

# A Short-Term Comparative Evaluation of Efficacy of Hydroalcoholic Herbal Phytonutrient Mouthrinse as An Adjunct with Scaling & Root Planning in Old Age Home Inmates with Chronic Periodontitis: A Randomized Control Clinical Trial

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## ABSTRACT:

**AIM:** The aim of this study is to compare & evaluate clinical efficacy of a herbal phytonutrient mouthrinse with Hedychium coronarium, Echinacea, Calendula-officinalis and Ocimum sanctum extracts in patients with gingivitis & chronic periodontitis in adjunct with scaling & root planning.

**MATERIAL & METHODS:** 30 subjects diagnosed with chronic periodontitis based on periodontal examination and microbiological evaluation, were selected from an Old Age Home. The study population was randomly divided into 3 groups of 10 subjects each: **Group I** - Phytonutrient herbal mouthrinse, **Group II** - 0.2% chlorhexidine gluconate and **Group III** –Distilled water.

**RESULTS:** ANOVA test showed significant difference in the mean values of FMPI, FMBI and PPD variables– PHT: (FMBI-P value- .005); (FMPI- P value- .002); (PPD- P value- <0.001), CHX: (FMBI- P value- .003); (FMPI- P value- .441); (PPD- P value- 0.049), DW: (FMBI-P value- .089); (FMPI- P value-.081); (PPD- P value- 0.104). There was statistically significant difference in the efficacy of PHT when compared with CHX and DW mouthrinse on plaque accumulation, gingival health and oral hygiene status.

**CONCLUSION:** Herbal phytonutrient rich-mouthrinse can prove to be effective alternatives to CHX with minimal side effects.

**KEYWORDS:** PHT- phytonutrient mouthrinse, CHX- chlorhexidine-0.2% gluconate mouthrinse and DW- distilled water mouthrinse.

## INTRODUCTION:

Periodontitis is a chronic inflammatory and destructive periodontal disease characterized by periodontals

pocket formation and bone adsorption. Its progression is caused by multifactorial interactions, including a susceptible host, the presence of periodontopathogens in subgingival plaque biofilm and the status of the local environment. Among these factors, periodontopathogens are considered to be the main initial etiological agents. A nonsurgical periodontal treatment that involves scaling and root planing to remove the components of the subgingival plaque biofilm is the basis of any periodontitis management plan.<sup>1</sup>

The traditional modality of nonsurgical therapy is to perform scaling and root planing. However, mechanical plaque control methods although routinely employed, have certain inherent limitations.<sup>2</sup>

Triphala, for instance is a mouth rinse composed of T. bellirica, T. chebula, and P. emblica which showed positive effects similar to that of 0.2% Chlorhexidine gluconate. Plant secondary metabolites including menthol from mint species and curcumin from turmeric also showed considerable therapeutic activity for the management of gingivitis-induced inflammation, bleeding, and plaque formation.<sup>3</sup>

Till date, there are numbers of evidence-based studies where often, Herbal medicines are preferred over chemical drugs due to their wider biological activities and higher safety but lower cost has compared which indicates herbs as sources of a variety of phytochemicals, many of which possess powerful antioxidant activities. But only few are there to be proven to be efficacious.

Thus, we formulated a clinical study and evaluated the efficacy of herbal phytonutrient mouthrinse with Hedychium coronarium, Echinacea, Calendula-officinalis and Ocimum sanctum extracts in patients with gingivitis & chronic periodontitis in three sub groups.

We employed clinical indices- FMBI, FMOI and PPD evaluate the effects herbal phytonutrient mouthrinse, which in near future may play potential role with remarkable antioxidant properties that might be used for the management of periodontal disease of systemic manifestation.

**AIM:** The aim of this study is to estimate clinically & microbiologically the: Efficacy of herbal phytonutrients mouthrinse: In patients with chronic periodontitis in adjunct with scaling & root planning.

### **OBJECTIVES:**

To estimate and compare clinically:

1. To assess clinically the reduced plaque formation.
2. To assess clinically the gingivitis.
3. To assess clinical periodontal pocket depth.

