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Comparative evaluation of efficacy of three different mouthwashes as an adjunct to nonsurgical periodontal therapy - A double blind clinical study

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ABSTRACT

Ayurvedic medicine was considered to be world's oldest medical system, which was originated in India dating back over thousands of years. There was a long history regarding plants for the improvement of dental health and oral hygiene. Dentistry, Herbal Medicine, Periodontitis. Current researches showed that herbal extracts are effective because of the interaction with specific chemical receptors within the body. Nowadays, there has been a sudden increase in the use of herbal extracts or plant products as an alternative approach to modern day medicines. This system originated from Atharvaveda, one of the four Vedas written before 5000 B.C. However its use in dentistry/oral health is very limited. Therefore the present study was done to evaluate the effeicacy of Triphala and Bakul in comparison with chlorhexidine as an adjunct to non surgical periodontal therapy.

Key words: Ayurveda, Oral Health, Triphala, Bakul, Chlorhexidine.

INTRODUCTION

Periodontal diseases in their various manifestations have afflicted mankind since the beginning of time. Several types of accretions occurring on the teeth are related to periodontal disease in one way or the other. Among these dental plaque has posed a real challenge. A major breakthrough was achieved in the field of Periodontology regarding the etiopathogenesis of periodontal disease when Harold Loe and colleagues in 1965 demonstrated the direct relationship between plague levels and the development of human gingivitis.^[1] Since bacterial

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plaque is the principal etiological agent in gingival and periodontal diseases, thus the most rational approach to the prevention of periodontal diseases would be regular and effective removal of plaque by personal hygiene measures. Mechanical methods oral (brushing) have proved to be very time consuming and their effectiveness would depend on the skill and technique of the individual carrying out these procedures.^[2] The fact that most people experience difficulty in maintaining adequate levels of plaque control, particularly at interproximal sites necessitates the chemical control of plaque as means of augmenting mechanical oral hygiene procedures. Several anti-plaque agents are being available in the market. However, due to several undesirable side effects associated with these agents^{[3],[4]} stimulated the search for alternative agents, in recent years, there has been focus on plants or plant products used in Unani, Homeopathic or Ayurvedic remedies.

Therefore the present study was done to evaluate the effeicacy of Triphala and Bakul in comparison with chlorhexidine as an adjunct to non surgical periodontal therapy.

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MATERIALS AND METHODS

Clinical Study

A total of 90 patients attending the OPD of Department of Periodontology, meeting the inclusion and exclusion criteria were selected for the study. And study was conducted as a double blind.

Patient Selection Criteria

Inclusion Criteria

- 1. Patients with chronic periodontitis.
- 2. Healthy patients in the age range of 25 to 60 years of age.
- 3. At least 25 erupted teeth in the mouth

Exclusion Criteria

- 1. History of any systemic illness.
- 2. History of taking any antibiotic/anti-inflammatory in the last three months prior to the study.
- 3. History of usage of any kind of mouthwash during the last three months prior to and during the study.
- Presence of any orthodontic/prosthetic appliances, improper restorations, poorly fitting crowns.
- 5. Presence of any deleterious habit like smoking, tobacco use.
- 6. Patients with mouth breathing.
- 7. Pregnant women.

After selection, their co-operation in the execution of the trial was taken and the patients were also informed about the nature of *Chlorhexidine, Triphala, Bakul* and their possible side effects. Total time duration of study was 12 weeks. On first day relevant data was recorded on the proforma designed for the study. After recording the preliminary examination, subjects were examined in a dental chair under standard conditions of light, using probe, mirror, tweezer, explorer and UNC15 probe for measurement of pocket depth. The patient were then assessed for their gingival index, oral hygiene index, plaque index, papillary bleeding index, probing pocket depth and clinical attachment loss of a single tooth with deepest pocket.

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After recording the above data for each patient on the day of examination, The patients were divided into three groups :

Group I : Triphala (TRI - 30 patients)

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Group II : Bakul (BAK-30 patients)

Group III : Chlorhexidine (CHX -30 patients)

Blinding was done by using following method

Measurement of all the powder and liquid preparation was made and packed in a opaque coloured bottles, at the same time all the three group bottles were kept in separate groups at different locations. After every three patients coin was tossed to arrange the proper sequence of mouth washes. During first toss if we decided to consider any two mouth washes i.e. *Triphala* and Chlorhexidine, in the next toss we considered *Bakul* and Chlorhexidine, or *Triphala* and *Bakul* vice-versa.

