Comparison of Plaque Removal Efficacy of Tooth Powder and Toothpaste in Young Adults in India: A Randomized Controlled Clinical Trial

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Abstract

Objective: A clinical equipoise exists between the plaque reducing efficacies of two of the most commonly used dentifrices in India. This study compared the plaque removal efficacy of a commercially available tooth powder with commercially available toothpaste in young adults.

Methods: This was an investigator-blinded randomized controlled clinical trial with crossover design conducted among 89 young adults aged 18 - 25 years. Interventions were a commercially available tooth powder and toothpaste. Plaque scores were measured at baseline, after 24 hours and seven days.

Results: At baseline, the mean plaque scores were 0.97 ± 0.30 and 0.93 ± 0.34 for the toothpaste and tooth powder groups, respectively. After 24 hours without any oral hygiene activity, the scores increased to 2.41 ± 0.54 and 2.42 ± 0.52, respectively. After seven days of using the intervention, the mean plaque scores were 2.12 ± 0.53 in the toothpaste group and 2.11 ± 0.56 in the tooth powder group. There was no significant difference between the groups at baseline and follow-up visits. Within each group, there was a significant difference in the plaque scores between the follow-up visits.

Conclusions: The present study suggests comparable plaque removal efficacy of tooth powders and toothpastes.

Key words: Appropriate technology, dentifrice, dental plaque, tooth powder

Introduction

Dental caries and periodontal diseases can both occur following the formation of bacterial plaque on and around the teeth. One of the common methods for effective plaque control is tooth brushing (Murray *et al.,* 2003). Dentifrice is a general term used to describe preparations that are used with a toothbrush to clean and/or polish the teeth. Over the years, cleaning of teeth with toothbrush and toothpaste has been the most practiced method of oral hygiene across the world (Oberoi *et al.*, 2014; Gopikrishna *et al.*, 2016).

While toothpaste is preferred over tooth powder due to its superior handling characteristics, tooth powder use is still dominant in countries such as India, typically in the rural and tribal pockets (Chandrashekar *et al.,* 2016; John *et al.,* 2015; Varsha *et al.*, 2014). This could be attributed to the cultural and lifestyle practices, and also to an age-old affinity towards herbal products in the country. According to the National Oral Health Survey 2002-03, a quarter of the country's population uses tooth powder for brushing their teeth. The prevalence of tooth powder usage in India, according to other studies, ranges between 4.8% to 37% (Archana and Jagat, 2010; Muttappillymyalil *et al.,* 2009; Paul *et al.,* 2014; Narasimhan *et al.,* 2014; Punitha and Sivaprakasam, 2011; Nishi Rath, 2011).

Though the plaque removing efficacy of various formulations of toothpastes has been studied abundantly (Paraskevas *et al.,* 2006, 2007; Sälzer *et al.,* 2016a; Sälzer *et al.,* 2016b), studies intended to compare the superiority of either product in relation to plaque removal are very few. A randomized controlled trial conducted among dental students in Pakistan in 2009 showed that the mean plaque scores of subjects using tooth powder was significantly lower than that of the toothpaste group (Khan *et al.,* 2009).

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India's relationship with traditional practices requires technology to approximate and adapt to their social and cultural milieu, which is also known as appropriate technology, one of the key principles of primary health care. If tooth powder shows comparable evidence in reduction of dental plaque, it would lead to a situation where the practice of technology being ingrained into local needs and customs is adopted. Furthermore, advocacy of tooth powder manufactured according to standard guidelines brings about freedom of personal choices for oral hygiene practices rather than attempting a radical behavioral change in use of dentifrices by promoting the use of toothpaste.

Thus, the primary objective of this study was to compare the plaque removal efficacy of commercially available tooth powder and toothpaste in young adults in India.

Materials and methods

This was a single center, randomized, controlled, investigator blinded clinical trial with a crossover design (1:1 ratio). The study participants were young adults aged 18 - 25 years and recruited from a dental school in India. This population was chosen as the study required multiple follow-up visits and strict adherence to the protocol. Ethical approval was obtained from the Institution Review Board. The trial was registered with the Clinical Trial Registry of India (Reg No. CTRI/2017/01/007680).

