Original Research Paper

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Comparative Evaluation of Efficacy of Drynaria Herbal Mouthwash and Chlorhexidine Mouthwash on Gingivitis: A Randomized Controlled Trial.

Abstract:

Introduction: Herbal products are preferred widely to synthetic medications owing to their minimal adverse effects and cost effectiveness. Drynaria is a herb used for bone regeneration, inflammation, hyperlipidemia, arteriosclerosis, rheumatism, and osteoporosis. This study was aimed to evaluate the effectiveness of Drynaria mouthwash in reduction of gingival inflammation in comparison with commercially available chlorhexidine (CHX) mouthwash.

Materials and Methods: This parallel arm, randomized controlled clinical trial was carried out on 30 participants with mild to moderate gingivitis who were divided into two groups. Scaling and root planning were done. Group A patients were given Chlorhexidine mouthwash (CHX) and Group B patients were given Drynaria Herbal mouthwash for 21 days. The clinical parameters assessed were Bleeding on Probing (BOP), Plaque Index (PI), and Gingival Index (GI) at baseline, 2 weeks, 3 weeks, and 4 weeks post use of the mouthwash.

Result: Drynaria mouthwash provided results that were significantly effective in improving all the clinical parameters.

Conclusion: Based on the results of the study, Drynaria as a mouthwash is nearly effective as Chlorhexidine mouthwash for the treatment of gingivitis.

Key-words: Chlorhexidine gluconate, Drynaria, Herbal, Mouthwash, Gingivitis

Introduction:

The inflammatory response of the gingiva, known as gingivitis, is brought on by substances derived from microbial plaque that build up at or close to the gingival sulcus; all other possible local and systemic etiologic factors either worsen the retention or accumulation of plaque or increase the gingival tissue's vulnerability to microbial attack.[1] Inflammation, redness, swelling, and bleeding upon mild stimulation of the gingival sulcus are indicators of gingivitis. [2] Moreover, it rarely results in spontaneous bleeding, is frequently painless, and manifests as mild clinical changes. Consequently, unless they experience gingival bleeding, the majority of patients are either ignorant of the illness or choose not to seek treatment. Gingivitis can evolve to Periodontitis if not treated, leading to the loss of alveolar bone and periodontal attachment, which ultimately results in tooth loss and has a detrimental effect on quality of life. Gingivitis differs from periodontitis in that, with appropriate management of biofilm, the tissue alterations are reversible.[3] A number of techniques, including

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mechanical and chemical ones, have been suggested for eliminating microbial plaque. Nonetheless, the most effective method for eliminating the buildup of microbial plaque is Scaling and Root Planing (SRP). Data indicates that under some circumstances, SRP does not seem to be completely effective. Therefore, as an adjunct Chemical plaque control has drawn a lot of interest. [4]

Chemical agents designed to control plaque possess antibacterial, anti-plaque, and anti-inflammatory characteristics. One type of antibacterial agent is chlorhexidine. It is a biguanide with the strongest inhibitory effect on gingivitis and plaque development. Because of its chemical substantivity and clinical effectiveness in chemical plaque management, CHX is regarded as the gold standard agent. Long-term daily use is not advised, as it has been linked to a number of local side effects, including altered taste [5], microbe resistance, vomiting, diarrhea, and tooth staining or brownish discoloration of teeth, restorative materials, and the dorsum of the tongue.[6]

Drynaria (also known as Gol-Se-Bo in Korean, Gu-Sui-Bu in Chinese, and Aglaomorpha in India) is a widely used traditional medicine that is used to treat inflammation, hyperlipidemia, rheumatism, osteoporosis, and oral bacterial infection.[7,8,9]

Known locally as "Marappan-nakizhangu" or "Attukal-kizhangu," Drynariaquercifolia is an epiphytic medicinal pteridophyte that is widely spread in the evergreen forests of Kerala's Western Ghats. Tribal groups in Tamil Nadu and Kerala are said to employ the rhizome (root) to treat a variety of illnesses, including cough, dyspepsia, and phthisis.[9] The leaves are applied topically to enlargements. The plant's rhizome is used as an anti-inflammatory by the tribal people of Tamil Nadu's Kolli Hills.[10] Strong anti-inflammatory and analgesic qualities of Drynaria quercifolia rhizome ethanolic extract (DQ) corroborate its purported usage by many Indian ethnic groups for the treatment of rheumatic illnesses and the relief of excruciating inflammatory conditions.[9]

