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## RESEARCH ARTICLE

# LOCAL DELIVERY OF TRIPHALA IN A GEL FORM AS AN ADJUNCT TO SCALING AND ROOT PLANING (SRP) IN THE TREATMENT OF CHRONIC PERIODONTITIS: A RANDOMIZED CONTROLLED CLINICAL TRIAL

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### ABSTRACT

To evaluate the adjunctive effect of Triphala gel with scaling and root planing in the treatment of chronic periodontitis.

#### Materials and Methods:

Subjects diagnosed with localized or generalized chronic periodontitis with pocket depth  $\geq 4$ mm were selected for study. Two non-adjacent sites in different quadrants of the mouth were randomly divided into control sites and experimental sites. 30 control sites were treated by SRP alone, and 30 experimental sites were treated with SRP followed by placement of 6% Triphala Gel in the periodontal pocket.

Following parameters will be recorded at baseline and after 30 days:

- Plaque index (Turesky- Gilmore- Glikman modification of Quigley Hein plaque index)
- Gingival index.
- Sulcus bleeding index
- Pocket probing depth
- Clinical attachment level.
- Trypsin-like activity of "red complex" microorganisms by BAPNA assay

**Results:** The test group exhibited a significantly lower mean score for the recorded parameters as compared to the control group. The difference between two groups was statistically significant.

**Conclusion:** The experimental local drug-delivery system containing 6% triphala can be effectively used as an adjunct to scaling and root planing and is more effective than scaling and root planing alone in the treatment of periodontal pockets.

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## INTRODUCTION

Periodontitis is a multifactorial disease, with primary etiologic factor being the pathogenic bacteria that reside in the sub gingival area. The periodontal therapy aims towards prevention and control or elimination of periodontitis and to restore the lost form and function. Routine basis of periodontal treatment is mechanical debridement of the tooth and root surface and adequate maintenance of oral hygiene. However, it is difficult to accomplish comprehensive mechanical debridement at sites with deep periodontal pockets (Cobb, 1996). Mechanical debridement may, in some cases be inefficient to eliminate the pathogenic microflora because of their location deep within the gingival and dental tissues. Systemic or local administration of antibiotics is done as adjuncts to mechanical debridement, because of the microbial etiology of periodontitis. Systemic antibiotic therapy may cause, bacterial resistance, hypersensitivity reaction, organ

toxicity because of its requirement of higher dosage to attain required GCF concentration at the target site. This led to evolution of local drug-delivery system (Greenstein, 2006). Many local delivery agents are used till date such as chlorhexidine, tetracyclines, doxycycline, metronidazole and minocycline. However, these agents are relatively expensive. Ayurvedic drugs have been used to treat periodontal diseases since ancient time (Abraham, 2005; Champaklal Pranalal Boghani, 2004). TRP is a traditionally used ayurvedic medicine that is a mixture fruits obtained from medicinal trees: 1) Amalaki (*Emblia officinalis*); 2) Bibhitaki (*Terminalia belerica*); and 3) Haritaki (*T. chebula*) (Abraham, 2005). It is said to have antibacterial, antiseptic and anti-inflammatory properties (Nariya, 2009; Sireeratawong *et al.*, 2012). According to the 20<sup>th</sup> slokha of Sushruta Samhita (an ancient Sanskrit text on medicine and surgery), triphala (TRP) can be used as a gargling agent in dental diseases (Sabina, 2008).

This study was therefore planned to evaluate triphala, as a component of local drug-delivery system.

## MATERIALS AND METHOD

**Materials:** St. John Institute of Pharmacy & Research, Palghar, Maharashtra, India; provided 6% triphala gel. The gel composed of triphala extract, 6%; pluronic polymer, 20%; and water.

### Methods

**Clinical evaluation:** Thirty subjects, from the outpatient department of Periodontology, Yogita Dental College and Hospital, Khed, Ratnagiri diagnosed with localized or generalized chronic periodontitis with pocket depth  $\geq 4$ mm were selected in a split-mouth study design. Subjects presented with pockets in at least 2 nonadjacent sites in different quadrants of the mouth and with at least 20 remaining teeth.

**Study protocol:** Relevant data was recorded in a specially designed proforma. Clinical examination was done in a dental chair, under standard conditions of light, using a mouth mirror, explorer and UNC 15 graduated periodontal probe. Selected sites were randomly divided into control sites and test sites, which were treated by using split-mouth design. Thirty control sites were treated by scaling and root planing alone, and 30 test sites were treated with scaling and root planing followed by placement of the test material (6% triphala gel) in the periodontal pocket. All the participants were explained about the need, design of the study and its potential benefits and written informed consent was obtained. The study protocol was approved by the Ethics Committee of the institution.