Selection criteria

Patients with mild to moderate gingivitis having at least 20 natural teeth with no history of periodontal therapy or antibiotic medication for the past 6 months were included in the study. Exclusion criteria were a known allergy to the constituents of toothpaste or tooth powder, advanced periodontal diseases (loss of attachment, purulent exudate and tooth mobility), undergoing orthodontic treatment, pregnancy or lactation, and smoking.

Organizing the study

Eligibility was assessed by the principal investigator (RV) and the participants were detailed regarding the procedures to be conducted during each visit. Voluntary informed consent was obtained from willing participants.

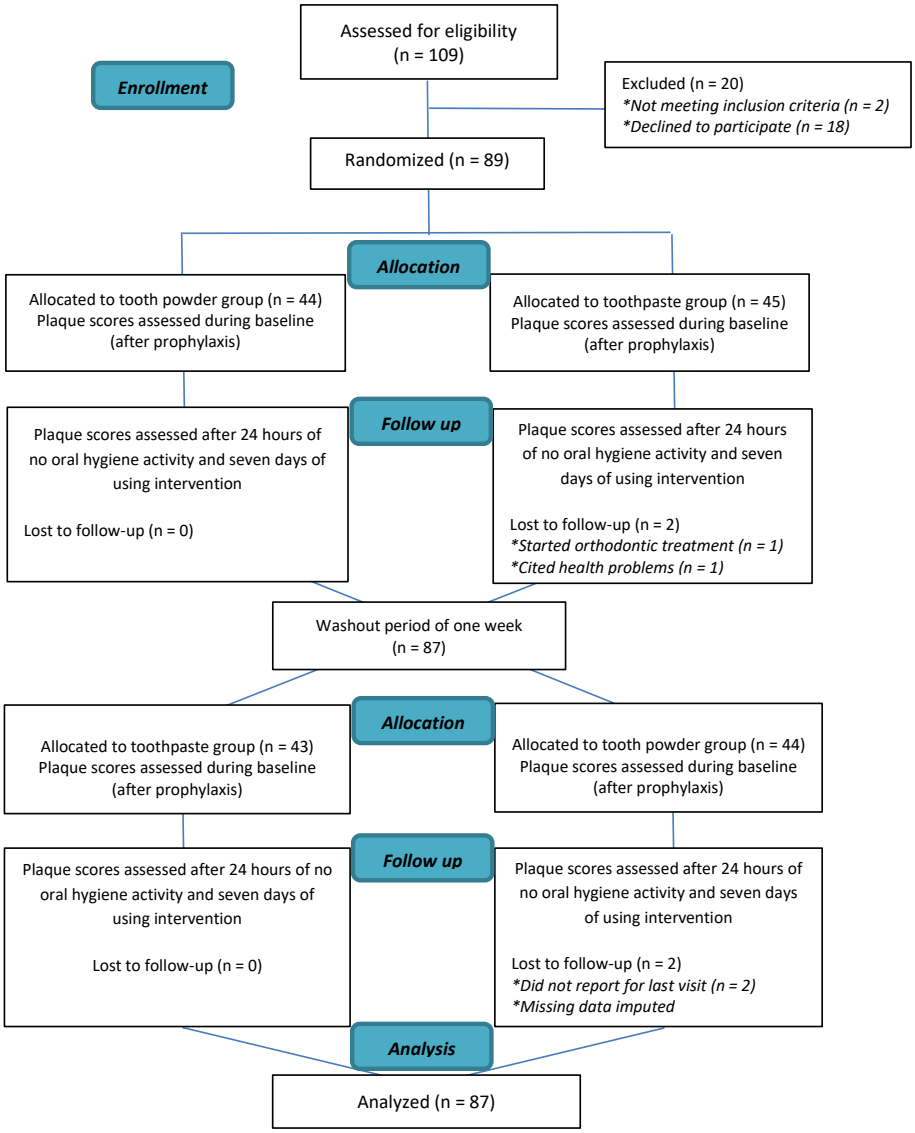

Figure 1. CONSORT flow diagram.

Because the principal investigator was blinded to the intervention, two trial coordinators were appointed for the randomization, allocation of intervention and demonstration of toothbrushing technique. A trial register was maintained to record the date and time of each visit.

