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Comparative Evaluation of the Effectiveness of 0.6% Triphala Mouthrinse and Listerine on Gingival Health of Patients Undergoing Fixed Orthodontic Therapy

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Abstract

Background: Ayurvedic drugs have been used since ancient times. Oral rinses having ayurvedic background are used in periodontal therapy for reducing inflammation and as an antimicrobial plaque agent. Triphala is one of the agent having wide spectrum of activity and extensively researched for its various therapeutic effects including its anticaries, antioxidants, anticollagenase and antimicrobial activities.

Aims and Objectives: The aim of the study was to assess the effect of 0.6% triphala mouth rinse as compared to listerine on the gingival health of patients undergoing fixed orthodontic therapy at an interval of 7 days, 14 days and 30 days.

Materials and Methods: The study was a randomized, single- blinded, controlled trial done on parallel groups with a total of 10 patients (n = 5 in each group). At the beginning of the study, patients were divided into two groups of 5, which will either receive cool mint listerine or triphala mouthwash for 15 days. modified gingival index, plaque index, gingival enlargement index and oral hygiene index-simplified were recorded to evaluate the scores at baseline, 7 days, 14 days and 30 days.

Results: The intergroup comparison of all the clinical parameters between two study groups were found to be statistically non-significant. Only the intergroup comparison of mean reduction in plaque index scores were found to be statistically significant, with a greater mean reduction in the triphala group as compared to the listerine group ($p < 0.05$). The intragroup comparison of all the clinical parameters at different time intervals was found to be statistically significant for both listerine and triphala group ($p < 0.05$).

Conclusion: It was concluded that orthodontic treatment might deteriorate gingival health and hence application of mouthwash with scaling and root planning is useful in maintenance of oral health. A household remedy like triphala enhances oral and general health needs require more exploration.

Keywords: *Triphala; Listerine; Essential Oil Mouth Rinse; Orthodontic Treatment; Herbal Mouth Rinse*

Introduction

In humans, dental biofilm accumulates on the daily basis. The basic research during the last century has clearly established the role of the dental plaque at the interface of the tooth and gingiva as the main cause of gingival inflammation which could lead eventually to periodontitis.

Gingivitis, the commonest of all periodontal diseases is the inflammation of gingiva characterised by host-tissue inflammation due to bacterial plaque accumulation. It may be characterized by the presence any of the following clinical signs: redness and oedema of the gingival tissue, bleeding upon provocation, changes in the contour and consistency, presence of calculus and/or plaque and no radiographic evidence of crestal bone loss [1]. The conventional methods of controlling periodontal disease involves the mechanical removal of plaque biofilm and calculus. Maintaining an effective plaque control is the cornerstone of any attempt to prevent and control periodontal disease. However, the quality of self-performed mechanical plaque control is not sufficiently effective in most individuals and needs an improvement [2].

Practicing a satisfactory oral hygiene is one of the major challenge for orthodontic patients. Failure to maintain oral hygiene by the orthodontic patients may lead to inflammatory diseases such as gingivitis and periodontitis. Regarding the assessment of oral hygiene practices is an essential step to understand the patient's oral health care needs [3]. However, Hadler-Oslen., *et al*. found that it was very difficult to practice a satisfactory oral hygiene regimen in orthodontic patients [4].

Formation of dental plaque around the fixed orthodontic appliances: orthodontic bands, brackets and wires is very difficult to clean around the teeth. Orthodontic patients during the treatment period are prone to develop generalised gingivitis, dental caries, periodontal disease, oral malodour and staining of the teeth [5]. Griffiths and Addy suggested that more plaque accumulation is seen around maligned anterior teeth than aligned teeth. Orthodontic patients as well as dental professionals play an active role in controlling plaque build-up by maintaining the oral hygiene through various aids [6].