### Triphala Gel



### Local Delivery of triphala gel



**Evaluation of clinical parameters:** The following clinical parameters were recorded at baseline and after 30 days:

- Plaque index (Turesky-Gilmore-Glickman modification of the Quigley-Hein, 1970) (Turesky *et al.*, 1970);
- Gingival index (Loe and Silness, 1963) (Loe, 1963);
- Sulcus bleeding index (Muhlemann and Son, 1971) (Muhlemann, 1971);
- Pocket depth measurement using UNC 15 probe (Clark, 1987);
- Clinical attachment level (Clark, 1987);

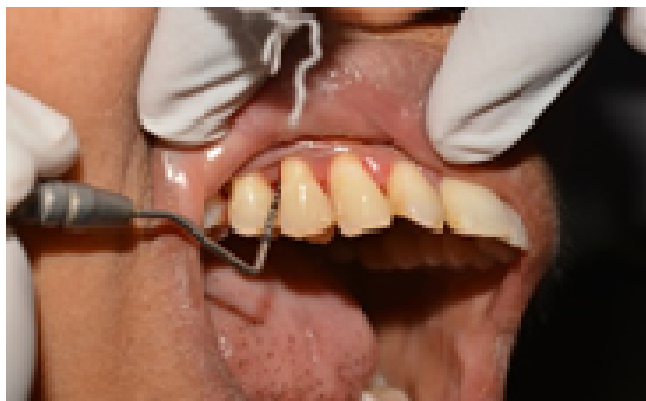
**Microbiological analysis:** Microbiological analysis was done by collecting plaque samples for trypsin-like activity of “red complex” microorganisms by BAPNA assay (Syed, 1984) at baseline and after 30 days. Subgingival plaque samples were collected by a sterile Gracey curette after removing supragingival debris. The samples were transferred to a coded micro centrifuge tube containing Tris HCl buffer (pH, 6.8) and stored at a temperature of  $-80^{\circ}\text{C}$ . 1 mL of a solution containing (N-benzoyl-L-arginine-p- itroanilide, BAPNA; Sigma, St. Louis, Missouri, USA) was then added to the tubes. This suspension was vortexed and then placed on ice in an ultrasound bath for 10 minutes with 2-second cycles and 2-second intervals at 17 W. Samples were incubated at  $37^{\circ}\text{C}$  for 17 hours. The reaction was stopped by the addition of 100 mL of glacial acetic acid. The absorbance was read at 405 nm by a spectrophotometer. The results were given in nanomoles of the product per minute per milligram of dental plaque wet weight (Del Peloso Ribeiro *et al.*, 2007).

**Treatment protocol:** The clinical and microbiological parameters for selected sites were evaluated at the baseline and thorough scaling and root planing (SRP) was done. Thereafter, the test sites were isolated with cotton rolls to prevent contamination from saliva. The test material was in liquid form (under refrigeration) and was carried in a syringe with a canula attached to it. Test material was introduced into the pockets at test sites. With increasing temperature as in oral cavity, gel formation occurred. The pocket opening was covered with Coe-Pak to prevent the material from flushing out of the pocket, Subjects were recalled after 7 days for removal of the periodontal dressing and after 30 days for evaluating the clinical and microbiological parameters.

**Statistical analysis:** Post-intervention changes in various clinical parameters from baseline occurring at different time intervals were evaluated by paired *t* test (intra-group). Inter-group comparisons of post-intervention changes were evaluated by unpaired *t* test.  $P < 0.05$  was considered as significant difference (Epi Info version 6.0).

## RESULTS

Out of 60 sites in 30 patients, thirty sites received triphala gel as a local drug (test sites) following scaling and root planing, and 30 sites received only scaling and root planing. After 30 days of observation, all the sites healed uneventfully. No allergic reaction was encountered. In the present study, statistically significant reduction in all the recorded clinical parameters was observed in both the groups after 30 days [Fig. 1 and 2]. Significant reduction in the trypsin-like enzyme activity of “red complex” microorganisms (BAPNA values) was observed for both the groups when compared to the baseline activity [Fig 3].



Reduction in Pocket depth

However, greater reduction was observed in the experimental sites in comparison with the control sites.

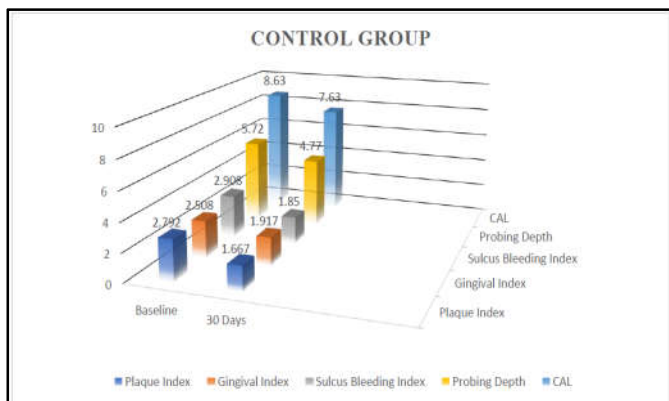


Figure 1.

