propolis containing mouthrinse formulated at himalaya pharmaceuticals limited, Bengaluru, Karnataka. Propolis and food grade alcohol were procured from Hi Tech Natural Products Limited, India. All raw materials such as Glycerine IP, Sorbitol 70% solution IP, Menthol crystal build IP, Saccharin IP, Benzyl alcohol IP and flavour Anise Mint were obtained from The Himalaya Drug Company.

Clinical Procedure

The subjects were examined on a dental chair under standard conditions of light using diagnostic instruments (mouth mirror, probe, explorer and tweezer). Forty (40) subjects with moderate to severe gingivitis were included in this study. They were randomly divided into 2 groups; Group 1- Propolis group and Group 2- Chlorhexidine group. An informed written consent was obtained from each subject, and plaque index (Turesky-Gilmore Glickman modification of Quigley Hein 1970) and gingival index (Loe and Silness 1963) were recorded.

For group-1 (20 subjects) and group-2 (20 subjects) at baseline, clinical parameters plaque index and gingival index were recorded. Supragingival ultrasonic scaling was carried out in the same appointments.

This groups i.e. group 1(propolis) and group 2 (chlorhexidine) was prescribed 20% propolis mouthwash and 0.2% chlorhexidine digluconate respectively, 10 ml twice daily for 2 weeks. Subjects were assessed again after 2 weeks for recording plaque index and gingival index.

After a wash out period of 30 days, mouth washes were exchanged between the two groups where in Group 1 (Propolis group) received chlorhexidine and Group 2 (Chlorhexidine group) received propolis mouthwash.

The plaque index and gingival index were re-recorded in both groups and instructions were given to use 10 ml twice daily for two weeks. Again after an interval of 2 weeks, patient were follow up and clinical parameters were recorded. The data obtained was arranged in a master chart and subjected to statistical analysis.

Statistical Analysis

A paired sample t test was used for intragroup comparison and an independent sample t test was used for intergroup comparison in this study. To evaluate the clinical significance of mouthwashes, an effect size was assessed before cross over and after cross over for both the groups.

Results

Intra Group Comparison

The Plaque index scores were found to be higher at baseline in Group 1 (propolis - 1.25 ± 0.09) and Group 2 (chlorhexidine - 1.38 ± 0.14) as compared to the scores at 15th day in Group 1 (1.12 ± 0.04) and Group 2 (1.26 ± 0.13).

A Statistically significant difference was seen in both the groups (chlorhexidine and propolis) when paired sample t test was applied to compare the values between baseline and 15th day (p = 0.000).

The gingival index were found to be higher at baseline in both the groups (Group I Propolis - 1.30 ± 0.11) and (Group 2 Chlorhexidine -1.18 ± 0.03) as compared to the values at 15th day in Group 1(1.10 ± 0.03) and Group 2 (1.12 ± 0.098).

A Statistically significant difference was seen in both the groups (chlorhexidine and propolis) when paired sample t test was applied to compare the values between baseline and 15th day (p = 0.000) (Table 1).

Plaque index		Group 1	% change	Paired t test
Chlorhexidine	Baseline	1.38 ± 0.14	46.82	0.000*
	15th day	1.26 ± 0.13		
Propolis	Baseline	1.25 ± 0.09	35.85	0.001*
	15th day	1.12 ± 0.04		
*significant				
Gingival index		**Group 1**	**% change**	**Paired t test**
Chlorhexidine	Baseline	1.30 ±0.11	44.57	0.000*
	15th day	1.12 ± 0.098		
Propolis	Baseline	1.18 ± 0.03	24.37	0.001*
	15th day	1.10 ± 0.03		
*significant				

Table 1

The percentage change (baseline to 15thday) was found to be higher in Group 2 chlorhexidine group (46.82%) than Group 1 - propolis group (35.85%) for plaque index and 44.57% for Group1 and 24.37% for Group 2 respectively for gingival index (Figure 1 and 2).

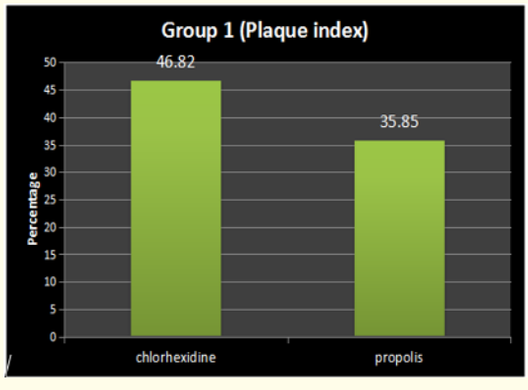

Figure 1: Percentage change in plaque index.