All the patients were asked not to change their brushing techniques and also patients were not demonstrated any brushing technique throughout the study.

Complete scaling and root planning was done in two sections within the 24 hours with the help of ultrasonic, hand scaling instruments and curettes to achieve full mouth disinfection. Patients were then prescribed with medicines for 14 days from the day of examination and asked to follow the written instructions given over the printed paper about how to prepare and use the mouthwash.^[11]

Preparation method for Triphala

One part of standardized *Triphala* powder contains {*Terminalia Chebula* (*Haritaki*), *Terminalia Belerica* (*Vibhitaki*), *Emblica Officinalis* (*Amla*)} with sixteen parts of water and mixture will be boiled until 1/4th of the solution remains.^[9] Patients were asked to rinse at least two minutes thrice a day for fourteen days. Then patients were given with the instructions about the follow up visits on 2, 4, 6, 8 and 12 week basis.

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RESULTS AND DISCUSSION

Periodontal disease arises from the interaction of pathogenic bacteria with a susceptible host. The main aims of disease management have been to establish a high standard of oral hygiene and to professionally and thoroughly debride the root surface. Chemical agents could be considered for both aspects of management. Chemoprevention using supragingivally delivered agents such as chlorhexidine may be questioned for value in the pre-treatment hygiene phase but have well-established efficacy immediately preoperatively and during the postoperative weeks. Long-term maintenance with the use of chlorhexidine is problematic due to local side effects such as staining, altered taste sensation, mucosal reactions and enhanced supragingival plaque formation. And therefore the search for more suitable antimicrobial continues. In recent years due to renewed interest in alternative medicine such as Ayurveda and other herbal, a lot of data regarding some of the potential agents is slowly emerging and appears promising. Herbal plant extracts have been shown to have inhibitory effect on the oral pathogenic bacteria.^[5] Due to certain of their properties Triphala and Bakul may have potential periodontal application.

Triphala

Triphala is among the most common formulas used in Traditional Ayurvedic Medicine. Composed of the fruits of three trees, Indian gooseberry *Amalaki* (*Embilica officinalis*), *Bibhitaki* (*Terminalia beleria*), and *Haritaki* (*Terminalia chebula*), *Triphala* is mentioned throughout the ancient literature of *Ayurvedic* medicine as a tonic, highly prized for its ability to regulate the process of digestion and elimination. Study done by Maurya *et al.*^[7] supports the use of *Triphala* for the cure of periodontal diseases. Certain shortcomings of this study were paucity of knowledge, short time interval, small sample size, no well-defined criteria for assessing periodontal disease, and no measurement of plaque and caries scores.

Jagtap and Karkera^[6] tested the efficacy of Triphala mouthwash in the inhibition of Streptococcus counts.

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However, this research lacked enough studies to support results. Thus, the effects of *Triphala* mouthwash on the gingival and periodontal health status have to be assessed. In this context, a study was undertaken to ascertain the effects of a mouthwash prepared with *Triphala* on the oral health status and compare it with commercially available *Chlorhexidine* mouthwash.

Bakul

Bakul is also one of the most commonly used drugs in avurveda. Prabhat A, Navneet, Avnish C^[5] has done the in-vitro study to evaluate the antimicrobial activity of six medicinal plants against dental pathogens. In their study it has been already proved that *Bakul* is having antimicrobial effect over Staphylococcus Streptococcus mutans, aureus, Streptococcus Lactobacillus sanquis, salivarius, Streptococcus acidophilus and Candida albicans.^[5] However, this research lacked clinical studies to support results.

Thus the available literature supports the potential periodontal application of both of these agents. However the clinical studies to support this evidence are lacking.

Therefore the present study was conducted to compare and evaluate the clinical effectiveness of *Triphala* and *Bakul* as an adjunct to non surgical periodontal therapy in the treatment of chronic periodontitis while comparing it with the gold standard chlorhexidine.

After selection of the patient complete case history was taken and following parameters were recorded; Oral hygiene index, Gingival index, Plaque index, Papillary bleeding index, Probing pocket depth and Clinical attachment level, After obtaining the baseline parameters and informed consent, complete scaling and root planning was performed in a two sections in 24 hours to achieve full mouth disinfection as recent studies have shown somewhat beneficial effects of full mouth disinfection.^[11] After completion of scaling and root planning patients were prescribed and provided with unlabeled bottles of randomly assigned mouthwashes for 14 days and oral & written,

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instructions were given regarding its use. Patient were also asked to report adverse effects if any.

Table 1: Within group comparison of variousperiodontal parameters studied (Group I only).