Strong antibacterial activity against oral bacteria was demonstrated by the chloroform fraction of D. fortunei in a dose- and time-dependent manner. Furthermore, the time-kill curves for S. mutans and P. gingivalis showed that Streptococcus was killed considerably more slowly than Porphyromonas, indicating the distinct effects of D. fortunei extract and fractions on bacteria linked to caries and oral periodontal infections. Due to the high flavonoid content of D. fortunei, it may have potent antibacterial effects on oral microorganisms.[7]

The abundance of phenolic chemicals in plant extracts from Drynaria quercifolia is primarily responsible for their antioxidant properties, which follows that there's a chance these fractions contain a lot of phenolic chemicals.[11]

To the best of our knowledge, no research has been published assessing Drynaria's clinical effectiveness as a mouthwash for gingivitis. This study aimed to compare Drynaria herbal mouthwash with commercially available CHX mouthwash to see how successful it was at reducing gingivitis. The null hypothesis states that drynaria and chlorhexidine are equally effective in reducing gingivitis.

Materials And Methods:

Study Description: This parallel arm randomized controlled clinical trial included a total of 30 participants who were randomly selected from those who reported to the outpatient department of periodontics of the institution and allocated into 2 groups - Chlorhexidine & Drynaria mouthwash group. The study protocol was approved by the ethical committee of the institution. A written informed consent was taken from all participants recruited in the study.

Sample Size Determination: The sample size was calculated using G Power software version 3.1.9.7., based on the study by Pradeep AR et al[5] keeping the power 99%, alpha error 0.05% with the effect size of 1.67. The sample size came out to be 30 (n=30),15 per group.

Study Design: Using lottery method, the individuals were assigned to one of the two groups. Figure 1- shows the study design. The present study was carried out in a triple blinded design wherein the participants, researcher and the outcome accessor were blinded. The masking was done by transferring both the mouthwashes in similar bottles.

1. Group A: 15 individuals undergoing scaling and prescribed to use 0.2% CHX mouthwash for 21 days
2. Group B: 15 individuals undergoing scaling and prescribed to use Drynaria Herbal mouthwash for 21 days

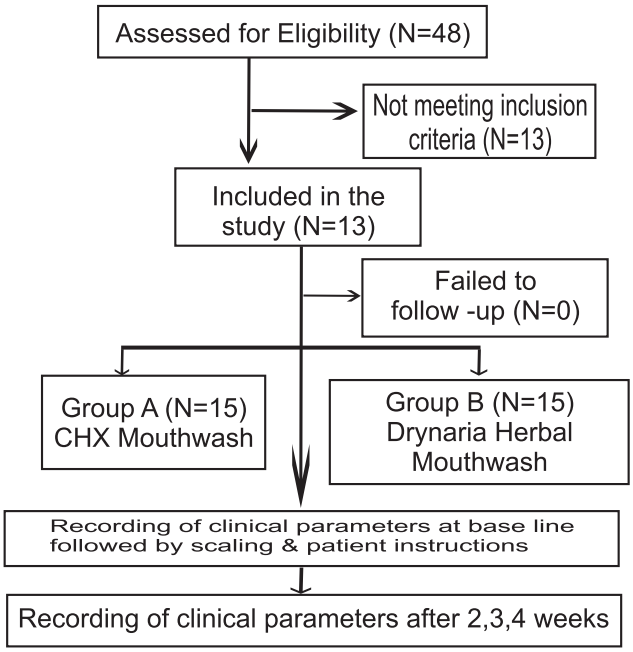

Figure 1- showing the study design

Inclusion Criteria:

Systemically healthy induviduals within the age group of 25–45 years, with minimum 20 teeth and with mild-to-moderate gingivitis, were recruited as participants.

Exclusion Criteria:

Patients using Nosteroidal Anti-inflammatory drugs and Antibiotics in the past 3 months, underwent scaling in the past 6 months, with prosthetic or orthodontic appliances, allergic to active ingredients, Pregnant or lactating females, Smokers, Alcoholics,and Drug abusers, and current users of any mouth rinse for any dental problems were excluded.

