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Full Length Research Paper

A study to assess the plaque inhibitory action of herbal-based toothpaste: A double blind controlled clinical trial

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Incorporating herbal extracts in the formulation of toothpastes is becoming an accepted mode of chemical plaque control. This study has been conducted to determine whether an herbal-based toothpaste would inhibit de novo plaque formation beyond that of a conventional fluoride Toothpaste. Fifteen adult volunteers, meeting the inclusion criteria (age range 19 - 22) participated in a double-blind, cross-over controlled clinical trial, based on a variation of a 4 day plaque regrowth model. After professional tooth cleaning, subjects were asked to refrain from all mechanical hygiene measures for the next 96 h, and to use two rinses (1 min) a day as the only oral hygiene measure. At day 4, teeth were stained to assess the whole mouth plaque index (PI) using Turesky modification of Quigley Hein PI (TMQH), and to evaluate the PI for anterior teeth using a 10 scaled method of plaque scoring (NMPS). Herbal-based toothpaste provided statistically significant plaque inhibitory action measured by whole mouth plaque index, over control toothpaste (P = 0.032). There was no significant difference between test and control dentifrices in plaque index for anterior teeth using NMPS index. Pearson´s correlation coefficient showed significant values indicating close similarity between the two indices (r = 0.962, P < 0.0001). This study demonstrated the effectiveness of herbal-based toothpaste in the control of dental plaque formation over control paste. Further investigation into the potential value of this formulation among target population is recommended.

Key words: Plaque inhibition, herbal based toothpaste, clinical trial, plaque index.

INTRODUCTION

Based on large epidemiologic studies, dental plaque is the primary etiologic factor in gingival inflammation, the condition that is followed by chronic periodontitis in majority of patients, due to apical extension of supragingival plaque to the subgingival area (Hancock, 1996), which is a favorable ecological niche for the accumulation of anaerobic gram-negative bacteria such as *Porphyromonas gingivalis*, *Tannerella forsythia*, *Actinobacillus* sp., *Prevotella* sp., and *Fusobacterium* sp., known as putative periodontal pathogens (Socransky and Haffajee, 2005; Haffajee and Socransky, 2006; Haubek et al., 2004). In developed countries, people practice mechanical tooth brushing as the most common and potentially effective form of oral hygiene. Unfortunately, a significant proportion of all individuals fail to practice an acceptable standard of mechanical plaque removal which arises either or both from chaotic tooth brushing or lack of dexterity in performing tooth cleaning methods (Jepsen, 1988; Attin and Hornecker, 2005). Chemical preventive agents would therefore, add beneficial effects as adjunct to daily mechanical oral hygiene measures. In this regard, carriage of chemical agents into the mouth has involved varied range of vehicles among which, toothpaste for its common usage, is considered the ideal. In many countries and among certain nations, there is a

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tendency towards using plant-based products especially if their long-term and routine application is intended. It is estimated that 25% of prescriptions written in the US contain plant-derived ingredients, while 75 - 90% of the rural population of the rest world still relies on herbal medicine as their only health care (Kim, 2005). Parodontax®–PAR-(GlaxoSmithKline, Middlesex, United Kingdom) is a dentifrice containing herbal ingredients and sodium bicarbonate abrasive, which has received great attention. It is composed of sodium bicarbonate, sodium fluoride (1,400 ppm) and herbal ingredients: *chamomile*, which is supposed to have anti-inflammatory properties and to decrease gingival inflammation; *echinacea*, which is reputed to stimulate the immune response; *sage* and *rhatany*, which have anti-hemorrhagic properties*; myrrh*, claimed to be a natural anti-septic; and *peppermint oil*, which has analgesic, anti-septic and anti-inflammatory properties. Some studies have reported that Parodontax® is able to significantly decrease plaque and gingivitis (Yankell and Emling, 1988; Yankell et al., 1993), while others showed no additional benefits for the dentifrice when compared to a control (Mullally et al., 1995; Saxer et al. 1995).

In addition, to the best of our knowledge, there is no clinical trial comparing anti-plaque properties of Parodontax® with a commercial toothpaste in the form of slurries. For a clearly evident effect of an active substance against dental plaque, its activity apart from indeterminate action of tooth brushing should be demonstrated. The aim of this study was to evaluate the efficacy of the Parodontax® dentifrice in the form of slurry, in reduction of plaque among subjects with healthy periodontium.