### **MATERIALS AND METHOD:**

The present study was randomized controlled trial with three parallel groups. \ Trial registry was done at Clinical Trials Registry India- ICMR: National Institute of Medical Statistics. Reference number was obtained-*CTRI/2022/05/042473 (Registered on: 11/05/2022 - Trial Registered Prospectively)*. The permission and NOC to conduct study was obtained from the site of study. The study was conducted at from old age home-Andagaon, Chhattisgarh, India for one month & in-vivo analysis was conducted by Department of Microbiology, Government V.Y.T. Autonomous Science College- Durg, Chhattisgarh for one week. The selected sites were randomly divided into three groups:

- 30 subjects were divided into three groups of 10 each (Groups I, II and III) each group was randomly assigned one mouthrinse by randomisation application.

**MASKING & ALLOCATION:**

- The random allocation sequence was generated employing random number method.
- The random allocation sequence was concealed from the main investigator until mouthrinse were assigned to the participants.
- The blinding and concealment were controlled by a third person (pharmacist) who distributed mouthwashes in brown plastic bottles of same size and colour coded differently following 10 in each group so as to maintain uniformity and identified as Group I, Group II and Group III.
- All the study subjects received the colour coded mouthrinse of same made to overcome the confounding bias.

**DURATION OF THE STUDY:** Patients were followed up for 30 days with clinical evaluation at baseline 15<sup>th</sup> day and 30<sup>th</sup> day, respectively.

**SELECTION CRITERIA****❖ Inclusive criteria:**

1. Patients in 60-89 years age range.
2. Mentally and systemically healthy.
3. Mentally disabled.
4. Handicapped & disability.
5. Diagnosis of severe (at least 2 interproximal sites with CAL  $\geq$  6 mm and 1 interproximal site with PD  $\geq$  5 mm) or moderate (at least 2 interproximal sites with CAL  $\geq$  4 mm or 2 interproximal sites with PD  $\geq$  5 mm) periodontitis.
6. Patients who had not received any type of periodontal therapy for the past 6 months.

**❖ Exclusion criteria:**

1. Patients with history of any systemic disease.
2. Patients allergic or sensitive to any drug.
3. Patients who had taken antibiotic therapy in past 3 months.
4. Patients who have undergone any form of periodontal therapy in past 6 months.
5. Patients on immunosuppressive therapy, steroid therapy.
6. Pregnant and lactating women.

**METHOD OF COLLECTION OF DATA:****Clinical parameters:**

1. Full Mouth Bleeding Score recording using Gingival Index (GI) by Silness J. & Loe H. (1963) at baseline & 15<sup>th</sup> day.
2. Full Mouth Plaque Score recording using Plaque Index (PI1) by Silness J. & Loe H. (1967) at baseline & 15<sup>th</sup> day.
3. No. of Pockets with Depth  $\geq$  5mm (No. of specific sites with PPD  $\geq$  5mm) at baseline, & 30<sup>th</sup> day.

**These three groups were then compared with questionnaire analysis & reminder software at baseline, 15<sup>th</sup> day & 30<sup>th</sup> day.**

**Materials to Be Used:**

- Conventional periodontal instruments used for diagnosis and treatment.

- UNC 15 probe
- Phytonutrients rich mouthrinse
- Chlorhexidine gluconate – 0.2%
- Distilled water.

**Direction of use of mouthrinse**

All the subjects received complete scaling & root planning to remove all plaque, stains and calculus at baseline. The colour coded mouthrinse was allocated in each group. The participants were instructed to withdraw the use of mouthwashes and report immediately if they experienced any side effects due to the use of mouthwashes.

**STATISTICAL ANALYSIS:**

All the data obtained after clinical and radiographic examination was compiled and subjected to statistical analysis was carried out using statistical software (Statistical Packages for Social Sciences) IBM SPSS Software version 22.0 for Windows. Descriptive statistics and statistical Test were applied.

**RESULTS:**

All patients were treated according to the clinical protocol. There were no postoperative complications. All included patients completed the study with two dropouts. The study population in PHT CHX and DW belong to mean age group of 67years,69-70years and 67 years respectively. The Gender distribution in PHT CHX and DW was almost equal.