Preparation of Drynaria Mouthwash:

1. Procurement and preparation of powder:

The *Drynaria* plant was procured from Udhagamandalam, Ooty, Tamil Nadu (India). The rhizome (Figure 2) of the same was cleaned, cut into pieces, and shade-dried for 3 days. Afterwards, it was pulverized using the Kenstar® high-speed electric mixer grinder and passed through the sieves until a fine powder was obtained. The resultant powder was transferred to a dry, clean, sterile air-tight container until further study.

2. Preparation of herbal mouth-wash:

The mouthwash (Figure 3) was prepared using the cold maceration method. The 500 gm of *Drynaria* powder was weighed using an electronic balance and soaked in 100 ml of aqueous solution for 72 hours and then after, the mixture was filtered thrice using Whatman filter paper in a 1000 ml conical flask. Furthermore, glycerin 2mg/ml, sweetening agent (sucralose 30 mg/ml) and preservative (methylparaben 0.5 mg/ml), and the coloring agent 0.1 mg/ml were added into the conical flask making up the volume to obtain the final mouth wash.[12,13] The prepared herbal mouthwashes were dispensed in bottles and were sequentially numbered.

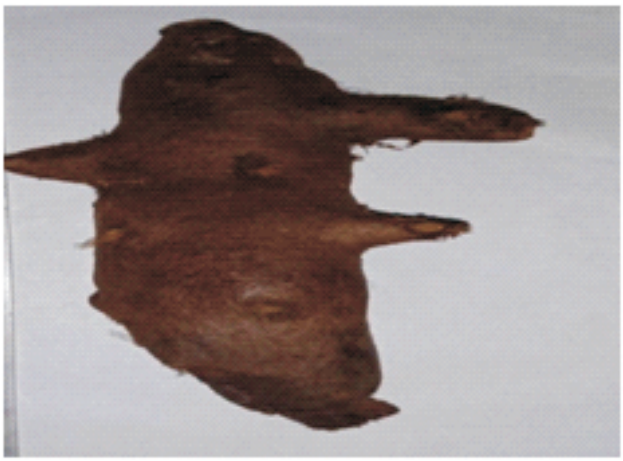

Figure 2: Drynaria Rhizome

Figure 3: Drynaria mouthwash

Oral Prophylaxis followed by Prescription of Mouthwash:

After Oral prophylaxis, the individuals were instructed to follow the modified bass brushing technique, and instructed to use 10 ml of mouthwash twice daily, 30 min after brushing and were instructed not to drink or eat anything within 30 min after using the prescribed mouthwashes. They were advised to use the mouthwash for 21 days and discontinue later.

Assessment of Clinical parameters:

The clinical parameters assessed were Plaque Index (PI)[14], Gingival Index (GI)[15] and Bleeding on Probing (BOP)[16]. They were recorded at baseline, 2 weeks, 3 weeks and 4 weeks (1week follow up after discontinuing the mouthwash). The clinical parameters were recorded by the examiner who was blinded toward the allocation of participants.

Statistical Analysis:

The data collected were entered in Microsoft Excel, and statistical analyses were performed using IBM SPSS version 21 software. Man-Whitney test for inter group comparison, Friedman test for intra group comparison. Independent t test for inter group comparison. Repeated measure ANOVA for Intra group comparison. In the above-used tests, $P \leq 0.05$ was considered as statistically significant.

Observation & Results:

Total 30 individuals who were selected after the assessment for the eligibility, were randomly divided into two groups. Demographic and clinical parameters were recorded.

Table 1 shows the PI scores for Group A, Group B at baseline, 2 weeks, 3 weeks, and 4 weeks. At baseline the mean difference in scores between the groups was statistically non-significant. On intragroup comparison at the different time intervals, the p value was significant in both the groups ($p< 0.001$), but the intergroup comparison is statistically non-significant (Figure 4).