MATERIALS AND METHODS

In this double blind, cross-over, two period, two-treatment clinical trial, fifteen subjects (age range : 18-22) were recruited from initially 36 volunteer students of Guilan University, Rasht, Iran. Prior to the start of the study, ethical approval was obtained from Guilan University of Medical Sciences ethics committee. Eligible cases met the following inclusion criteria: Good general health, minimum of 20 scorable teeth, pocket probing depth (PPD) ≤3 mm as measured by a periodontal probe (Williams, Hu-Friedy, USA) and high standard of oral hygiene and gingival health.

Exclusion criteria were: Wearing fixed or removable appliances or dental prosthesis, and having any medical or pharmacological history which could affect the performance of the study. Teeth with grossly carious, fully crowned or extensive facial or lingual restorations and third molars were excluded.

To avoid carry-over effects, a 2 day wash out phase (according to Newcombe et al., 1995) was allowed between each study cycle. The order of toothpaste use was determined by blocked randomization, a random number sequence was also used to choose a particular block. The test toothpaste contained six herb extracts: *Chamomile*, *Sage, Myrrh, Rhatany, Echinacea and Peppermint oil*, and the control toothpaste was a conventional dentifrice which contained a standard fluoride system.

We used a classical 4 day growth model (Addy et al., 1983; 1991) to assess the plaque inhibitory effect of the toothpaste slurries. After receiving a professional tooth cleaning on day 0, all subjects refrained from any oral hygiene measures and were instructed to rinse with freshly made slurries (3 gm toothpaste in 10 ml water) by the use of a coded mini kit containing 8 plugged tubes of 3 gm toothpaste, a 10 ml syringe and a bottle of 100 ml distilled water. On day 4, the Tureskey et al. (1970), modification of the Quigley-Hein (1962), plaque index (TMQH) was recorded for all teeth.

The maxillary and mandibular anterior teeth were photographed and the plaque scores were assessed by a New Method of Plaque Scoring-NMPS-(Dababneh et al., 2002) after transmitting the digital photos to the computer.

Statistical analysis was performed using SPSS version 16 software. Each participant had a whole mouth average TMQH score for test and another for control toothpaste, and also an average NMPS score for labial surfaces of 12 anterior teeth with either test or control toothpaste. To be able to compare two plaque scoring systems used in this study, all the data was arranged on the basis of percent indices, as follows:

TMQH % = (sum of scores for all surfaces ÷5) / Number of surfaces × 100

NMPS % = (sum of scores for all surfaces ÷10) / Number of surface × 100

Using the Kolmogorov-Smirnov test, the distribution of variables appeared to be normal, so we used two-tailed paired t-test for the comparison between test and control toothpastes, and Pearson correlation test was also used for assessing the agreement between two indices applied in this study. All statistical tests employed a level of significance of $\alpha = 0.05$.

RESULTS

From the initial 17 subjects, 15 (9 males, 6 female, age range 19 - 22) completed the study. No side-effects occurred. Table 1 depicts the overall mean differences in plaque accumulation between test and control groups with either toothpaste slurries using TMQH and NMPS indices. While there existed a statistically significant difference in the full mouth plaque index, between test and control toothpastes, a similar result was not achieved for facial surfaces of anterior teeth neither with TMQH nor with NMPS indices (Table 1).

Analysis of plaque accumulation on facial and lingual surfaces indicated superior results for PAR on the buccal surfaces of maxillary and lingual surfaces of mandibular teeth (Table 2).

Pearson correlation test showed agreement between TMQH and NMPS plaque indices for anterior teeth according to Figures 1 and 2.

DISCUSSION

The primary purpose of this study has been to evaluate the plaque inhibitory action of Parodontax® toothpaste as a whole, in comparison to commercial fluoride toothpaste with no antimicrobial action. Thus, we did not focus on any particular ingredient in the formulation of PAR. Much of the existing data pointing to PAR dentifrice are principally based on home use studies, reporting the

Table 1. Statistical comparison of test and control toothpastes using TMQH and MMPS indices.