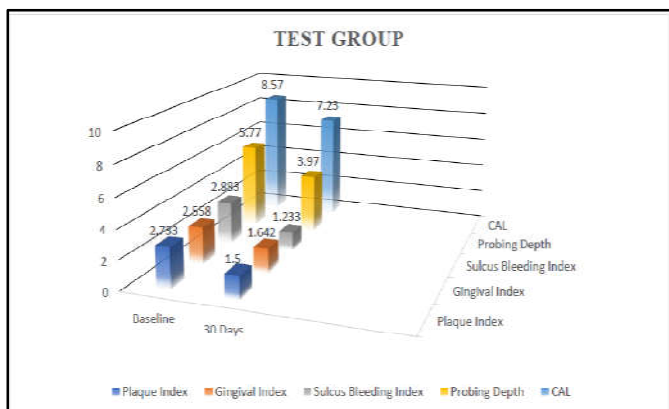


Figure 2.

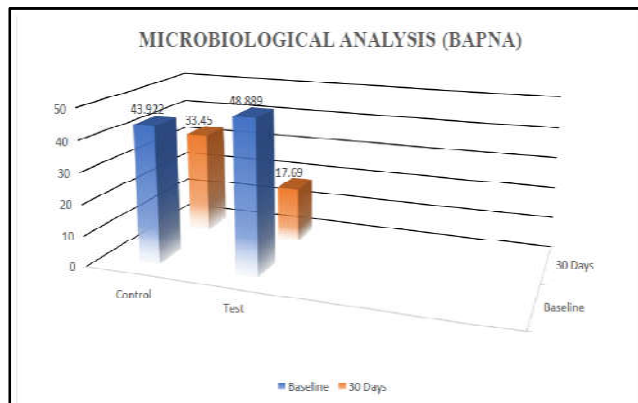


Figure 3.

DISCUSSION

Local delivery of antimicrobial agent to periodontal pockets provides additional benefits in PD reduction and clinical attachment level (CAL) gain when combined with SRP, compared to SRP alone.<sup>14</sup> Abundant locally delivered antimicrobial agents are available commercially. However, the need for safe, effective, and economical agents has motivated the use of various natural extracts. Various herbal products and their extracts such as green tea, cranberry, grapeseed, pomegranate, neem, propolis, tulsi, etc. in the form of mouthwashes and gels have shown significant advantages over the chemical ones in the treatment of periodontal diseases (Kukreja, 2012; Desai, 2010; Reddy, 2010). Adriana *et al.* found that the use of 1% chlorhexidine gel as an adjunct to SRP led to reductions in mean plaque index, gingival index, sulcus bleeding index, probing pocket depth; and gain in clinical attachment level (Vinholis, 2001). The local drug-delivery system containing 2% whole turmeric gel has been effectively used as an adjunct to scaling and root planing and is found to be more effective than scaling and root planing alone in the treatment of periodontal pockets (Behal, 2011). TRP mouthwash was found to decrease inflammatory parameters and, lead to improvement in gingivitis. Results were comparable to those of CHX mouthwash, which has been used as the gold standard in treatment of gingivitis and periodontitis (Pradeep *et al.*, 2016). In the present study, triphala was used in gel form. AR Pradeep used triphala in the form of a mouthwash (Pradeep *et al.*, 2016).

To the best of our knowledge, no studies on triphala (in a gel form) as a local drug-delivery system and its microbiological evaluation by BAPNA (quantitative) assay have been reported in literature. Chainani S. *et al.* concluded that triphala extract demonstrated antimicrobial property against Lactobacilli and C. albicans with maximum zone of inhibition of 22 mm at 6% and 20 mm at 9% (Chainani, 2015). Sheta M. conducted a study to identify the antimicrobial effect of triphala and its individual components against common bacterial components. He concluded that triphala and its individual components have significant antibacterial activity (Sheta *et al.*, 2016). The reduction in BAPNA values in our study could be attributed to antibacterial activity of triphala. The experimental material was found to be acceptable in terms of taste and comfort, by all the subjects in our study. It is evident from the results of the present study that local delivery of triphala along with scaling and root planing is effective in eradicating the local irritants, reducing gingival inflammation, reducing pocket depth and also results in gain in clinical attachment.

The local drug-delivery system used in the present study is simple and easy to use. Its suitability for use with a syringe allows easy insertion into the periodontal pocket. Also, better retention is achieved because of its bioadhesive property. It is also biologically accepted without any side effects.

## CONCLUSION

Within the limitations of the study it can be concluded that 6% triphala gel can be effectively used for local drug delivery as an adjunct to scaling and root planing. It is found to be effective than scaling and root planing alone in the treatment of periodontal pockets. 6% triphala gel, when used as an adjunct to scaling and root planing, promotes pocket depth reduction and leads to gain in clinical attachment. It is a beneficial antimicrobial, anti-inflammatory and anti-septic agent. It has also shown considerable reduction of trypsin-like enzyme activity of microorganisms associated with periodontal disease. The experimental material was biologically well accepted by the subjects included in the study, without any side effect.

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