

Anti-gingivitis Effects of *Acacia arabica*-containing Toothpaste

Pradeep S. TANGADE¹, Anmol MATHUR¹, Amit TIRTH¹, Soumik KABASI¹

Objective: To evaluate the anti-plaque and anti-gingivitis properties of *Acacia arabica*-containing toothpaste in an adult population.

Methods: Sixty subjects with gingivitis were randomly assigned to a test group (*Acacia arabica*-containing toothpaste) or control group (regular toothpaste). An analysis of plaque index (PI), gingival index (GI) and bleeding on probing index (BOP%) were carried out at baseline and after 28 days followed by a washout period. After the washout period, the test and control groups were crossed over and the assessments were repeated.

Results: Reductions in PI, GI and BOP% were observed in the test group compared with the control group.

Conclusion: Brushing with *Acacia arabica*-containing toothpaste may help inhibit gingivitis. It can be recommended for daily oral hygiene procedures.

Key words: *Acacia arabica*, dentifrice, plaque, gingivitis.

Dental plaque plays an important role in the aetiology of gingivitis and periodontitis. The control of periodontal disease progression is dependent on optimal plaque control¹. Supragingival plaque control is an effective method of controlling gingivitis and is an important component of periodontal therapy². Elimination of microbial dental plaque biofilm prevents gingivitis, periodontitis and dental cavities³.

Tooth brushing with a dentifrice is the most widely practised form of oral hygiene in most countries⁴. As a consequence, toothpastes provide an ideal vehicle for chemical adjuncts.

A wide range of chemicals, mainly antimicrobial agents, have been added to dentifrices to produce a direct inhibitory effect on plaque formation^{5,6}. This use of chemicals in toothpaste is now a well-established approach in improving gingival health^{7,8}. However,

these chemical agents may not achieve permanent complete plaque removal, therefore additional application of herbal microbial agents^{6,9} is the subject of interest. New formulations, using new or recognised toothpaste additives, need to be assessed as to whether their anti-plaque potential is realised. Interest in alternative toothpastes based on herbal extracts has increased recently⁹.

Babul, whose botanical name is *Acacia arabica*, occurs wild in the Indian subcontinent and tropical Africa. Babul trees are planted for their bark, which yields a gum known as babul gum. Babul contains tannin and gallic acid, which has medicinal properties. The leaves, the bark and the gum of the tree all have medicinal qualities, such as antibacterial, antihistaminic, anti-inflammatory, astringent and haemostatic properties.

The purpose of the present study was to evaluate the anti-plaque and anti-gingivitis properties of *Acacia arabica*-containing toothpaste using a commercially available conventional toothpaste as control.

¹ Department of Public Health Dentistry, Kothiwal Dental College and Research Centre, Mora Mustaqueem, India.

Corresponding author: Dr Pradeep S. TANGADE, Department of Public Health Dentistry, Kothiwal Dental College and Research Centre, Mora Mustaqueem, Moradabad-244001, India. Tel: 91-999-7466339; Fax: 91-591-245299; E-mail: ptangade@rediffmail.com

Materials and methods

The present study was designed as a randomised, double-blind, crossover controlled trial carried out during the period from December 2010 to March 2011. Initially

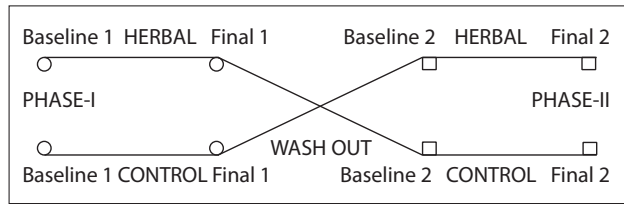
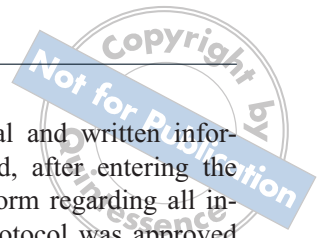


Fig 1 A randomised double-blind two arm cross-over experimental design.