Variable	Mean ±SD		95% CI		P value
	Test	Control	Test	Control	
TMQH	45.2±9.3	54.9±10	40.05-50.35	49.36-60.44	0.012*
NMPS†	48.06±15.1	51.8±12.5	39.70-56.42	44.88-58.72	0.579**
TMQH†	52.6±19.2	57.2±13.4	41.97-63.23	49.78-64.62	0.438**

*Significant.
**Non-significant.
†Facial surface of anterior teeth only.

Table 2. Mean (±SD) and comparison between groups according to TMQH plaque index at buccal and lingual/palatal aspects.

Variable	Mean ±SD		95% CI		P value
	Test	Control	Test	Control	
Maxillae buccal	2.91±0.95	3.33±0.74	2.38-3.44	2.92-3.74	0.12**
Maxillae palatal	1.64±0.46	2.11±0.65	1.39-1.89	1.75-2.47	0.04*
Mandible buccal	2.41±0.69	2.78±0.73	2.03-2.79	2.38-3.18	0.12**
Mandible lingual	1.96±0.32	2.39±0.49	1.78-2.14	2.12-2.66	0.006*

*Significant.
**Non-significant.

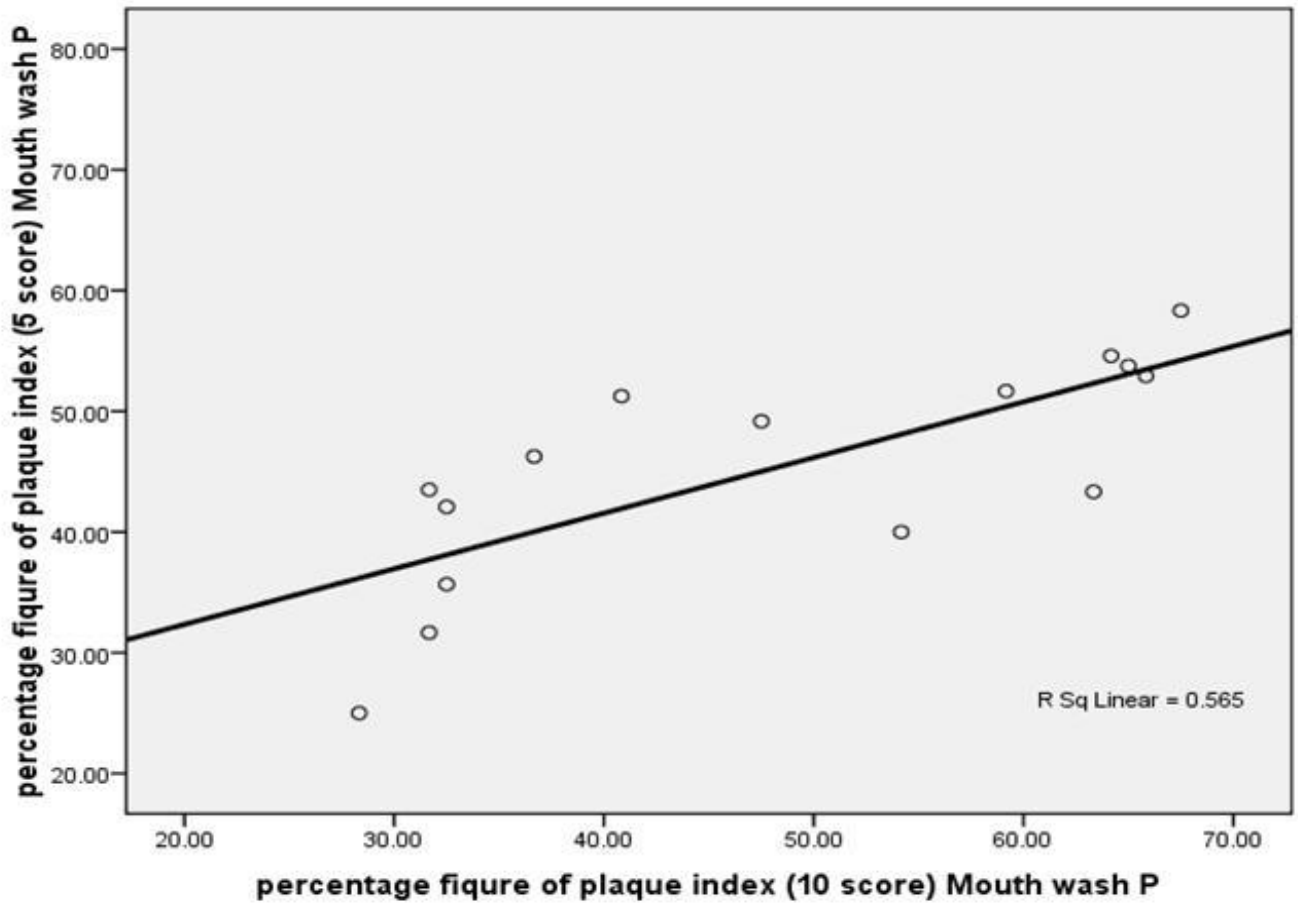

Figure 1. Correlation between TMQH and NMPS mean plaque scores of anterior teeth in the test group ($r = 0.794$, $p < 0.0001$).

