

## Evaluation of Clinical Efficacy of Unani Toothpowder (Payorin) on Plaque and Gingivitis- A Randomized Clinical Trial



### Medical Science

**KEYWORDS :** toothpaste, tooth powder, gingivitis, plaque, stain

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### ABSTRACT

**Introduction:** Dental plaque, known as dental biofilm, is implicated as the primary etiological agent responsible for oral inflammatory diseases. Dentifrices are commonly used for oral hygiene with some formulated with antimicrobial agents to control plaque. There is little information regarding the effects of Unani Medicine based toothpowder on controlling dental plaque and gingivitis amongst Indian subjects. **Objective:** This study was conducted to evaluate the efficacy of Unani toothpowder (Payorin) in alleviating gingivitis, controlling dental plaque, and inhibiting extrinsic stains. **Methodology:** A single-blind, parallel arm 6-month randomized clinical trial (RCT) was carried out on 100 subjects ageing 30-40 yrs. After an oral and periodontal examination subjects were divided into test (tooth powder=50) and control group (tooth paste=50). All participants received an adult-sized, soft-bristled toothbrush, and were instructed to brush their teeth for 2-3 minute two times a day, using the Bass technique, and to refrain from any other oral hygiene procedures throughout the duration of the study. Plaque, gingivitis and external stain assessments were carried out on at baseline, 4, 8, 12 and 24 weeks. **Results:** Plaque index, gingival index and Lobene index showed a linear decrease from baseline to 24 weeks. However there was no significant difference between the parameters measured in the two groups at 24 months. **Conclusion:** Both the dentifrices (toothpowder and toothpaste) were able to reduce plaque, gingivitis and stain although no additional benefit of the toothpowder over the positive control toothpaste could be observed.

### INTRODUCTION

Plaque induced chronic gingivitis is an oral health problem prevalent worldwide, affecting the dentition in people of all ages. Dental plaque, a well organized biofilm, has been established as the cause of chronic gingivitis [1]. The inflammatory and immune responses to these biofilms are primarily responsible for the subsequent destruction of the periodontal tissues leading to periodontitis. (2) Modern research suggests that systemic health may be affected by oral hygiene more than previously recognized. Associations have been found between periodontitis and cardiovascular disease in general and infective endocarditis specifically as well as rheumatoid arthritis, pneumonia, and preterm birth and low birth weight.(3) In the present era prevailing treatment modalities, such as scaling and polishing, root planning, and gingivoplasty, use of chemicals, that is, mouth wash, irrigation and so on are expensive as well as time consuming. Therefore, prevention and the control of plaque and gingivitis which is the precursor of periodontitis are essential in every case.

Unani system of medicine is a great healing art as well as science.(4) The World Health Organization (WHO) has recognized the Unani System of Medicine (USM) as an alternative system to cater the health care needs of human population. Unani healing is vibrant and vigorous today and is being practiced, taught and researched under its local names in over 20 countries including Afghanistan, China, India, Canada, Denmark, Germany, Finland, Netherlands, Norway, Poland, Korea, Japan, Saudi Arabia, Sweden, Switzerland, Turkey, UK and USA [5]. India has accepted it as one of the alternative health care system and has given it official status.(6)

Many Unani physicians advocate use of herbal formulations in their Usool-e-Ilaj (Unani principles for treatment) for the prevention and management of dental health. However, since most of the drugs which have been described in Unani materia medica and are widely used by the physicians of Unani medicine in the treatment of dental diseases

have still not been studied scientifically for their claimed effects.(6) With the intention to advance the knowledge on this issue as well as close the research gap, this study was conducted to evaluate the efficacy of Unani toothpowder *Pyorin* [22] in alleviating gingivitis, controlling dental plaque, and inhibiting extrinsic stains. The tooth powder is well available and has been described in Unani Medical literature having good effects in cases of Taqayyuh e Lissa (Pyorrhoea), Lissa Damiya (Gingivitis), Bahrul Fam (Ozostomia/Halitosis), Waj ul Dahan (Odontalgia/Toothache), Mutayyib e Dahan (Fragrant/Mouth freshner), Daf e Taqayyo he Lissa (Anti septic for gums), Habis ud Dam (Haemostatic/ Styptic), and Anti Pyorrhoea [22].