60 patients (range 18–37 years and with the mean age of 28.8 ± 3.28 years) were enrolled randomly into the study. They were included in the study after meeting the following eligibility criteria: age ≥ 18 years, a minimum of 15 teeth, good general health, a baseline plaque index (PI) mean $> 1.5^{10}$ and presence of established gingivitis. Established gingivitis was defined as a baseline using the gingival index (GI)¹¹. A mean gingivitis score should be > 1.0 , according to the criteria used by Binny et al¹². Subjects were recruited from low socio-economic status groups that used only neem twigs for brushing. Exclusion criteria were: presence of systemic disease, using drugs affecting periodontal disease, antibiotic therapy for periodontitis or gingivitis during the previous three months, using orthodontic appliances, continuous use of mouth rinses containing chemical agents in the previous three months and any history of allergies to toothpaste or herbal medicine.

All subjects were given verbal and written information concerning the study and, after entering the study, signed a written consent form regarding all information received. The study protocol was approved by the Ethics Committee of Kothiwal Dental College, Moradabad, India. All procedures in this experiment were performed according to the ethical principles established by the Declaration of Helsinki.

The present study consisted of two 4-week experimental periods, separated by a 10-day washout period to avoid the carry-over effect¹³.

For phase one scoring, the baseline PI, GI and bleeding on probing index (BOP%) were measured for all teeth on the buccal, mesial, distal and lingual aspects, with the exception of third molars. The dental plaque was stained using an erythrosine disclosing solution and cotton swabs. The amount of plaque was scored using the Turesky¹⁰ modification of the Quigley-Hein¹⁴ PI, gingival inflammation was recorded using GI¹¹, and bleeding in response to gentle probing in the gingival sulcus¹⁵ was assessed at the mid-buccal, mesiobuccal, mid-palatal/lingual and distopalatal/lingual surfaces of each index tooth and the percentage of sites which bled was calculated for each subject. All measurements were conducted by the main investigator, who was previously calibrated. For calibration, two measurements were performed with a 1-h interval. Intra-examiner calibration was performed in five patients until an 80% agreement was obtained.

Table 1 PI, GI and BOP% median scores for herbal and control groups for phase one (before crossover) and phase two (after crossover)

PI score	Before crossover					After crossover					
	Group	Baseline	Final	Change	T	P	Baseline	Final	Change	T	P
Herbal		2.07	1.4	0.69	1365	*	1.9	1.5	0.4	466.5	*
	Control	2	1.8	0.18			1.7	1.7	0.1		
GI score	Before crossover					After crossover					
Group	Baseline	Final	Change	T	P	Baseline	Final	Change	T	P	
Herbal	2.01	1.08	0.94	1365	*	1.9	1.5	0.5	465	*	
Control	1.91	1.82	0.1			1.45	1.45	0			
BOP% score	Before crossover					After crossover					
Group	Baseline	Final	Change	T	P	Baseline	Final	Change	T	P	
Herbal	11.3	8.5	2.4	1260	*	11.7	8.5	3.1	484	*	
Control	11.7	10.9	1.5			10.9	10.5	0.8			

* $P < 0.001$

All patients were instructed in the use of the oral hygiene items. They were asked to brush their teeth thrice daily using the Bass technique for approximately 2 minutes. The subjects were randomly assigned to the test or control group. The random allocation sequence was generated by one of the authors, who used a random-number table. The random allocation sequence was concealed from the main investigator until the dentifrices were assigned to the participants. The investigator and subjects were unaware of the contents of toothpaste. The blinding was maintained throughout the study period.

Subjects in the test group received 50 g of non-fluoridated toothpaste containing *Acacia arabica*, calcium carbonate, sorbitol, water, silica, sodium lauryl sulphate, flavour, cellulose gum, carrageenan, sodium silicate, sodium saccharin, formaldehyde and foaming. Subjects in the control group received 50 g of commercially available toothpaste containing calcium carbonate, sorbitol, silica, sodium lauryl sulphate, titanium dioxide, sodium silicate, carrageenan, sodium monofluorophosphate, sodium bicarbonate, sodium saccharin, triclosan and flavour, in aqueous base. No prophylaxis was undertaken prior to commencement of the study, and no attempt was made to modify the volunteers' oral hygiene habits.

After 28 days, the subjects returned for another appointment, in which the amounts of plaque, gingival inflammation and bleeding on probing were scored again by the same investigator. The scores were recorded as the final scores for phase one. To check for compliance, the participants were asked to return their assigned toothpastes, so that the investigator could verify the amount of dentifrice that had been used.