Intervention

Two commercially available products for maintenance of oral hygiene were used for this study. The active arm consisted of twice daily brushing with tooth powder [Colgate Super Rakshak, Colgate Palmolive (India) Ltd.™] and control arm was twice daily brushing with toothpaste (Colgate Strong Teeth, Colgate Palmolive (India) Ltd.™]. The test and control products were similar in composition. Both groups received a soft-bristled toothbrush (Colgate Cibaca 1-2-3) for using the assigned dentifrice. The brushing technique was standardized wherein the participants were trained and advised to follow modified Stillman's technique of toothbrushing. At the first visit, all participants underwent an oral prophylaxis, following which baseline scores were recorded. They were then asked to refrain from any oral hygiene practices for 24 hours. At the second visit (24 hours after the first visit), plaque scores were assessed before brushing. The participants then used the allotted intervention for seven days with a washout period of one week before the interventions were crossed over (*Figure 1*). Tooth powder was dispensed in the form of small sachets. Each sachet contained one gram of tooth powder weighed using a measuring spoon. The participants were instructed to empty the contents of the sachet onto their palms. The toothbrush was moistened and loaded with toothpowder. This was done to ensure minimal wastage of tooth powder. Toothpaste was dispensed as a single tube of 15 grams. Participants were advised to load one half of the toothbrush with toothpaste for brushing. This was done to ensure that 1 gram of toothpaste was used each time. Brushing duration was fixed at 5 minutes. Toothbrushing was done in the presence of the trial coordinator at baseline and after the 24-hour visit at the study centre. For the next seven days, participants brushed independently in their homes.

Outcomes evaluated

Reduction in plaque scores between the groups was the primary outcome. Plaque scores were assessed by the principal investigator (RV) using the Turesky-Gilmore-Glickmann modification (Turesky *et al.*, 1970) of the Quigley Hein plaque index (Quigley and Hein, 1962) at baseline, after 24 hours before brushing, and seven days after using the intervention according to the specified instructions. A disclosing agent was used (AlphaPlac, Two-Tone disclosing agent, DPI, Mumbai) prior to the assessment of plaque scores.

At the end of the trial, the participants also answered a query on their preferred choice of dentifrice and reasons for the same.

Sample size

A pilot study was conducted on four subjects and the results were analyzed. Sample size was calculated using nMASTER software for sample size calculation. The following parameters (equivalence-two group-two means-equal allocation) were used to calculate the sample size: Equivalence limit difference in means = 0.41; expected difference = 0.25; standard deviation = 0.43; effect size = 0.11; power (%) = 80; alpha error (%) = 5; required samples in each group = 89.

Randomization

A computer-generated randomization sequence was adopted for this trial. Allocation was given in closed opaque boxes, thereby ensuring blinding of the principal investigator.

Statistical analysis

Statistical Package for Social Sciences (SPSS, IBM Version 20) software was used for analysis. Initially the data obtained were tabulated and analyzed using descriptive statistics. The oral hygiene practices were expressed in the form of frequencies. The total plaque scores of each visit were expressed as mean and standard deviation. Per-protocol analysis was done for this study. The Kolmogorov-Smirnov test was used to assess the normality of the distribution in terms of plaque scores at each visit. Intergroup comparison was done using independent *t*-tests. Within-group comparison was done using paired *t*-tests. Repeated measures analysis of variance (ANOVA) test was applied to test the statistical significance of plaque scores between the two groups at baseline, 24-hour and seven-day follow-up visits. Missing data analysis was done using the regression mean imputation method.

Results

The trial was conducted during the period of July 2015 to October 2016. A total of 89 participants were enrolled for the trial.

Table 1 outlines the characteristics of the study participants. Two participants dropped out of the trial after the first intervention and thus were excluded from analysis. Two participants did not complete the follow-up (last visit of the second intervention; *Figure 1*). However, they were included in the analysis and the missing values were imputed. The response rate was 97.75%. Per-protocol analysis was done for all results. The mean age of the participants was 22 years. Males comprised 36.8% of the sample.

Table 1. Characteristics of study population.

Characteristics	n
Total number of patients enrolled	89
Lost to follow-up	2
Total number of participants analyzed	87
Mean age of participants	22.01 ± 2.27
Males	32
Females	55

The mean plaque scores during each visit are outlined in *Table 2*. No statistically significant difference was observed at baseline, after 24 hours without oral hygiene activity, or after seven days of brushing with the allotted intervention between tooth powder and toothpaste groups.