**Table 1: Comparison of Full Mouth Bleeding and Plaque Index at baseline and at 15<sup>th</sup> day.**

Group	Index	At Baseline	At 15 <sup>th</sup> Day	MD ± SD	T	P value
		Mean ± SD	Mean ± SD			
PHT	FMBI	1.63± 0.59	1.02 ± 0.07	0.61± 0.53	3.631	0.005*
	FMPI	1.80± 0.57	1.01 ± 0.03	0.79± 0.57	4.432	0.002*
CHX	FMBI	1.78 ± 0.58	0.93 ± 0.12	0.49 ± 0.38	4.013	0.003*
	FMPI	1.64 ±0.79	1.42 ± 0.37	0.22 ±0.86	0.806	0.441
DW	FMBI	1.73± 0.43	1.53± 0.56	0.20± 0.33	1.906	0.089
	FMPI	1.714± 0.438	1.711±0.439	0.003± 0.005	1.964	0.081

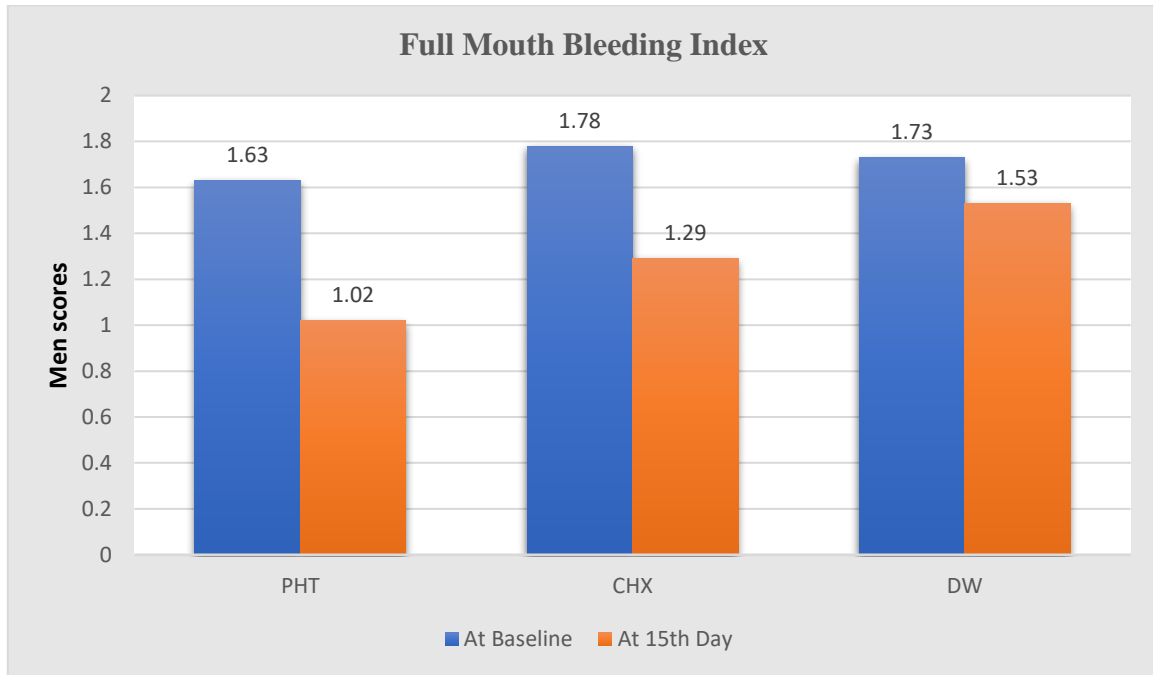
Paired sample t test, \* p value <0.05 statistically significant.

**Table 2: Inter group comparison of Full Mouth Bleeding Index at 15<sup>th</sup> day between three groups.**

Group	At 15 <sup>th</sup> day	P value	Post Hoc test	
	Mean ± SD		Compared Groups	p value
PHT	0.93 ± 0.12	0.003*	PHT vs CHX	0.043*
CHX	1.29 ± 0.30		PHT vs DW	0.001*
DW	1.53 ± 0.56		DW vs CHX	0.333

ANOVA followed by post hoc; \*p<0.05 significant.