### MATERIAL AND METHODS

#### Trial design

This study was a single-blind, parallel arm 6-month randomized clinical trial (RCT) with blinding of the participants. It was conducted at the two outreach centre of Dept of Periodontology and Community Dentistry (urban health training centre and rural health training centre), and Jarahat (Surgery) OPD, Ajmal Khan Tibbiya College Hospital, Aligarh Muslim University, Aligarh. The test drug is already the part of National Formulary of Unani Medicine Part VI; Published by the Department of AYUSH, Ministry of Health & Family Welfare, Government of India, in 2011 and has been in use since decades. Informed consent was obtained from all participants by voluntarily signing a witnessed agreement after receiving verbal and written information about the study.

#### Study population

Based on previous studies on toothpaste a sample of 35 was required in each group to detect 30% reduction in bleeding on probing with 85% power. To compensate for the dropouts the sample size was increased to 100. 30-40yrs old subjects were recruited for the study including both the genders. Participants were selected from patients attending outreach centre of Dept of Periodontology and Community Dentistry (urban health training centre and ru-

ral health training centre), Aligarh Muslim University Aligarh, Aligarh after an oral and periodontal examination.

#### Inclusion criteria

1. Patients having a minimum of 20 natural teeth with generalized chronic gingivitis with over 30% sites with bleeding
2. Patients willingness to cooperate with the study protocol and attend all visits and agreeing to sign the consent form

#### Exclusion criteria

1. Patients having any systemic diseases, that affect the integrity of periodontium or oral mucosa, any other chronic diseases that have an effect on periodontal disease i.e., diabetes mellitus, hypertension, hematological disorders etc.
2. Patients using any systemic drugs
3. Pregnant woman
4. Smokers or tobacco users
5. Presence of gross oral pathology
6. Need for antibiotic prophylaxis before the dental examination, or history of antibiotic use within the past three months.
7. Patient with periodontitis or history of treatment for periodontitis within the past twelve months,
8. Having any fixed/removable appliance (including permanent orthodontic retainers)

#### Examination

All examinations were carried out by a single examiner, standardised with an experienced clinician and calibrated for intra-examiner variability (Kappa 0.85). After screening and consent, eligible subjects received mechanical periodontal therapy (oral Prophylaxis). Subjects were then randomized to Test group and Control group at a 1:1 ratio using the random sampling technique by lottery method to maintain the uniformity in both groups.

**Test group** – Unani toothpowder Payorin

**Control group** – Fluoridated tooth paste

All participants received an adult-sized, soft-bristled toothbrush, and were instructed to brush their teeth for 2-3 minute two times a day, using the Bass technique, and to refrain from any other oral hygiene procedures, including mouthwashes, throughout the duration of the study. They were also instructed to use the assigned dentifrice for 6 months.

#### Primary Outcome Measures:

Gingivitis - Gingival Index (Löe and Silness, 1963) modified by Talbott et al. (1977) was used for the assessment of the gingival condition and record qualitative changes in the gingiva (7,8). Its scores (0 to 3) recorded the marginal and interproximal tissues separately. The criteria are: 0= normal gingiva, 1= mild inflammation - slight change in color and slight edema but no bleeding on probing, 2= moderate inflammation - redness, edema and glazing, bleeding on probing and 3= severe inflammation - marked redness and edema, ulceration with a tendency to spontaneous bleeding.

#### Secondary Outcome Measures:

##### Plaque

Quigley-Hein (Tuersky) Index was used for assessing plaque deposits (9,10). This index is based on the visual checking of non-restored surface of all the teeth except third molars; this is done on a scale from score 0 to score 5. An index for the entire mouth is determined by divid-

ing the total score by the number surfaces examined. The criteria for scoring are: 0 = no plaque, 1 = separate flecks of plaque, 2 = continuous band of 1 mm, 3 = >1mm and <1/3 of tooth surface, 4 = >1/3 and <2/3 and 5 = >2/3 of tooth covered with plaque.

#### External tooth stains

Lobene index (11) based on the intensity and area of stains covered on the labial surfaces of the anterior teeth was used. Buccal surfaces of teeth are divided into two gingival crescent and body. In this index intensity and area measured on gingival crescent and body separately and also in combination by multiplying intensity and area. An index for the entire mouth is determined by dividing the total score by the number surfaces examined.