Follow- up	OHI-S	GI	PI	PBI	PD	CAL
On Exam	3.36 ± 0.57	1.63 ± 0.34	2.06 ± 0.39	1.49 ± 0.31	4.40 ± 0.62	3.27 ± 0.77
2-wks	0.78 ± 0.22	0.47 ± 0.29	0.69 ± 0.32	0.39 ± 0.27		
4-wks	0.77 ± 0.25	0.58 ± 0.22	1.03 ± 0.31	0.48 ± 0.25		
6-wks					4.08 ± 0.67	3.12 ± 0.70
8-wks	1.40 ± 0.30	0.62 ± 0.18	0.91 ± 0.27	0.50 ± 0.16		
12-wks	1.67 ± 0.47	0.60 ± 0.18	0.88 ± 0.20	0.52 ± 0.17	3.95 ± 0.67	3.00 ± 0.70
P - values	1	-	-		-	
On Exam v/s 2- wks	0.001	0.001	0.001	0.001		
On Exam v/s 4- wks	0.001	0.001	0.001	0.001		
On Exam v/s 6- wks					0.001	0.001
On Exam v/s 8- wks	0.001	0.001	0.001	0.001		
On Exam v/s 12- wks	0.001	0.001	0.001	0.001	0.003	0.001

Table	2:	The	within	group	comparison	of	various
period	lon	tal pa	iramete	rs stud	ied (Group II	only	y).

Follow- up	OHI-S	GI	PI	PBI	PD	CAL
On Exam	2.91 ± 0.72	1.66 ± 0.26	1.94 ± 0.27	1.73 ± 0.44	5.05 ± 0.81	3.73 ± 0.90
2-wks	0.88 ± 0.45	0.49 ± 0.13	0.92 ± 0.22	0.42 ± 0.24		
4-wks	1.11 ± 0.43	0.60 ± 0.29	1.02 ± 0.27	0.48 ± 0.28		
6-wks					4.84 ± 0.79	3.63 ± 0.94
8-wks	1.46 ± 0.37	0.67 ± 0.16	1.07 ± 0.33	0.55 ± 0.15		
12-wks	1.53 ± 0.39	0.71 ± 0.17	1.24 ± 0.34	0.57 ± 0.09	4.73 ± 0.89	3.40 ± 1.11
P - values	·					
On Exam v/s 2- wks	0.001	0.001	0.001	0.001		
On Exam v/s 4- wks	0.001	0.001	0.001	0.001		
On Exam v/s 6- wks					0.001	0.001
On Exam v/s 8- wks	0.001	0.001	0.001	0.001		
On Exam v/s 12- wks	0.001	0.001	0.001	0.001	0.035	0.007

Table	3:	The	within	group	comparison	of	various
perioc	lon	tal pa	aramete	rs stud	ied (Group III	on	ly).

Follow- up	OHI-S	GI	PI	PBI	PD	CAL
On Exam	3.23 ± 0.64	1.72 ± 0.35	1.98 ± 0.41	1.62 ± 0.46	4.65 ± 0.73	3.43 ± 0.76
2-wks	0.84 ± 0.42	0.48 ± 0.28	0.84 ± 0.41	0.39 ± 0.28		

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4-wks	0.90 ± 0.53	0.59 ± 0.27	0.99 ± 0.36	0.46 ± 0.26		
6-wks					4.37 ± 0.71	3.22 ± 0.75
8-wks	1.39 ± 0.32	0.64 ± 0.20	1.02 ± 0.35	0.50 ± 0.19		
12-wks	1.51 ± 0.41	0.66 ± 0.19	1.06 ± 0.30	0.54 ± 0.18	4.29 ± 0.72	3.14 ± 0.76
P - values						
On Exam v/s 2-wks	0.001	0.001	0.001	0.001		
On Exam v/s 4-wks	0.001	0.001	0.001	0.001		
On Exam v/s 6-wks					0.001	0.001
On Exam v/s 8-wks	0.001	0.001	0.001	0.001		
On Exam v/s 12- wks	0.001	0.001	0.001	0.001	0.001	0.001

Values are mean ± Standard deviation. P-values are obtained using paired 't' test. P-value < 0.05 is considered to be statistically significant.

Table 4: The between group comparison of relative percentage change at 2-wks follow-up in various periodontal parameters studied.