The inter group and intra group comparison of FMBI at baseline to 15<sup>th</sup> day. The mean  $\pm$  SD values at baseline and 15<sup>th</sup> day were (1.63 $\pm$  0.59); (1.02  $\pm$  0.07) respectively for PHT, (1.78  $\pm$  0.58); (0.93  $\pm$  0.12) respectively for CHX and (1.73 $\pm$  0.43) and (1.53 $\pm$  0.56) respectively for DW. The values decreased in both groups from baseline to 15<sup>th</sup> day in PHT group. The ANOVA followed by post hoc found highly significant differences on intragroup comparison from baseline to 15<sup>th</sup> day, in PHT group. However, the inter group comparison at different interval of time period reveals significant differences with PHT. (t=3.631; p<0.005\*); (t=4.013; p<0.003\*) and (t=1.906; p<0.089).



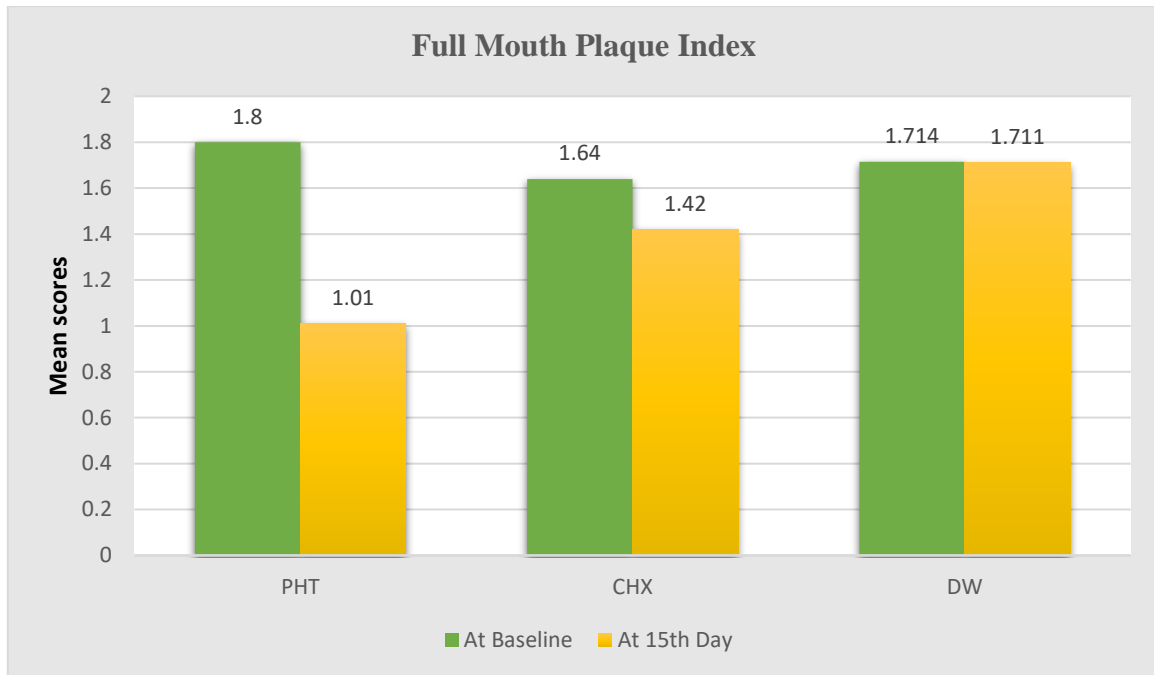
**Graph 1: Full Mouth Bleeding Index at baseline and at 15th day.**

The inter group and intra group comparison of FMPI at baseline to 15<sup>th</sup> day. The mean  $\pm$  SD values at baseline and 15<sup>th</sup> day were (1.80 $\pm$  0.57); (1.01  $\pm$  0.03) respectively for PHT, (1.64  $\pm$  0.79); (1.42  $\pm$  0.37) respectively for CHX and (1.714 $\pm$  0.438) and (1.711 $\pm$ 0.439) respectively for DW. The values decreased in both groups from baseline to 15<sup>th</sup> day in PHT group. The ANOVA followed by post hoc found highly significant differences on intragroup comparison from baseline to 15<sup>th</sup> day, in PHT group. However, the inter group comparison at different interval of time period reveal significant differences with PHT. (t=4.432; p<0.002\*); (t=0.806; p<0.0441) and (t=1.966; p<0.081).