Each parameter was recorded at baseline, 4, 8, 12 and 24 weeks.

#### Statistical analysis

Data analysis was carried out using SPSS 16 software. ANOVA (analysis of variance) test was carried out to observe the comparative effect of therapies on various parameters at different time intervals. Student t Test was carried out to find out the difference between test and control group.

#### RESULTS

Ninety two patients (test n=45, placebo n=47) completed the 24-week trial. Mean age of the participants in Group 1 was 34.1±2.3 years and Group 2 it was 33.9±3.8 years. There were more female patients in both the test and control, 32 (64%) and 28 (56%) respectively. Maximum, 74.04% of the female patients were house wives. Majority of patients (i.e. 61.32% belonged to rural area, 44.91% were educated up to secondary education level. Majority of the patients i.e., 63.9% were found to have moderate gingivitis and 35.57% were reported chronicity between 6 to 12 months. A maximum of 76.83% patients brushed their teeth once daily to keep the oral cavity clean.

There was no statistically significant difference between the two groups in relation to plaque index, gingival index and Lobene index at baseline. Plaque index, gingival index and Lobene index showed a linear decrease from baseline to 24 weeks (table 2). However there was no significant difference between the parameters measured in the two groups at 24 months. None of the patients showed any adverse effects with either of the products.

**Table 1 demographic data**

parameters	Toothpowder (45)	Toothpaste(47)
age	34.1±2.3 years	33.9±3.8 years
Sex(M:F)	18:32	22:28
Plaque index	1.41±0.24	1.32±0.38
Gingival index	1.07±0.41	1.12±0.39
Stain index	3.18± 0.4	3.25±.17

**Table 2: Effect of tooth powder and tooth paste on various dental parameters at baseline, 4, 8, 12 and 24 weeks**

parameters	toothpowder					toothpastes				
	baseline	4 weeks	8 weeks	12 weeks	24 weeks	baseline	4 weeks	8 weeks	12 weeks	24weeks

Stain index	Gingival index	Plaque index
3.18± 0.4	1.07±0.41	1.41±0.24
2.45±0.12	.89± 0.37	1.36±0.20
1.91±0.9	.72±0.18	1.19±0.16
1.67±0.5	.64±0.24	.98±0.74
1.42±0.3	.53±0.11	.71±0.81
3.25±.17	1.12±0.39	1.32±0.38
2.93±0.12	.92± 0.27	1.28±0.20
2.31±0.9	.85±0.28	1.14±0.16
1.97±0.5	.71±0.31	.92±0.74
1.58±0.3	.60±0.21	.80±0.21

\*P<0.05 statistically significant

## DISCUSSIONS

Periodontal diseases are prevalent in populations around the world (12). The focus of any attempt to prevent and control periodontal disease is the maintenance of an effective level of plaque control by the individual at home.(13) The use of dentifrices such as toothpowder and toothpaste and its underestimation is impossible owing to their role in assuring dental health. Previous researches seeking to assess the efficacy of dentifrice on plaque-induced gingivitis are existent in literature. Despite their limitations in numbers and less specific focus on toothpowders other than focusing on dentifrices holistically, they show affirmative results regarding the issue in question. In essence, published articles on the efficacy of toothpowder in reducing plaque-induced gingivitis are not identifiable despite the problems being predominant in contemporary societies. (14) Agrawal and Ray (2012) accentuate to these sentiments highlighting a need for intensive research if the present scenario is bound to change for the better. (15)

Lately there has been growing interest in natural products especially in dentistry. Even though the studies in animal and in vitro may show the beneficial properties of several of these products, there is no other way of knowing their real clinical benefit without conducting a randomized clinical trial (16-18). Therefore this randomized clinical trial was undertaken to find out efficacy of unani toothpowder in the management of chronic generalized gingivitis in comparison to toothpaste.