Chemotherapeutic and antimicrobial agents are commonly used as an adjunct to mechanical hygiene measures to facilitate the control of supragingival plaque and gingivitis and its use has been known for decades. Mouth rinses represent one form of attack on oral microbes and malodour. The advent of chemotherapy, antiseptics and antimicrobial compounds eventually paved way for a variety of chemical formulations which possessed anti-plaque activity. Mouth rinses have been introduced as an effective method for reducing dental plaque accumulation and dental practitioners usually prescribe various chemical agents such as chlorhexidine listerine, etc. to orthodontic patients [7,8].

Essential oils (EO) containing mouth rinse is an organic natural compound that has been widely prescribed to the orthodontic patients [9,10]. Listerine (Pfizer Consumer Healthcare, Morris Plains, NJ) is an over-the-counter mouthwash containing two phenol related essential oils, thymol 0.064% and eucalyptol 0.092%, mixed with methanol 0.042% and methyl salicylate 0.060% in a 22% hydroalcoholic vehicle [11]. Essential oils have proved to be effective at controlling inflammation and supragingival biofilm. They have the ability to alter the cell surface of specific micro-organisms and eliminate their enzymatic activity [12]. They can also inhibit the endotoxins of gram-negative pathogens. Phenolic compounds also show anti-inflammatory actions and inhibit prostaglandin synthesis, act as a scavenger of oxygen free radicals, thus affecting the leucocytic activity. The long-term use of EO was shown to be safe without any undesirable shift in the supragingival microbial composition [13]. Similar to chlorhexidine mouthwash, listerine mouthwash also have certain side effects such as alteration in the taste, oral ulceration and burning sensation reported by the patient and usually patients avoid using this mouthwash.

Nowadays, majority of population are choosing natural herbal products for the prevention or treatment of diseases. Ayurvedic medicinal plants are used in various treatment because of no or minimal side effects. Various ayurvedic formulations are available in the

literature but triphala is a well-known powdered preparation recommended by Indian System of Medicine (ISM), being used in Ayurveda since ancient times. Triphala consists of mixture of equal parts of Indian gooseberry Amalaki (*Emblica officinalis*), Bibhitaki (*Terminalia beleria*), and Haritaki (*Terminalia chebula*). Triphala has a wide spectrum of activity. The 20th Shloka of Sushruta Samhita states that Triphala can be utilized as a gargling agent in dental diseases because of its anti-microbial, antiseptic and anti-inflammatory properties. It also exhibits antioxidant and a strong anti-collagenase activity against the polymorphonuclear leukocytes type collagenase, especially MMP-9 which is involved in the extracellular matrix degradation during periodontitis [14]. Triphala is available in various formulations such as triphala tablet and triphala churna. Various studies available in the literature suggested that triphala mouth rinse when combined with SRP showed a significant reduction in various clinical parameters without any evidence of tooth staining [15]. Therefore, triphala seems to fulfil all the ideal requirements without any adverse effects on the oral tissues at a very minimal cost as compared to the commercially available products.

Purpose of the Study

The purpose of this study is to assess the effect of triphala mouth rinse as compared to listerine on the gingival health of patients undergoing fixed orthodontic therapy at an interval of 7 days, 14 days and 30 days.

Materials and Methodology

Study population: For the pilot study, a total of 10 patients were selected from the Outpatient Department of Orthodontics, National Dental College and Hospital, Derabassi, Punjab. The study was conducted in the Department of Periodontology and Oral Implantology, National Dental College and Hospital, Derabassi, Punjab.

An ethical approval for the study was obtained from the Institutional Ethical Board Committee at National Dental College and Hospital, Derabassi, Punjab with an Ethical Clearance no. NDCH/0002/042. Each patient was given a detailed verbal and written description of the study and all the selected patients were required to sign an informed consent form prior to commencement of the study.