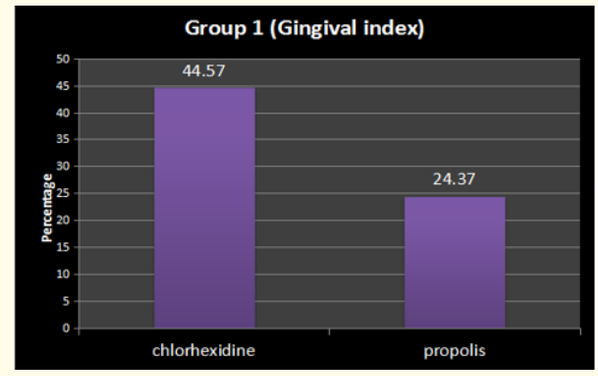

Figure 2: Percentage change in gingival index for Group I for Group I.

After the cross-over, where in Group 1 was subjected with 0.2%chlorhexidine Gluconate and Group 2 was subjected with propolis. The results were similar with both the groups where the baseline scores for plaque index were higher in both the groups, Group 1 (chlorhexidine - 1.14 ± 0.03) and Group 2 (propolis - 1.22 ± 0.11).

Paired t test showed statistically significant difference between baseline and 15th day in both the groups (p = 0.001) and (p = 0.002). Paired t test showed statistically significant difference (p = 0.000) between baseline and 15th day after cross over in both the groups i.e. Group 1- chlorhexidine and Group 2 - propolis. The mean scores were highest at baseline for both the groups(1.27 ± 0.09) and (1.24 ± 0.06) respectively. (Table 2).

Plaque index		Group 2	t value	P - value
Propolis (P)	Baseline	1.27 ± 0.09	9.41	.000*
	15 days	1.14 ± 0.04		
Chlorhexidine (C)	Baseline	1.24 ± 0.06	4.86	.000*
	15 days	1.16 ± 0.04		
*significant				
Gingival index		**Group 2**	**t value**	**P - value**
Propolis (P)	Baseline	1.22 ± 0.11	3.74	0.001*
	15 days	1.12 ± 0.06		
Chlorhexidine (C)	Baseline	1.14 ± 0.03	3.52	0.002*
	15th day	1.1 ± 0.05		
*significant				

Table 2

After cross-over, the percentage change (baseline to 15th day) was found to be higher in (Group 2 propolis - 37.91%) than (Group 1 chlorhexidine - 31.35%) for plaque index and 29.92% and 17.77% for gingival index respectively (Figure 3 and 4).

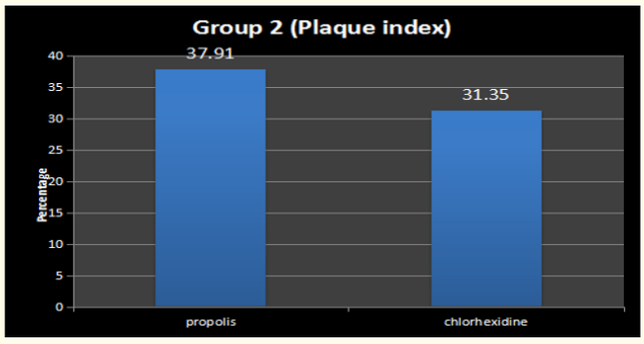

Figure 3: Percentage change in plaque index for Group II.

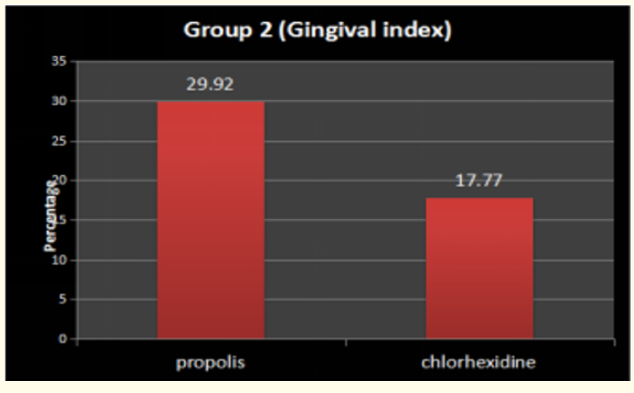

Figure 4: Percentage change in gingival index for Group II.

Intergroup Comparison

At first stage (before cross-over), independent sample t test was applied to compare the difference between two groups (Group I- Propolis and Group II- Chlorhexidine) at baseline and 15th day. There was statistically significant difference found at baseline for plaque index (p = 0.011); and also at 15th day (p = 0.001); Similarly a significant difference was found at baseline for gingival index (p = 0.023) also at 15th day (p = 0.829) (Table 3).