Unani toothpowder Payorin [22] in 50 gram packs comprising the fine powder of Amla Khushk Sokhta (*Embllica officinalis*) burnt 12 gm, Sang e Jarahat (Hydrated Magnesium Silicate or Soap Stone) 35 gram, Taj Qalmi (Cinnamomum Cassia) 01 gram, Hamiz e Fehmi (Carbolic Acid) 0.1 ml, Roghan e Asfedar (Eucalyptus Oil) 0.5 ml, Kafoor Khalis (Cinnamomum Camphora) 500 mg.

*Embllica Officinalis* (Amla) used as protective as well as therapeutic edicine n various diseases in Ayurvedic /Unani medicine. Amla is known to slows down ageing process (Vayasthapana), good for eyes (Chakshushya), anti-diabetic (Pramehaghna), cures anemia (Panduhara), cures bleeding from body orifices (Raktapittaghna), aphrodisiac (Vrsya). Amla Contains Vitamin C (L- ascorbic acid), gallic acid, ellagic acid, phyllemblic acid, emblicol. Alkaloides ie., phyllantidine, phyllantine. Pectin and minerals [23]

Sang e Jarahat (Magnesium Silicate)is Unani Medicine for its Habis dam (Haemostatic or haemostyptic) effects[24]

Taj Qalmi (*Cinnamomum Cassia*) is known for its Medicinal properties in Unani and Ayurveda. It is aromatic, anodyne, antiseptic, antirheumatic (branches / twigs); circulatory, digestive and metabolic stimulant (bark); diaphoretic (Spanish / Ceylon, branches / twigs), stomachic, carminative and tonic [25], [26]

The main active principles in Cinnamon are to be found in its essential oil; being slightly astringent, tannins are also present in the bark. The essential oil consists mainly of Cinnamic aldehyde, cinnamaldehyde, cinnamyl acetate, eugenol and phellandrene. Coumarins have also been discovered in Cinnamon [25], [26]

Carbolic Acid, is an organic compound with aromatic properties having the molecular formula  $C_6H_5OH$ . It is also used as an oral anesthetic/analgesic in medicinal products. The antiseptic properties of phenol were used by Sir Joseph Lister (1827–1912) in his pioneering technique of antiseptic surgery [27].

Eucalyptus Oil has been found effective in reducing Dental plaque in some people [28]. Eucalyptus oil is rich in cineole, an antiseptic that kills the bacteria that can cause bad breath. Some antiseptic mouthwashes use eucalyptus along with other oils, and have been shown to help prevent plaque and gingivitis [29].

It has long been used as a medical substance in ancient India, where it generally goes by the name Karpūra. It has been described in the 7th-century Āyurvedic work Mādhavācikitsā as being an effective drug used for the treatment of fever. The plant has also been named Hima and has been identified with the plant *Cinnamomum camphora*. Camphor acts as slight local anesthetic and antimicrobial substance. Camphor was used in ancient Sumatra to treat sprains, swellings, and inflammation [30]

The clinical variables, plaque score, gingival bleeding on probing and staining were evaluated during the six-month study period. At all re-examinations the test group had reduced plaque score ( $P<0.05$ ), gingivitis score ( $P<0.05$ ) and stains score ( $P<0.05$ ). However these reductions were not statistically significant between groups. In other study conducted by Hosein et al it was found that toothpowder was significantly stronger dentifrice compared to toothpaste in plaque removal.(19)

Initial oral prophylaxis and the Hawthorn effect may have contributed partly to the general reduction of all clinical parameters in this clinical trial. However, the finding that the use of unani toothpowder resulted in statistically significantly greater reduction of all clinical parameters from baseline could be due to the antibacterial and anti-inflammatory properties of the ingredients used in the toothpowder.

Generally it is assumed that the toothpowders causes more abrasion than toothpastes and are likely to cause tooth wear, our results are in contrast because the relative dental abrasivity (RDA) of toothpowder used in this study was 150, which is in the normal range (20-21) (below 250 as recommended by ADA). Even the long time users of this tooth powder did not reported of abressions and were found with a healthy oral cavity.

## CONCLUSIONS

It is evident on literature analysis that gaps regarding the efficacy of toothpowder in eliminating plaque induce gingivitis exist and this study seeks to close these gaps and

add more knowledge in this field. Both the dentifrices (toothpowder and toothpaste) were able to reduce plaque, gingivitis and stain although no additional benefit of the toothpowder over the positive control toothpaste could be observed.

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