This was followed by a washout period of 10 days, during which the subjects returned to their regular oral hygiene practice using neem twig. The test and control toothpastes were interchanged at the beginning of the second study phase and the scorings were repeated at same time intervals. The scores were recorded as baseline and final scores for phase two, as shown in Fig 1.

Statistical analysis

Statistical analysis was performed using SPSS version 11.0 for Windows (Statistical Package for Social Sciences, SPSS Inc, Chicago, IL, USA). A median value was calculated for each of the study phases and an overall median of the differences from baseline was calculated for both phases (before and after crossover). Mann-Whitney *U* test was applied to examine the difference between the test and control groups. A value of $P < 0.05$ was considered significant.

Results

Table 1 shows that for PI the highest median score change between baseline and 28 days was recorded in the test (herbal) group before crossover (0.69), whereas the lowest score differential was recorded in the control group after crossover (0.1). The difference between the test group and control group was statistically significant for pre- and post-crossover phases.

The maximum reduction of median GI score between baseline and 28 days was recorded in the test group before crossover (0.94), whereas the lowest median GI score reduction was recorded in the control group after crossover (0). Thus, there was a significant reduction between the GI scores of the test group and control group before and after crossover.

For BOP% scores, there were marked differences after crossover among the test and control groups, which were reported to be 3.1 and 0.8, respectively.

Figure 2 shows steep decreases in PI median scores of the test group, from 2 to 1.4 before crossover and from 1.9 to 1.5 after crossover. In comparison, negligible reductions of PI median scores can be seen in the control group in both the pre- and post-crossover phases.

Figure 3 shows sharp reductions in GI median scores in the test group in both the pre- and post-crossover phases, whereas minimal reduction of GI median scores can be seen in the control group both before and after crossover.

Figure 4 shows steep reductions in BOP% median scores in the test group before crossover, from 11.3 to 8.5, and after crossover, from 11.7 to 8.5. Much lower reductions in BOP% median scores can be seen in the control group in both pre- and post-crossover phases.

Discussion

Recently, there has been a growing interest in natural products. While *in vitro* and animal studies may reveal the antimicrobial properties of these products, the only way to find out their real clinical effects is to conduct randomised clinical trials. It is important that clinical trials verify the efficacy of any medicinal product, instead of simply assuming that the product is effective based on the results of laboratory studies. In this trial, we examined a dentifrice containing *Acacia arabica* to evaluate its effects on periodontal health using a randomised, double-blind, two-arm crossover study design.

The plaque-reducing effects of other herbal-based active agents have previously been described by various studies¹⁶⁻¹⁸. In the present study, the application of

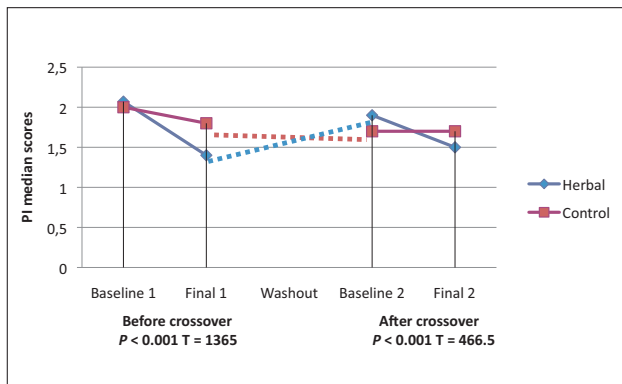
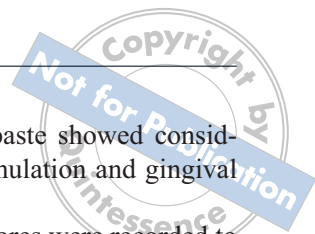


Fig 2 PI median scores before and after crossover among test (herbal) and control groups.