Study design: It was a single parallel design randomized clinical trial conducted on 10 patients. They were randomly divided into two groups by block randomization:

- **Group 1:** Active arm- 0.6% triphala mouth rinse (20 ml twice daily for 15 days).
- **Group 2:** Reference arm- Essential oil mouth rinse (Listerine 20 ml twice daily for 15 days).

Inclusion criteria:

(i) Age: 18 - 30 years

(ii) Minimum of 20 teeth

(iii) Patient undergoing (straight wire) fixed orthodontic therapy with initial teeth alignment completed

(iv) Good general health- Absence of any systemic illness

(v) Gingival enlargement- Grade 1 or 2 (Bokenkamp)

(vi) Gingival index above 2 (Modified Gingival Index) by Lobene.

Exclusion criteria:

(i) Known hypersensitivity to the mouth rinses under study

(ii) Active periodontitis

(iii) Hard and soft tissue tumours

(iv) Oral red and white lesions

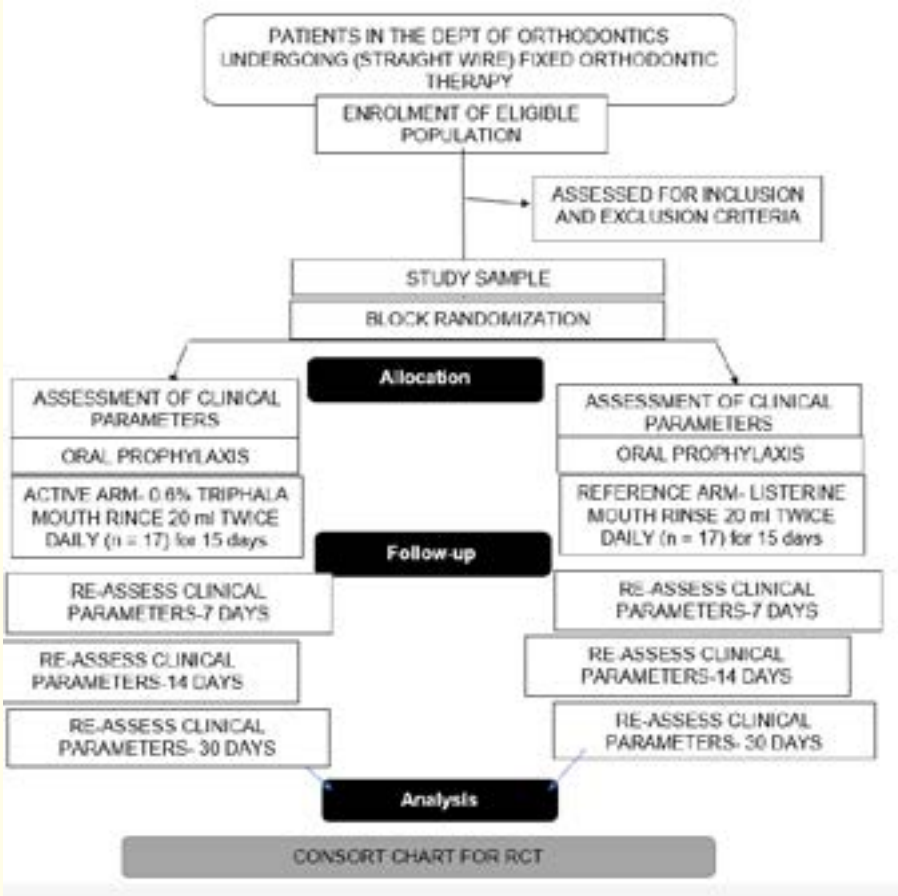
(v) Antibiotic therapy in past 30 days

(vi) Use of mouthwash in last 3 months

(vii) Medications with an effect on oral tissues

(viii) Habits-smoking, tobacco or pan chewing.