Parameter	Grou	Grou	Grou	P-values			
S	p I n=30	p i p ii p iii n=30 n=30 n=30		Grou p I v/s Grou p II	Grou p I v/s Grou p III	Grou p II v/s Grou p III	
OHI-S	75.9 ± 8.3	68.9 ± 15.2	73.4 ± 14.3	0.090	0.723	0.366	
GI	70.4 ± 18.2	70.2 ± 9.2	70.9 ± 16.8	0.998	0.988	0.976	
PI	64.9 ± 20.0	52.5 ± 11.0	56.4 ± 22.2	0.029	0.178	0.695	
РВІ	71.9 ± 20.3	75.4 ± 15.1	74.8 ± 18.6	0.743	0.820	0.990	

Table 5: The between group comparison of relative percentage change at 4-wks follow-up in various periodontal parameters studied.

Parameter	Grou	Grou	Grou	P-values			
s	p I n=30	p II p III n=30 n=30		Grou p I v/s Grou p II	Grou p I v/s Grou p III	Grou p II v/s Grou p III	
OHI-S	76.3 ± 9.9	61.6 ± 11.8	70.9 ± 18.9	0.001	0.307	0.034	
GI	63.2 ± 13.6	63.9 ± 17.3	64.9 ± 15.7	0.981	0.911	0.972	
Ы	48.1 ± 17.8	45.8 ± 16.6	48.2 ± 20.4	0.872	0.999	0.868	
РВІ	66.7 ± 17.0	73.4 ± 13.8	71.3 ± 15.2	0.212	0.485	0.850	

 Table 6: The between group comparison of relative
percentage change at 6-weeks follow-up in various periodontal parameters studied.

Parameter Grou G		Grou	Grou	P-values			
S	p I n=30	p II n=30	p III n=30	Grou p l v/s Grou pll	Grou p l v/s Grou p lll	Grou p II v/s Grou p III	
PD	7.3 ± 5.1	4.1 ± 3.2	5.9 ± 4.3	0.135	0.704	0.495	
CAL	5.5 ± 3.2	2.8 ± 1.2	6.1 ± 3.4	0.395	0.954	0.252	

Table 7: The between group comparison of relative percentage change at 8-weeks follow-up in various periodontal parameters studied.

Parameter	arameter Grou Grou Grou		Grou	P-values			
S	p I n=30	p II n=30	p III n=30	Grou p l v/s Grou pll	Grou p l v/s Grou p lll	Grou p II v/s Grou p III	
OHI-S	57.9 ± 8.9	48.2 ± 11.7	55.9 ± 10.9	0.002	0.764	0.016	
GI	60.7 ± 11.6	59.2 ± 11.0	62.0 ± 11.9	0.877	0.889	0.611	

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Ы	54.5 ± 14.1	42.7 ± 22.6	47.0 ± 19.7	0.049	0.288	0.658
РВІ	65.0 ± 11.2	67.8 ± 6.1	67.9 ± 10.8	0.512	0.474	0.998

Table 8: The between group comparison of relativepercentage change at 12-weeks follow-up in variousperiodontal parameters studied.

Parameter s	Grou p I n=30	Grou p II n=30	Grou p III n=30	P-values		
				Grou p l v/s Grou pll	Grou p l v/s Grou p lll	Grou p II v/s Grou p III
OHI-S	49.3 ± 15.8	45.9 ± 12.8	52.6 ± 11.9	0.602	0.631	0.150
GI	61.9 ± 11.5	56.7 ± 11.8	60.9 ± 11.3	0.195	0.950	0.324
Ы	56.4 ± 10.8	33.5 ± 22.4	44.8 ± 18.3	0.001	0.036	0.043
РВІ	64.6 ± 11.3	65.1 ± 9.5	65.9 ± 10.1	0.981	0.870	0.946
PD	10.2 ± 7.9	6.6 ± 6.0	7.8 ± 4.5	0.076	0.314	0.739
CAL	9.3 ± 8.3	9.3 ± 7.8	8.5 ± 7.8	0.999	0.967	0.973

Values are mean ± Standard deviation of percentage change at 12-weeks follow-up with respect to on exam values. P-values are obtained using one-way analysis of variance (ANOVA) with Tukey's correction for multiple group comparisons,. P-value < 0.05 is considered to be statistically significant.

Table 9: The comparison of subjective criteria at 2weeks follow-up between three study groups.