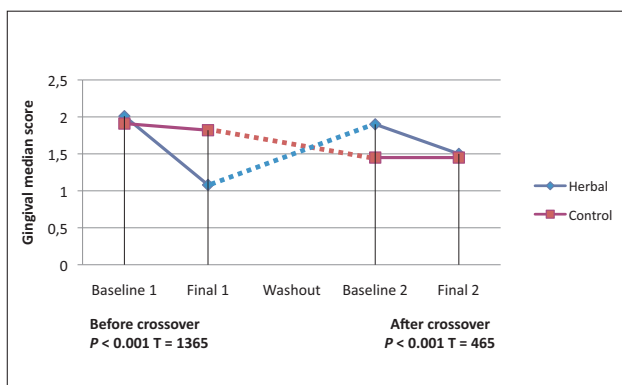


Fig 3 GI median scores before and after crossover phases among test (herbal) and control groups.

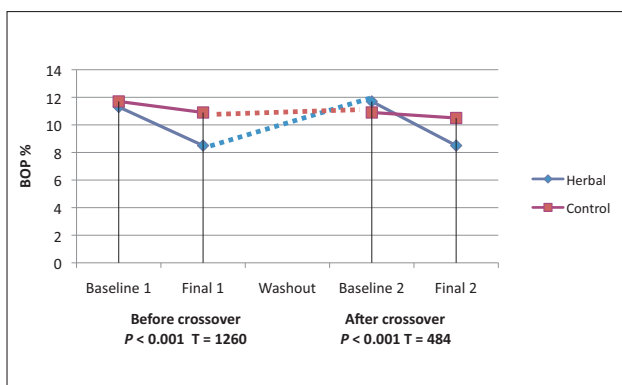


Fig 4 BOP% median scores before and after crossover phases among test (herbal) and control groups.

Acacia arabica-containing toothpaste showed considerable reductions in plaque accumulation and gingival inflammation.

Reductions in the PI median scores were recorded to be 0.69 and 0.4 for the test group and 0.18 and 0.1 for the control group, before and after crossover respectively, showing there was higher reduction of plaque in the test group than in the control group. This kind of reduction in PI in the group using *Acacia arabica*-containing toothpaste was in accordance with previous studies^{10,17,19}. The reduction in PI scores may be due to the antimicrobial property of *Acacia arabica*, which is supported by Almas²⁰, Gazi²¹ and Tambekar et al²².

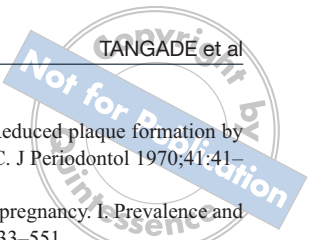
Median GI scores recorded for the two arms of the crossover design were also higher for the test group in both phases of the study. These results were in accordance with a study conducted with other herbal products¹⁷. The anti-inflammatory property of *Acacia arabica* may be responsible for the significant reductions in GI scores.

A study by Willerhausen et al¹⁷ reported that the pH of total saliva was significantly displaced into the alkaline range by the use of herbal products, which may be another reason for the antimicrobial efficiency of *Acacia arabica*.

In the present study, a significant reduction in BOP% was observed in the test group using the *Acacia arabica*-containing toothpaste in comparison with the control group. This reduction was in line with the findings of Amoian et al¹⁶. This reduction in bleeding may be due to astringent and anti-inflammatory effects of *Acacia arabica*.

A prospective, randomised, placebo and positively controlled clinical trial²³ designed to evaluate the clinical effects of a commercially available *Acacia arabica*-containing gel reported significant reduction of plaque and gingival inflammation in subjects with gingivitis, which is in accordance with the findings of the present study. However, Pannuti et al¹⁸ did not observe reductions of PI or GI scores when comparing herbal with control dentifrices. The reason given by the authors was that the study population participating in the study was composed of dental students, who presented with low PI and GI scores at baseline.

Other studies on herbal products, such as calendula¹⁶ and Parodontax⁹, did not report reductions in periodontal scores comparable to those for *Acacia arabica*-containing dentifrices. The authors feel that further reductions in plaque accumulation could be achieved if herbal dentifrices are used in combination with herbal-based mouth rinse. This will open vistas for further studies.



Conclusions

The present study shows that *Acacia arabica*-containing toothpaste can decrease plaque, gingivitis and BOP% scores. It is suggested that *Acacia arabica*-containing toothpaste could be a useful approach for gingivitis prevention and that it may be recommended for daily oral hygiene procedures.

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