Study design flow chart



Assessment of clinical parameters

Clinical parameters such as modified gingival index (MGI), plaque index (William's modification of Silness and Loe plaque index), gingival enlargement index and oral hygiene index-simplified (OHI-S) were recorded at baseline, 7 days, 14 days and 30 days. All the measurements were recorded using a UNC 15 (University of North Carolina) periodontal probe at baseline, 7 days, 14 days and 30 days. Measurements were recorded to the nearest millimetre.

Preparation of 0.6% triphala mouthwash

Triphala is accessible as churna, a finely sieved powder. Churna has a shelf life of 6 months. The aqueous triphala mouth rinse (0.6%) was prepared indigenously in collaboration with Divya Pharmacy, Patanjali Ayurved Limited, India:

- 6 gm of triphala churna dissolved in 1000 ml of water brought to a boil and filtered.
- Triphala has a flavour of a raw fruit. To mask this flavour and improve patients' compliance, 2 ml of glycerine (sweetening agent) and 1 ml of pudin hara, a commercially available mint extract, was added.
- The solution was cooled and 100 ml was measured and dispensed in amber coloured opaque bottles.

Study procedure

A total of 10 patients in the age group of 18 - 30 years undergoing fixed orthodontic therapy with initial teeth alignment completed were selected in the study. Only those patients with gingival enlargement (Grad1 or 2) and gingival index (score above 2) were included in the study and the rest were excluded. The patients were divided into two groups by block randomization:

- **Group 1:** Active Arm- 0.6% triphala mouth rinse (20 ml twice daily for 15 days)
- **Group 2:** Reference arm- Essential oil mouth rinse (Listerine 20 ml twice daily for 15 days).

Each participant received an initial prophylaxis by the same dental operator after the baseline assessment. Patients were instructed on how to brush and how to use the mouthwash. 20 ml of the assigned mouthwash for 30 seconds twice a day for 15 days were given. Patients were provided with orthodontic tooth brush and toothpaste (Colgate- strong teeth) for standardizing oral hygiene practice. They were also abstained from using interdental cleaning aids like inter dental brush and dental floss. All clinical parameters were recorded at baseline 7 days, 14 days and 30 days, by the same blinded examiner. Group 1 received 0.6% Triphala mouth rinse (60g of Triphala churna dissolved in water and distilled) and Group 2 received cool Mint Listerine (Pfizer Consumer Healthcare, Morris Plains, NJ), the essential oil- containing mouth rinse.

Patients were asked to report the issues associated with the use of prescribed mouth rinse.

Results

Statistical analysis

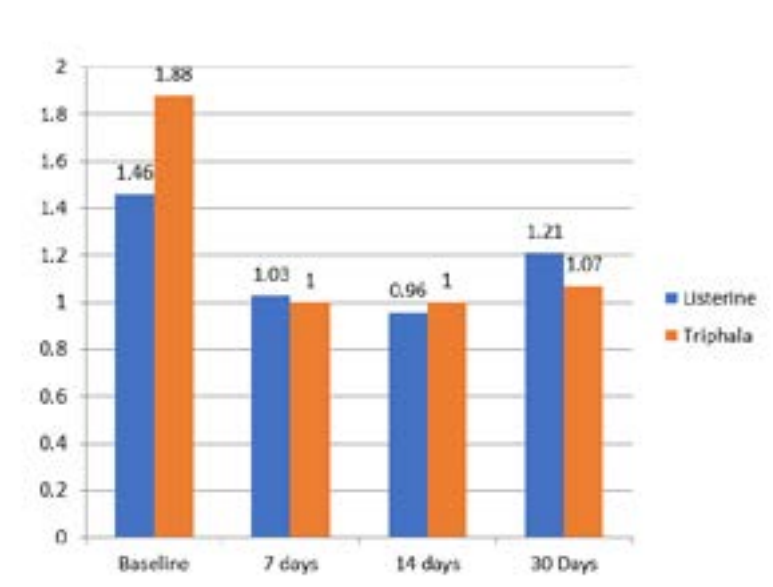
The data for the present study was entered in the Microsoft Excel 2007 and analysed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation. The intragroup comparison for the different time intervals was done using repeated measures ANOVA to find the difference between the individual time intervals. The level of the significance for the present study was fixed at 5%.