After cross-over, independent sample t test was applied to compare the difference between two groups (Group I- chlorhexidine and Group II- propolis) from baseline to 15th day. There was statistically significant difference found at 15th day for plaque index (p = 0.008); also at baseline for gingival index (p = 0.002); whereas there was no significant difference found at baseline for plaque index (p = 0.77) and 15th day for gingival index (p = 0.746) (Table 4). The effect size for both the groups at 15th day before and after cross over study was found to be 0.15 and 0.33 respectively showing there is a lesser clinical differences between the two groups (Table 5).

Group 1 and 2 (Before cross over)		t value	P value
Plaque index	Baseline	2.658	0.011*
	15th day	3.565	0.001*
Gingival Index	Baseline	2.366	0.023*
	15th day	0.217	0.829*

Table 3

*significant

Group 1 and 2 (After cross over)		t value	P value
Plaque index	Baseline	0.295	0.770
	15th day	2.790	0.008*
Gingival Index	Baseline	3.401	0.002*
	15th day	0.326	0.746

Table 4: After Cross-Over (Group I using chlorhexidine and Group II using propolis).

Group 1 and Group 2		Before cross over	After cross over
Effect Size	Baseline	0.4	0.31
	15th day	0.15	0.33

Table 5

Discussion

Epidemiological studies like experimental gingivitis in human beings and clinical research studies have concluded that plaque is the main etiological factor in gingival inflammation and has been found to be associated with the initiation and progression of periodontal diseases [11-15].

Mechanical measures such as tooth brushing on daily routine basis is carried out to maintain oral hygiene. However, mechanical plaque control is not always completely effective as it is based on the dexterity and motivational level of individual. As these methods may be inadequate to achieve optimum results, a common strategy has to supplement mechanical plaque removal with mouth washes since mouth wash has come a long way from preventing oral malodor to reducing the oral microbial load.

Even though the chemotherapeutic agents are effective in plaque control, limitations such as various adverse effects on prolong usage are noted and search for an alternative agents continues. Hence propolis an natural ingredient was choosen to carry out the present study to compare the clinical efficacy between propolis (20%) and chlorhexidine gluconate (0.2%).

The present study is one of the first one to follow a crossover design since this study design reduces the influence of confounding factors that arises because of individual variables that effect plaque formation like the salivary flow and composition, existing plaque retention sites, pre-existing gingivitis, dietary habits, and the composition of pellicle. A washout period of 30 days was done to prevent the "carryover effect" of experimental mouthwash.

In this study, the clinical efficacy was assessed by two clinical parameters plaque index(PI), gingival index (GI). A statistically significant (p = 0.000) reduction in mean plaque index (PI) was observed in both the groups i.e. Group 1- propolis and Group 2- chlorhexidine from baseline to 15th day follow up and also after crossover (Group 1- chlorhexidine; Group-2 propolis), indicating that propolis can also effectively reduce experimentally induced plaque accumulation. These results are in contrast with randomized controlled trial study conducted by Torwane., *et al.* [16], where the authors used 30% ethanolic extract of propolis, 0.2% Chlorhexidine and saline found no statistically significant difference between propolis and chlorhexidine groups. The present study reported statistically significant reduction in mean gingival index(GI) score in Group 1- propolis and Group 2 - chlorhexidine from baseline to 15th day follow up. However after crossover there was no statistically significant difference at 15th day (p = 0.746) between Group 1- chlorhexidine and Group 2-propolis. Similar results were found as conducted by Torwane., *et al* [18].

In this present study the effect size for both the groups before and after cross over study found to have minimal difference showing that both the mouth washes are almost equally effective. To our knowledge there is no previous crossover study where the antiplaque efficacy of propolis was done, hence our study couldn't get any collaboration to compare with other evidence literature.

However, as observed in the present study the significant improvement in plaque and gingival status may be attributed to its well documented antiplaque activity. This natural product propolis did not exhibit any adverse effects such as burning sensation nor staining of teeth.

The limitations of this study were smaller sample size, non-evaluation of substantivity of propolis and mouthwash was dispensed as suspension where in dilution was required before usage. As this is the first of kind of crossover study including propolis as the experimental group, further long term clinical trials with large sample size and antimicrobial efficacy with standardized controls, are desired to validate the superiority of propolis in the treatment of gingival diseases and definitely would have promising benefit.

Conclusion

Propolis (20%) and Chlorhexidine gluconate (0.2%) mouthwashes were equally effective in reducing plaque and gingival inflammation based on the results obtained. Propolis didn't exhibit any side effects, Further, long term trials with larger sample size, use of different vehicles and different concentrations of propolis extract are needed to affirm the findings of this study.

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