In the toothpaste group, there was a statistically significant difference between the visits as determined by one-way ANOVA (F (2,258) = 221.93, $p = 0.001$). A Tukey post hoc test revealed that the plaque scores after 24 hours before brushing (2.41 ± 0.54, $p = 0.001$) and seven days (2.12 ± 0.53, $p = 0.001$) were significantly higher than baseline (0.97 ± 0.30). There was a statistically significant difference in the plaque scores between 24 hours and seven days ($p = 0.001$; *Tables 3*, *4*).

Table 2. Comparison of mean plaque scores between groups at each visit.

	Intervention	n	Mean	Standard deviation	Standard error	*p* value
Baseline plaque index	Toothpaste	87	0.98	0.30	0.03	0.31
	Tooth powder	87	0.93	0.34	0.04	
After 24 hours	Toothpaste	87	2.42	0.54	0.06	0.88
	Tooth powder	87	2.42	0.53	0.06	
After 7 days	Toothpaste	87	2.12	0.54	0.06	0.49
	Tooth powder	87	2.12	0.57	0.06	

Table 3. Comparison of plaque scores at different visits for both groups using analysis of variance (ANOVA).

Intervention		Degrees of freedom	Mean square	F	*p*
Toothpaste group	Between groups	2	50.29	221.93	0.001
	Within groups	258	0.23		
	Total	260			
Tooth powder group	Between groups	2	53.70	223.47	0.001
	Within groups	258	0.24		
	Total	260			

Table 4. Post hoc results for toothpaste group (Tukey test).

		Mean difference	Standard error	*p*	95% Confidence interval	
					Lower bound	Upper bound
Baseline	After 24 hours	-1.44	0.07	0.001	-1.61	-1.27
	After 1 week	-1.14	0.07	0.001	-1.31	-0.97
After 24 hours	Baseline	1.44	0.07	0.001	1.27	1.61
	After 1 week	.29	0.07	0.001	0.12	0.46
After 1 week	Baseline	1.14	0.07	0.001	0.97	1.31
	After 24 hours	-.30	0.07	0.001	-0.46	-0.12

Table 5. Post hoc results for tooth powder group (using Tukey test)

		Mean difference	Standard error	*p*	95% Confidence interval	
					Lower bound	Upper bound
Baseline	After 24 hours	-1.49	0.07	0.001	-1.66	-1.31
	After 1 week	-1.18	0.07	0.001	-1.36	-1.00
After 24 hours	Baseline	1.49	0.07	0.001	1.31	1.66
	After 1 week	0.30	0.07	0.001	0.13	0.48
After 1 week	Baseline	1.18	0.07	0.001	1.00	1.35
	After 24 hours	-0.30	0.07	0.001	-0.48	-0.13

In the tooth powder group, there was a statistically significant difference between the visits as determined by one-way ANOVA [F (2,258) = 223.47, $p = 0.001$]. A Tukey post hoc test revealed that the plaque scores after 24 hours before brushing (2.42 ± 0.52, $p = 0.001$) and seven days (2.11 ± 0.56, $p = 0.001$) were significantly higher than baseline (0.93 ± 0.34). There was a statistically significant difference in the plaque scores between 24 hours and seven days ($p = 0.001$; *Tables 3*, *5*).

Few participants reported non-serious adverse events in the tooth powder group. Eight participants developed ulcers and three patients reported a burning sensation of the intraoral soft tissues at the start of the intervention. One participant reported that the ulcer was painful and was advised to discontinue the intervention on the fifth day. Participants were reassured and standard medical care for oral ulcers was given to the affected patients. All the patients reported healing of ulcers and reduction in symptoms within a week.

All participants originally used toothpaste and toothbrush as their oral hygiene method prior to the start of the study. However, at the end of the trial, 78% of the participants preferred to use toothpaste, 2% preferred tooth powder, and 20% did not have an opinion.

Discussion

Because the study objective was to compare the plaque removal efficacy of the two most common and commercially available products employed in the maintenance of good oral hygiene, a randomized clinical trial with crossover design was apposite. The crossover design was employed to ensure an efficient comparison of treatment effects, thereby eliminating comparison choice bias commonly noted in parallel design studies.