Criteria	Group I TRI n=30	Group II BAK n=30	Group III CHX n=30	P-values			
				Group I v/s Group II	Group I v/s Group III	Group II v/s Group III	
Burning sensation							
Absent	24 (80.0)	30 (100.0)	22 (73.3)	0.010	0.542	0.002	

Present	6 (20.0)	0	8 (26.7)			
Alerted test sensation						
Absent	30 (100.0)	30 (100.0)	29 (96.7)		0.999	0.999
Present	0	0	1 (3.3)			

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Table 10: The comparison of objective criteria at 2-weeks follow-up between three study groups.

Criteria	Group I TRI n=30	Group II BAK n=30	Group III CHX n=30	P-values			
				Group I v/s Group II	Group I v/s Group III	Group II v/s Group III	
Staining of tooth							
Absent	30 (100.0)	30 (100.0)	30 (100.0)				
Present	0	0	0				
Staining of tongue							
Absent	30 (100.0)	30 (100.0)	30 (100.0)				
Present	0	0	0				
Allergy or ulceration							
Absent	30 (100.0)	30 (100.0)	30 (100.0)				
Present	0	0	0				

Values are n (% of cases). P-values are obtained using Chi-Square test. P-value < 0.05 is considered to be statistically significant.

In the present study it was found that oral hygiene status improved significantly in all groups as compared to baseline. Also it was observed that there was no significant difference in the oral hygiene status amongst all the groups during the entire study period. Thus the level of oral hygiene in all the study group were similar and showed significant trend towards improvement.

The gingival index did not differ significantly among the three groups during the entire study period. Thus it may be inferred that *Triphala* and *Bakul* have

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comparable effect on gingival inflammation as that of chlorhexidine.

The finding regarding the gingival status with the use of *Triphala* is consistent with those found by D.K Maurya *et al.* (1996), Desai A *et al.* (2010), Bajaj N & Tandon S (2011) and Ruchi Pandey (2012). The antibacterial, anti-inflammatory, analgesic, haemostatic, wound healing properties and presence of vitamin 'C' may have contributed to the therapeutic effect of *Triphala* observed in the present study.^{[7],[13],[9],[12]}

The plaque index did not differ significantly among the three groups during the entire study period. Thus it may be inferred that *Triphala* and *Bakul* have comparable effect on plaque accumulation as that of chlorhexidine.

The finding regarding the plaque status with the use of *Triphala* is consistent with those found by Desai A *et al.* (2010)^[14] and Bajaj N & Tandon S (2011).^{[13],[9]} The antibacterial properties of *Triphala*, may have contributed to the therapeutic effect of *Triphala* observed in the present study. Mehta B K *et al.* (1993) have proved antimicrobial efficacy of *Triphala*.^[10]

In the present study the gingival papillary bleeding improved significantly in all the three groups as compared to baseline. The gingival papillary bleeding did not differ significantly among the three groups during the entire study period. Thus it may be inferred that *Triphala* and *Bakul* have comparable effect on gingival papillary bleeding as that of chlorhexidine.

The finding regarding the gingival papillary bleeding with the use of *Triphala* is consistent with those found by D.K Maurya *et al.* (1996), The anti-inflammatory, haemostatic, wound healing properties and presence of vitamin 'C' may have contributed to the therapeutic effect of *Triphala* observed in the present study.^[7]

Three male and three female patients complains of burning sensation in 2 week follow up from Group I. Six female and two male patients complains of burning sensation in 2 week follow up from Group III. Patients from Group II were not having any complaint of burning sensation and altered taste sensation. While assessing the objective criteria, none of the patient from any of the three groups complained of staining of teeth or tongue and allergy/ulceration to any drug. Burning sensation with *Triphala* may be because of tannic acid, galic acid chebulic acid, chebulagic acid in its contents.^{[6],[7]}

CONCLUSION

Although all six week and twelve week findings are statistically significant when compared with baseline, but their clinical significance is open to question, because the use of periodontal probe presents many problems in terms of sensitivity and reproducibility of the measurement. Readings of clinical pocket depth obtained with the periodontal probe do not normally coincide with histologic pocket depth because the probe normally penetrates the coronal level of the junctional epithelium,^[14] and precise location of probe tip is depends on the degree of inflammation of the underlying connective tissue.^[15] The disparity between measurements also depends on the probing technique, probing force, size of the probe, angle of insertion of the probe, and precision of the probe calibration.^[16] All these variables contribute to the large standard deviation (0.5 - 1.3mm) in clinical probing results, which make detection of small changes difficult. The finding regarding the pocket probing depth with the use of Triphala and Bakul could not be corroborated with any such similar study as the detailed perusal of the available literature failed to show any such similar study. Therefore it is not possible to compare our findings related to improvement in pocket probing depth with any other authors.

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