**Table 3. Inter group comparison of Full Mouth Plaque Index at 15<sup>th</sup> day between three groups.**

Group	At 15 <sup>th</sup> day	P value	Post Hoc test	
	Mean $\pm$ SD		Compared Groups	p value
PHT	1.01 $\pm$ 0.03	<0.001**	PHT vs CHX	0.024*
CHX	1.42 $\pm$ 0.37		PHT vs DW	<0.001**
DW	1.71 $\pm$ 0.44		DW vs CHX	0.225

ANOVA followed by post hoc; \*p<0.05 significant; \*\*p<0.001 highly significant



Graph 2: Full Mouth Plaque Index at baseline and at 15th day.

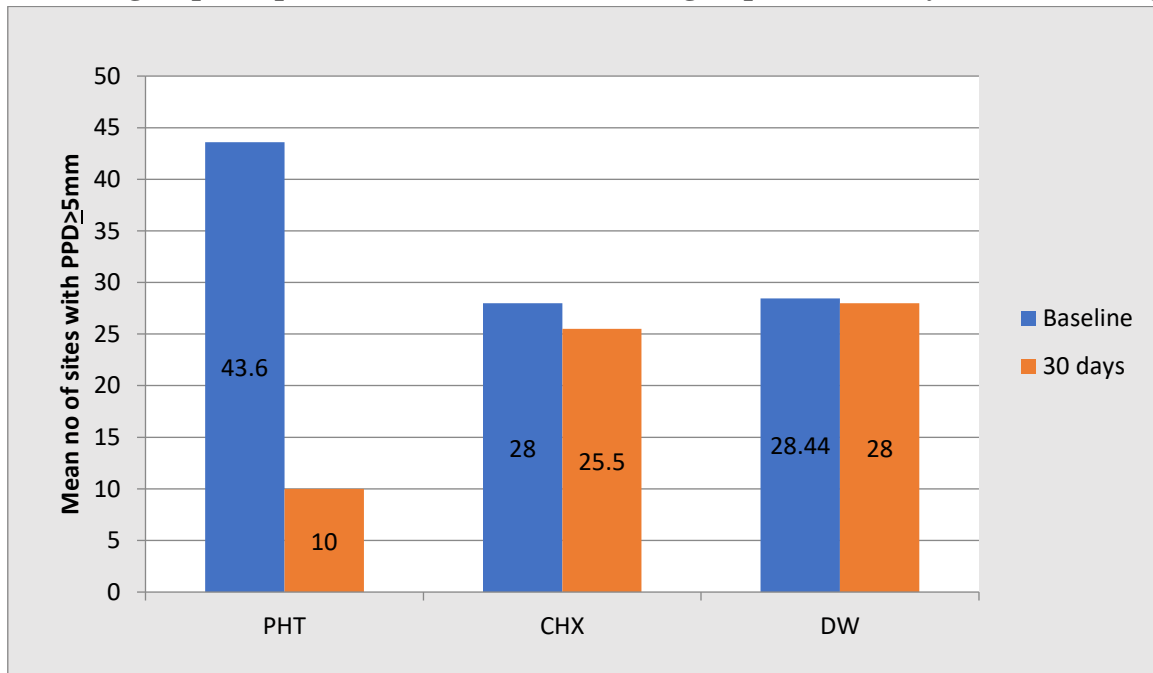
Table 4: Inter group comparison of Periodontal Probing Depth at baseline between three groups.

Group	Parameter	At Baseline	At 15 <sup>th</sup> Day	MD ± SD	T	P value
		Mean ± SD	Mean ± SD			
PHT	PPD >5mm	43.6± 17.10	10 ± 6.69	33.6± 18.21	5.83	<0.001**
CHX	PPD >5mm	28.0 ± 11.86	25.5 ± 11.75	2.5 ± 0.52	15.0	0.049*
DW	PPD >5mm	28.44 ± 10.27	28.0 ± 10.35	0.44 ± 0.72	1.83	0.104

Table 5: Inter group comparison of Periodontal Probing Depth at 30<sup>th</sup> day between three groups.