The intergroup comparison for the difference of mean scores between two independent groups was done using the unpaired/independent t test.

Table 1 showed inter group comparison of all the clinical parameters between 2 study groups. The gingival index scores at the baseline in the group 1 (Listerine) was 2.14 ± 0.27, at the 7^{th} day was 1.09 ± 0.18, at 14^{th} day was 0.60 ± 0.34 and 0.48 ± 0.13 at 30^{th} day. In group 2 (Triphala) the mean score was 1.90 ± 0.59 at the baseline, 0.82 ± 0.24 at 7^{th} day, 0.37 ± 0.12 at 14^{th} day and 0.43 ± 0.25 at 30^{th} day. The intergroup comparison of mean reduction in the gingival index scores from the baseline at 7^{th} day, 14^{th} day and 30^{th} was found to be statistically non-significant between the listerine and triphala group.

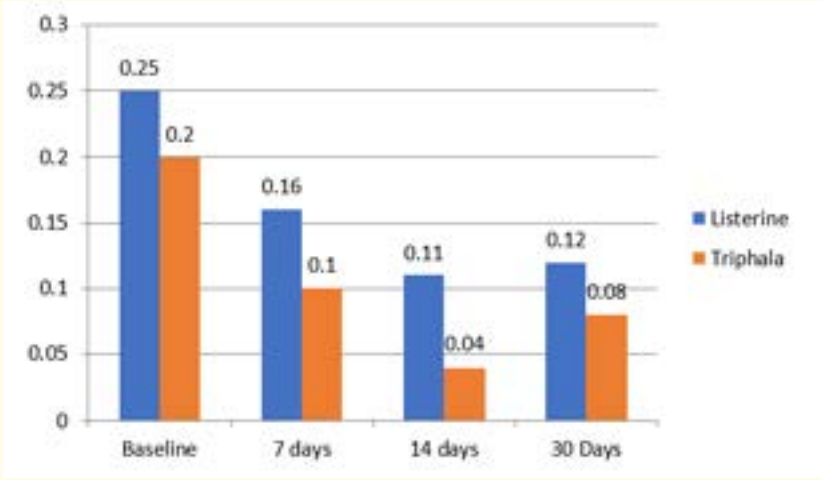
Clinical Parameters	Group 1 (Listerine)				Group 2 (Triphala)				P value
	Baseline	7 days	14 days	30 days	Baseline	7 days	14 days	30 days	30th day
Modified Gingival Index	2.14 ± 0.27	1.09 ± 0.18	0.60 ± 0.34	0.48 ± 0.13	1.90 ± 0.59	0.82 ± 0.24	0.37 ± 0.12	0.43 ± 0.25	0.644 (NS)
Plaque Index	1.46 ± 0.05	1.03 ± 0.13	0.96 ± 0.15	1.21 ± 0.18	1.88 ± 0.17	1.00 ± 0.01	1.00 ± 0.01	1.07 ± 0.08	0.001 (S)
Gingival Enlargement Index	0.25 ± 0.03	0.16 ± 0.06	0.11 ± 0.05	0.12 ± 0.05	0.20 ± 0.02	0.10 ± 0.03	0.04 ± 0.01	0.08 ± 0.02	0.644 (NS)
OHI-S	2.86 ± 0.15	1.24 ± 0.35	0.80 ± 0.32	2.50 ± 0.56	3.36 ± 0.33	1.48 ± 0.26	1.08 ± 0.30	1.48 ± 0.44	0.001 (S)

Table 1: *Intergroup comparison of all the clinical parameters between group 1 and group 2. Independent t test at p value less than 0.05 is significant.*



Graph 1: *Intergroup comparison of plaque index between group 1 (Listerine) and group 2 (Triphala).*