Several other biases that normally occur in randomized controlled trials were minimized in the present study design. Selection bias was minimized by ensuring complete randomization, which was achieved through computer generated random sequencing. Ascertainment bias was minimized to a considerable extent by the process of 'blinding' of the principal investigator. Allocation concealment was done using opaque sealed envelopes containing codes that corresponded to the randomization sequence. All these procedures were carried out by the trial coordinator. Measurements were carried out by a calibrated single outcome assessor (principal investigator) to avoid measurement bias. Data were coded and analysis was carried out by the principal investigator, thereby ensuring masking of statistical analysis.

There was only 2% dropout in this study. As a per-protocol analysis was adopted, the dropouts were excluded from the analysis. A missing data analysis was undertaken for participants (2%) who missed only one follow-up visit.

The role of dentifrice in plaque removal has been debatable. Formulations of different dentifrices are generally intended to fulfill a variety of aspects, such as to minimize plaque build-up, prevent dental caries, remove stains and provide fresher breath. The dentifrices hence contain different antiplaque and anti-inflammatory agents that enhance the mechanical action of toothbrushes in cleaning teeth (Jayakumar *et al.,* 2010). Several studies have also examined the effect of toothbrushing with and without dentifrice on plaque removal and the results have been inconclusive. While one study established that brushing with a dentifrice contributed to greater plaque removal than brushing without it (Eid and Talic, 1991), many of them concluded that the use of dentifrices did not contribute essentially to instant mechanical plaque removal during manual toothbrushing (Paraskevas *et al.,* 2006, 2007; Parizotto *et al.,* 2003).

The paucity of similar studies was an impediment for effective comparison of the present study results. A study conducted by Khan *et al.* (2009) reported a significant difference ($p = 0.009$) between the tooth powder and toothpaste groups, with the tooth powder group having lower mean plaque scores. However, the results were based on a single follow-up visit.

A systematic review on the role of dentifrice in removing plaque concluded that use of a dentifrice with toothbrushing does not have an added effect on plaque removal (Valkenburg *et al.,* 2016). This finding is significant as plaque removal is not the sole reason for toothbrushing. Fresher breath and benefits of other medications incorporated into dentifrices are also sought by users. Nevertheless, the difference in mean reduction of plaque scores could be attributed to effect of dentifrice alone, though the results were not statistically significant.

Regarding the reasons for preferred choice of dentifrice, the most common reason cited for the preference of toothpaste was the 'habit of using it from childhood'. Other reasons included ease of use, better cleaning ability and fresher breath. Reasons for non-preference of tooth powder pertained mainly to the burning sensation caused by the powder particles and the probable abrasive potential. The occurrence of ulcers in a few participants was also quoted as a reason for the non-preference of tooth powder.

The abrasive potential of dentifrices has been studied in the past, mainly in *in vitro* studies. Based on the results of these studies, it has been concluded that brushing without a dentifrice caused lesser abrasion than when a toothpaste was added (Tellefsen *et al.,* 2011), and that abrasion was a complex process depending not only on the type of dentifrice and toothbrush used (Magalhaes *et al.,* 2014) but also on patient-related factors such as tooth brushing frequency and force of brushing (Wiegand and Schlueter, 2014).

With the present study suggesting comparable plaque removal efficacy of tooth powders and toothpastes, indiscriminate promotion of toothpastes may be discouraged among tooth powder users in particular. However, in India, tooth powder is generally used with fingers rather than toothbrush (Jain *et al*., 2012; Archana and Jagat, 2010; Punitha and Sivaprakasam, 2011), which to a certain extent can affect the cleaning ability. Thus, to assess the effectiveness of tooth powder in real world settings, the authors recommend further studies with the traditional method of tooth powder use.

Conclusion

There was no statistically significant difference in the plaque reducing potential of tooth powder and toothpaste in controlled conditions. It was also observed that the study participants preferred toothpaste over tooth powder due to its relative ease of use. Probability of inducing burning sensation and oral ulcers were quoted as reasons for not using tooth powder. With the availability of tooth powders that differ in composition, physical properties and production, research can be attempted to further strengthen the study hypothesis while taking these factors into consideration. A similar study among the general population, and also amidst different ethnic groups around the globe, could further validate results of the present study.

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Conflict of interest:

The authors have stated explicitly that there are no conflicts of interest in connection with this article**.** The study was self-funded.

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