Group	PHT	CHX	DW	P value	Post hoc
Baseline	43.6± 17.10	28.0 ± 11.86	28.44 ± 10.27	0.025*	PHT vs CHX p<0.001**
30 days	10 ± 6.69	25.5 ± 11.75	28.0 ± 10.35	0.001*	PHT vs DW p<0.001** CHX vs DW p>0.05

**Graph 3: Inter group comparison of Periodontal Probing Depth at 30<sup>th</sup> day between three groups.**



The inter group and intra group comparison of PPD at baseline to 30<sup>th</sup> day. The mean  $\pm$  SD values at baseline and 30<sup>th</sup> day were (43.6 $\pm$  17.10) (10  $\pm$  6.69) respectively for PHT, (28.0  $\pm$  11.86); (25.5  $\pm$  11.75) respectively for CHX and (28.44  $\pm$  10.27) and (28.0  $\pm$  10.35) respectively for DW. The values decreased in both groups from baseline to 30<sup>th</sup> day in PHT group. The ANOVA followed by post hoc found highly significant differences on intragroup comparison from baseline to 30<sup>th</sup> day, in PHT group. However, the inter group comparison at different interval of time period reveal significant differences with PHT. (t=4.432; p<0.001\*); (t=0.806; p<0.049) and (t=1.966; p<0.104).

There was statistically significant difference in the efficacy of PHT compared with CHX and DW mouthrinse on plaque accumulation, gingival health and oral hygiene status.

## DISCUSSION:

The present study compared the efficacy of herbal phytonutrients-PHT, CHX and DW mouth rinse on oral health using three variables- FMBI, FMPI and PPD. The results showed that there was a significant improvement in gingival bleeding, plaque accumulation and oral hygiene after 15 days in all the three groups [Table-1,2,3,4,5 and Graph- 1,2,3]. This can be attributed to the antioxidant activity radical scavenging via hydrogen atom donation due to the reactivity and preventing the generation of ROS or scavenging of ROS or sequestering of metal ions, and acting as immune modulators. The consumption of exogenous antioxidants can maintain or re-establish the redox homeostasis directly by the inhibition of ROS generation and impact as well as indirectly by the enhancement of endogenous antioxidant systems and the regulation of immune responses, providing the prophylactic and therapeutic potency in many diseases, particularly chronic and inflammatory conditions. There has been a growing body of evidence indicating the promising effects of exogenous antioxidants in the management of periodontal disease. The herbal medicine has been demonstrated to possess a huge array of biological properties, such as antimicrobial, antioxidant, and anti-inflammatory effects, suggesting its implications in the control of periodontal disease.



Due to availability of a variety of mouthwashes with different active ingredients, there is always a dilemma among patients and practitioners regarding its choice. CHX, till date, is considered to be the most effective anti-plaque agent, but with certain limitations. Hence, search for an effective and safe alternative to CHX mouthwash has led to introduction of various herbal products in dentistry which are without any major side effects, besides being cheap and locally available. Natural herbs when used in mouthwashes, have shown significant advantages over the chemical ones.<sup>4</sup>

**Deshmukh AD et al in 2017**, conducted a study to evaluate the comparative efficacy of probiotic, herbal and CHX mouthrinse on gingival health of healthy individuals. Clinical and biochemical changes were analyzed. The authors concluded with No, Statistically Significant results with difference in the efficacy of CHX, HiOra regular and probiotic mouthrinse on plaque accumulation, gingival health and oral hygiene status. Henceforth, Herbal and probiotic mouthrinse can prove to be effective alternatives to CHX with minimal side effects.<sup>8</sup>

Literature is replete with evidence about its detrimental oral effects such as epithelial detachment, keratosis, mucosal ulceration, petechiae and oral pain which can be attributed to high alcohol content, thus restricting its prolonged use. Hence, the quest for a long-term, ideal and safe antiplaque and antigingivitis agent continues. In this context, synthetic antimicrobials have been analysed, but the increasing problems of resistance have encouraged the search for alternative agents based on herbal extracts bibhitaki, nagavalli, pilu, peppermint satva, yavani satva, gandhapura taila and ela.<sup>5</sup>

A comprehensive in vitro assay, which investigated the inhibitory effects of 48 polyphenolic compounds on periodontal bacteria growth and biofilm formation, found that curcumin was the most potent inhibitor, followed by pyrogallol, pyrocatechol, and quercetin. Consistently, common dietary sources of polyphenols, such as blueberry extract and tea polyphenols have also been proven to have plaque inhibitory activity in in-vitro studies. gandhapura taila) have encouraging antimicrobial activity that may be helpful in providing better oral care.<sup>6</sup>