Mean plaque index scores at the baseline in the group 1 (Listerine) was 1.46 ± 0.05, at the 7th day was 1.03 ± 0.13, at 14th day was 0.96 ± 0.15 and 1.21 ± 0.18 at 30th day. In group 2 (Triphala), the mean score was 1.88 ± 0.17 at the baseline, 1.00 ± 0.01 at 7th day, 1.00 ± 0.01 at 14th day and 1.07 ± 0.08 at 30th day. The intergroup comparison of mean reduction in the plaque index scores from the baseline at 7th day, 14th day and 30th was found to be statistically significant between the listerine and triphala group with mean reduction more in the triphala group as compared to listerine group.



Graph 2: Intergroup comparison of gingival enlargement between groups.

Mean gingival enlargement score at the baseline in the group 1 (Listerine) was 0.25 ± 0.03, at the 7th day was 0.16 ± 0.06, at 14th day was 0.11 ± 0.05 and 0.12 ± 0.05 at 30th day. In group 2 (Triphala), the mean score was 0.20 ± 0.02 at the baseline, 0.10 ± 0.03 at 7th day, 0.04 ± 0.01 at 14th day and 0.08 ± 0.02at 30th day The intergroup comparison of mean reduction in the gingival enlargements from the baseline at 7th day, 14th day and 30th was found to be statistically non-significant between the listerine and triphala group.

The OHI-S score at the baseline in the group 1 (Listerine) was 2.86 ± 0.15, at the 7th day was 1.24 ± 0.35, at 14th day was 0.80 ± 0.32 and 2.50 ± 0.56 at 30th day. In group 2 (Triphala), the mean score was 3.36 ± 0.33 at the baseline, 1.48 ± 0.26 at 7th day, 1.08 ± 0.30 at 14th day and 1.48 ± 0.44 at 30th day The intergroup comparison of mean reduction in the OHI-S scores from the baseline at 7th day, 14th day was found to be statistically non-significant between the listerine and triphala group but was statistically significant at 30th day.

Table 2 showed intra group comparison of all the clinical parameters at different time intervals between 2 study groups. The gingival index scores at the baseline in the group 1 (Listerine) was 2.14 ± 0.27, at the 7th day was 1.09 ± 0.18, at 14th day was 0.60 ± 0.34 and 0.48 ± 0.13 at 30th day. In group 2 (Triphala), the mean score was 1.90 ± 0.59 at the baseline, 0.82 ± 0.24 at 7th day, 0.37 ± 0.12 at 14th day and 0.43 ± 0.25 at 30th day The intra-group comparison between the different time intervals was found to be statistically significant in both listerine and triphala group ($p < 0.05$).

The plaque index scores at the baseline in the group 1 (Listerine) was 1.46 ± 0.05, at the 7th day was 1.03 ± 0.13, at 14th day was 0.96 ± 0.15 and 1.21 ± 0.18 at 30th day. In group 2 (Triphala), the mean score was 1.88 ± 0.17 at the baseline, 1.00 ± 0.01 at 7th day, 1.00 ± 0.01 at 14th day and 1.07 ± 0.08 at 30th day The intra-group comparison between the different time intervals was found to be statistically significant for both listerine and triphala group ($p < 0.05$).

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Clinical Parameters	Group 1 (Listerine)				P value	Group 2 (Triphala)				P value
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Plaque Index	1.46 ± 0.05	1.03 ± 0.13	0.96 ± 0.15	1.21 ± 0.18	0.001 (S)	1.88 ± 0.17	1.00 ± 0.01	1.00 ± 0.01	1.07 ± 0.08	0.001 (S)
Gingival Enlarge-ment Index	0.25 ± 0.03	0.16 ± 0.06	0.11 ± 0.05	0.12 ± 0.05	0.001 (S)	0.20 ± 0.02	0.10 ± 0.03	0.04 ± 0.01	0.08 ± 0.02	0.001 (S)
OHI-S	2.86 ± 0.15	1.24 ± 0.35	0.80 ± 0.32	2.50 ± 0.56	0.001 (S)	3.36 ± 0.33	1.48 ± 0.26	1.08 ± 0.30	1.48 ± 0.44	0.001 (S)