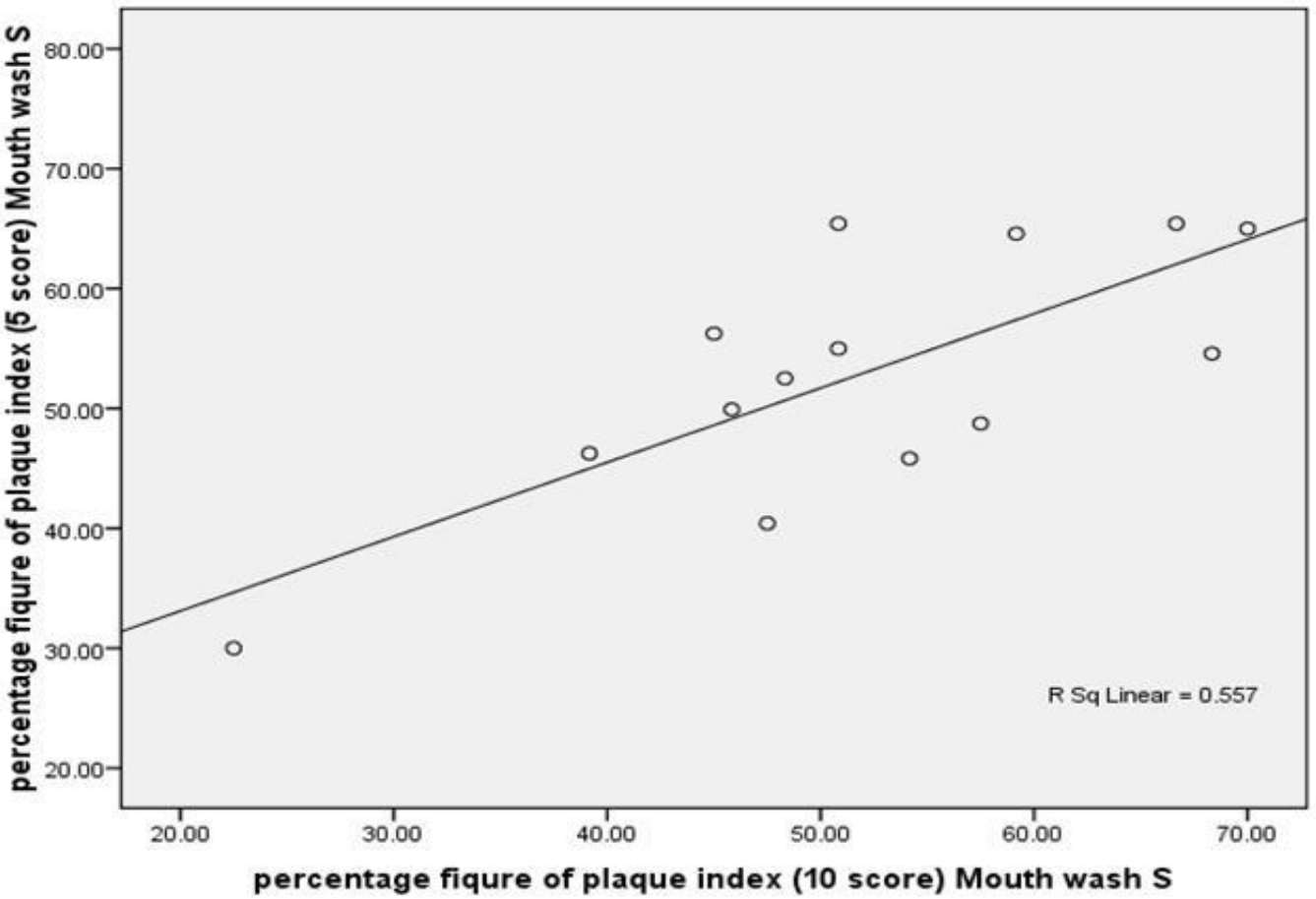

Figure 2. Correlation between TMQH and NMPS mean plaque scores of anterior teeth in the control group ($r = 0.962$, $p < 0.0001$).

control of gingivitis due to its significant action on plaque regrowth (Beller and Beller, 1988; Emling et al., 1988; Yankell et al., 1988; Saxer et al., 1994). PAR dentifrice used in this study was the active gel, containing 45% sodium bicarbonate, basically for two reasons; firstly the other variations of PAR with 67.7% $NaHCO_3$ (PAR original and PAR fluoride) have a unique salty taste and therefore less acceptable for the patients, specially during the 7 - 10 days of use, and the other reason is that the original form is fluoride free. Laboratory investigations indicate that PAR in concentrations of 0.25% is capable of inhibiting saliva glycolysis and acid formation during an incubation period of at least 5 h (Yankell et al., 1988). Alkaline environment is not favorable for and may hamper the formation of dental plaque, adding to the antimicrobial properties of its herbal component. In the present study the herbal PAR toothpaste provided a significant difference in the whole mouth averages of TMQH plaque index. Arweiler and his co-workers (2002), in an in vivo study comparing slurries of Colgate total (COL) with PAR indicated that COL has a significant action on plaque regrowth and a high substantivity during 24 h (28 - 50% reduction of plaque vitality), while PAR revealed a more moderate but still significant effect. COL contains Triclosan in a formulation to enhance its retention in the oral cavity for about 12 h after use, which can be an explanation for superior results reported with COL over PAR. Moreover Triclosan is an antimicrobial agent with a well established safety and efficacy. Ozaki et al. (2006), in a home use study comparing the effects of PAR and COL total on established gingivitis, reported similar results with both products indicating improvement of PI and GI but with no statistically significant difference between the preparations under investigation. In contrast, Pannuti et al. (2003), during a 21 day