**Safiaghdam H, Oveissi V, Bahramsoltan R et al in 2018**, conducted a review on current clinical trials to evaluate the efficacy of herbal products in gingivitis. Herbal medicines in the form of dentifrice, mouth rinse, gel, and gum were assessed in gingivitis via specific indices including plaque index, bleeding index, microbial count, and biomarkers of inflammation. Pomegranate, aloe, green tea, and miswak have a large body of evidence supporting their effectiveness in gingivitis. They could act via several mechanisms such as decrease in gingival inflammation and bleeding, inhibition of dental plaque formation, and improvement in different indices of oral hygiene. The authors concluded with statistically significant results with some polyherbal formulations.<sup>7</sup>

**Sparabombe S et al in 2019**, conducted a study to evaluate the anti-inflammatory effect and the incidence of adverse effects of an all-natural polyherbal mouthrinse in patients with periodontitis, after 3 months of use. These aims were accomplished by using full mouth bleeding score, full mouth plaque score, probing depth, clinical attachment level and a questionnaire recording any adverse events. The authors concluded with No, statistically significant result between the two group.<sup>8</sup>

**Alsaffar D & Alzoman H in 2020**, conducted a study to evaluate the efficacy of an antioxidant mouthrinse, and mouthrinse containing [0.05% chlorhexidine, 0.05% cetylpyridinium chloride, and 0.14% zinc lactate (CHX-CPC-Zn)] on volatile sulphur compounds. Two mouthrinse were randomly provided to each subject in addition to saline solution (NaCl 0.9%) as control. Subjects were instructed to rinse with 20 ml of the mouthrinse for 1 min twice daily for 2 weeks. At second visit, post-treatment breath sample was taken. Afterward, the patient was asked to refrain from using mouthrinse for a washout period of 1



week. A similar procedure was repeated for each mouthrinse interval. The authors concluded with No significant differences in VSC level between all three groups were detected at baseline.<sup>9</sup>

**Ciavoi G, Dobjanschi L, Jurca T et al in 2021**, conducted a study to s to comparatively evaluate the effectiveness of a commercial mouthrinse and of an herbal infusion on dental plaque formation and gingival inflammation. The participants in the study (90 patients) were divided into two groups, the CM group, which rinsed with a commercial fluoride-containing mouthrinse and the IM group, which used an herbal infusion. The authors concluded with statistically significant results with both types of mouthrinse demonstrated their efficacy in reducing PI and GI values. d.<sup>10</sup>

**Khobragade VR et al. in 2022**, conducted a study to determine and compare the antibacterial efficacy of indigenous herbal mouthrinse with 0.2% chlorhexidine gluconate. They concluded with statistically significant reduction in both clinical and microbiological parameters with the use of an indigenous herbal mouthrinse as well as 0.2% chlorhexidine gluconate. However, chlorhexidine mouthrinse was statistically efficacious at the 21st day in controlling plaque and gingivitis with potent antimicrobial activity.<sup>11</sup>

### CONCLUSION:

It can be concluded from this study that the three mouthwashes i.e., CHX, PHT and DW, where, PHT mouthrinse were effective in reducing FMBS, FMPI, PPD. Thus, improving oral health. This study on of phytonutrients rich herbal mouth rinse after conducting clinical trials on a small scale at Oldage home, so that risk of adverse effects is less and general health is promoted along with oral health. Herbal phytonutrient rich-mouthrinse can prove to be effective alternatives to CHX with minimal side effects. Herbal mouthrinse can be advocated as suitable alternatives to CHX if their use and with further more evidence based study on large sample size.

### ACKNOWLEDGEMENT:

We are very grateful to Mr. Manish Sharma- Mahesh Medical -Bhilai, Durg, Chhattisgarh, India for helping with pharmacological procurement of mouthrinse. Dr. Pragya Kulkarni Head of the Department of Microbiology- VYT Autonomous Government Science College-Durg, Chhattisgarh, India.

### Financial support and sponsorship

Nil.

### Conflicts of interest

There are no conflicts of interest.

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