Table 2: *Intragroup comparison of all the clinical parameters between group 1 and group 2 at different time intervals. Repeated measures ANOVA at p value less than 0.05 is significant.*

The OHI-S score at the baseline in the group 1 (Listerine) was 2.86 ± 0.15, at the 7th day was 1.24 ± 0.35, at 14th day was 0.80 ± 0.32 and 2.50 ± 0.56 at 30th day. In group 2 (Triphala), the mean score was 3.36 ± 0.33 at the baseline, 1.48 ± 0.26 at 7th day, 1.08 ± 0.30 at 14th day and 1.48 ± 0.44 at 30th day The intra-group comparison between the different time intervals was found to be statistically significant for both listerine and triphala group ($p < 0.05$).

Discussion

Plaque accumulation and subsequent gingivitis is common in orthodontic patients due to the challenge of controlling oral hygiene with the combination of brackets, bands, wires and elastomeric ligatures present. Poor oral hygiene can eventually lead to the formation of white spot lesions, decay and hyperplastic gingival tissues that may require interventions by a general dentist upon the completion of orthodontic treatment. There is a considerable clinical trial evidence to show that oral hygiene status is significantly improved when therapeutic mouth rinses are added into the daily oral hygiene regimen as compared to tooth brushing.

The aim of the present study was to compare the efficacy of essential oil mouth rinses (Listerine) with 0.6% triphala mouth rinse in preventing plaque formation and reducing gingival inflammation in patients with fixed orthodontic therapy. The changes in gingival inflammation were assessed using conventional clinical indices such as gingival index, plaque index, gingival enlargement index, oral hygiene index-simplified at baseline, 7th day, 14th day and 30th day. The results were in agreement with the previous studies that demonstrate the effectiveness of herbal mouth rinse, Triphala, in controlling plaque accumulation and gingivitis in numerous clinical trials who have fixed orthodontic appliances.

The use of essential oils is well documented in the literature and they have also been proven effective in reducing gingivitis in orthodontic patients as well as in the general population. Gunsolley., *et al*. carried out a systematic review which concluded that use of essential Oil mouth rinses provides improved oral hygiene and reduces plaque and gingivitis [9,16]. Additionally, Tufekci., *et al*. [9] showed that use of Listerine, and essential oil mouth rinse, reduces the amount of plaque and gingivitis in orthodontic patients. Listerine is one of the most frequently recommended mouth rinse for the patients undergoing fixed orthodontic treatment. The concentration of mouth rinse was comparable to those obtained with Chlorhexidine mouth rinse. Listerine, unlike chlorhexidine, did not discolour teeth and it is mostly suitable for the long-term use. Listerine contains 21 - 26% alcohol v/w. Although listerine meets the consensus requirements

for an effective antigingivitis or antiplaque product, but because of presence of alcohol, it may lead to epithelial detachment, keratosis, mucosal ulceration and oral discomfort.

Triphala is one of the most common formulations used as a traditional ayurvedic medication. Triphala is like a tonic in the ancient literature of ayurvedic medicine, with a potential to regulate the process of digestive system and excretory system [17]. It has been used to treat diseases and chronic conditions since ancient times. Triphala can be used for dental and oral diseases as mentioned in sushruta samhita. Triphala has broad antimicrobial and antifungal activity due to the triple constituents such as haritaki fruit, amalaki fruit and bibhitaki fruit [15].