home use clinical trial found no significant difference in mean plaque indices with either test (PAR) or control dentifrice. It should be emphasized that in our study we used a conventional sodium fluoride dentifrice as control which could have some inherent plaque –inhibitory action consequent upon ingredients such as sodium lauryl sulphate (SLS)detergent, although its substantivity has been reported to be moderate(Jenkins et al., 1991b).

While home use toothpaste studies are exposed to Hawthorne effect (where subjects knowingly involved in oral hygiene studies, improve their tooth cleaning), as the

most important confounding factor, experiments assessing the plaque inhibitory properties of the test preparations in the form of slurries independent of the mechanical action of brushing, are of short duration and as a consequence not designed to evaluate the parameters of gingival inflammation.

Within a dental arch, large differences in plaque growth rate can be detected. It has been shown that early plaque formation occurs faster in the lower molar teeth and in the interdental regions compared to the strict buccal or oral surfaces. While in the present study there existed no statistically significant difference in plaque indices of 12 anterior teeth between either toothpaste, PAR acted significantly better on lingual surfaces of molar-premolar teeth in both jaws, which are the most vulnerable sites to early plaque regrowth. We also observed the agreement of TMQH plaque index with the NMPS in mean plaque scores for buccal surfaces of 12 anterior teeth which suggests conduction of further experiments to evaluate if the NMPS plaque index is similarly feasible for scoring the posterior teeth *in vivo*.

This study suggests that outside the Hawthorne effect, Parodontax® toothpaste acts more effectively against plaque regrowth compared to a conventional control dentifrice. Studies using more detailed plaque indices such as NMPS and evaluation of plaque vitality and composition are recommended to further verify the quantity and quality of its action.

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