Triphala mouth rinse when combined with scaling and root planning showed significant reduction in plaque, gingival and oral hygiene indices without any evidence of staining of teeth at 7^{th}, 30^{th} and 45^{th} day which was comparable to reduction obtained by chlorhexidine mouth rinse in combination with scaling and root planning. Triphala mouthwash in a one mouth study showed improvement in clinical indices in terms of reduction in tooth mobility, pocket depth, bleeding gums, sensitivity to hot and cold and calculus formation with minimal recurrences in all the clinical parameters [18].

The inter-group assessment of both the groups were comparable for modified gingival index, gingival enlargement index and OHI-S. There was no statistically significant difference was found in both the groups. Only plaque index show more mean reduction in triphala (0.80 ± 0.02) even at 30^{th} day as compared to the listerine group. In light of the aforementioned findings, it was possible to infer that both listerine and 0.6% triphala were equally effective in reducing gingival inflammation and plaque management in patients receiving fixed orthodontic therapy, possibly enhancing gingival health. Furthermore, 0.6% triphala extract showed a statistically significant reduction in plaque and OHI-s score ($p < 0.05$) when compared to baseline parameters. However, additional scientific research comparing the gingival-improving effects of listerine and 0.6% triphala mouthwash is required.

Similar findings were observed by Bajaj., *et al*. (2011) [17] which states that 0.6% Triphala mouth rinse was effective in reducing gingival inflammation. The outcomes of a clinical experiment conducted by Pardeep., *et al*. (2016) [19] indicate that the improvement in gingival health in patients using Triphala was comparable to Chlorhexidine, suggesting that Triphala could be considered as a possible therapeutic agent for the treatment of gingivitis.

The results obtained in the current study to allocate the properties of antimicrobial and antiplaque activity of triphala as also found by Jagdish., *et al*. in 2009 studied the effect of triphala on dental biofilm. Biradar in 2008, chemically analysed triphala and reported that tannic acid, chebulic acid and flavonoids as its major constituents [20]. The presence of tannins in triphala during the initial stages of plaque formation could effectively decrease the number of anaerobic microflora which binds to the tooth surface and increases their physical removal from the oral activity through aggregate formation. Kaikuchi., *et al*. in 1986 reported that galloyl radical of the tannins was important for inhibition of glucan activity and antiplaque activity of tannins [21].

Maulana H., *et al*. in 2014 [22] did an experiment on animals in which the expression of MMP 9 and the number of fibroblasts were altered by the orthodontic stresses applied to diabetic rats. The expression of MMP 9 increased concurrently with the rise in orthodontic forces on both the tension and pressure sides. No clinical trials are known to exist. Abraham S., *et al*. (2005) [23] did a study to determine the inhibitory effect of Triphala on PMN-type matrix metalloproteinase (MMP-9) expression in adult patients with periodontitis. The study concluded that MMP-9 levels decreased significantly.

In interpreting the findings of the present study, it's important to outline the certain limitations. As it contains no additives or preservatives, triphala has an uncertain shelf life. Therefore, new batches are issued each time to the patient which was administered at a different time interval of the study. Triphala was distributed in amber coloured bottles. Also, patients who used listerine mouth rinse reported back

with complaint of burning sensation and slight gingival enlargement. However, no patient reported with the incidence of tooth staining.

Conclusion

Triphala has been mentioned in the ancient Ayurvedic literature as a measure to prevent and cure numerous oral and systemic diseases. Triphala has the ability to treat the oral diseases without any adverse effects and is also available at minimal cost than commercially available products in the market. It was concluded that orthodontic treatment might deteriorate gingival health, mouthwash application might improve gingival health and hence it is useful in oral health control methods for orthodontic patients. Therefore, a therapeutic effect of both of the commercial brands were assessed and confirmed.

A household remedy like triphala which saves both time and money and enhances oral and general health needs much more exploration. Extensive studies with large samples varying samples, varying time period and long term follow up time should be carried out to establish the efficacy of triphala therapy in prevention of plaque induced gingivitis.

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