TABLE 1 : Plaque Index

Plaque Index	Chlorhexidine (Mean±SD)	Drynaria (Mean±SD)	p value
Pre operative	2.12±0.64	2.12±0.66	0.83
2 weeks	0.07±0.13	0.12±0.18	0.72
3 weeks	0.37±0.34	0.20±0.25	0.16
4 weeks	0.54±0.36	0.46±0.32	0.55
p value	<0.001	<0.001	
p value <0.05 is considered as statistically significant value. **Man-Whitney test for inter group comparison. * Friedman test for intra group comparison			

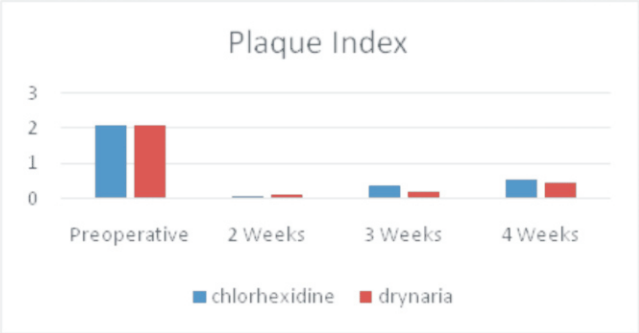

Figure 4: Plaque Index at different time intervals.

Table 2 presents the GI scores for Group A, Group B at baseline, 2 weeks, 3 weeks, and 4 weeks. The mean difference in scores between the groups was statistically non-significant. On intragroup comparison at the different time intervals, the p value was significant in both the groups (Figure 5).

TABLE 2 : Gingival Index

Gingival Index	Chlorhexidine (Mean±SD)	Drynaria (Mean±SD)	p value
Pre operative	2.00±0.78	1.98±0.70	0.94
2 Weeks	1.20±0.75	1.50±0.59	0.22
3 Weeks	0.71±0.48	0.58±0.55	0.12
4 Weeks	0.21±0.29	0.18±0.29	0.02
p value	<0.001	<0.001	
p value <0.05 is considered as statistically significant value. **Independent t test for inter group comparison. * Repeated measures ANOVA for intra group comparison.			

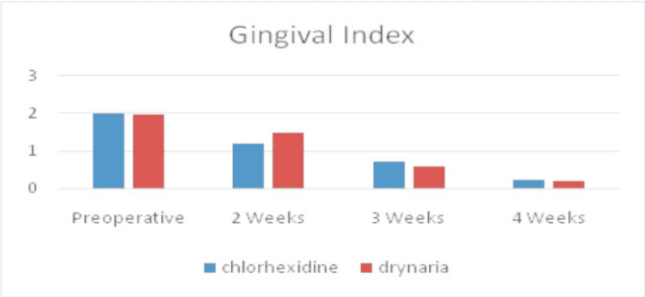

Figure 5: Gingival Index at different time intervals.

Table 3 presents the BOP scores for Group A, Group B at baseline, 2 weeks, 3 weeks, 4 weeks. The mean difference in scores between the groups was statistically non-significant at baseline, 1 week and 2 weeks, 3 weeks. On intragroup comparison at the different time intervals, the p value was significant in both the groups (Figure 6 & 7). On inter-group comparison of difference in all clinical parameters at baseline, 2 weeks,3 weeks and 4 weeks, both the groups were statistically non-significant difference.

Table 3: Frequency of Bleeding on Probing

Group	Sulcus bleeding score index	Pre operative	2 Weeks	3 Weeks	4Weeks	p value*
Chlorhexidine	0	0	0	3(20%)	11(73.3%)	<0.001
	1	0	0	12(80%)	4(26.7%)	
	2	4(26.7%)	7 (46.7%)	0	0	
	3	5(33.3%)	6(40%)	0	0	
	4	3(20%)	2 (13.3%)	0	0	
	5	3(20%)	0	0	0	
Drynaria	0	0	0	6(40%)	11(73.3%)	<0.001
	1	1(6.7%)	4(26.7%)	8(53.3%)	4(26.7%)	
	2	5(33.3%)	6(40%)	1(6.7%)	0	
	3	3(20%)	5(33.3%)	0	0	
	4	5(33.3%)	0	0	0	
	5	1(6.7%)	0	0	0	
p value**	0.46		0.65	0.40	1.00	

p value <0.05 is considered as statistically significant value.
**Man-Whitney test for inter group comparison. * Friedman test for intra group comparison.

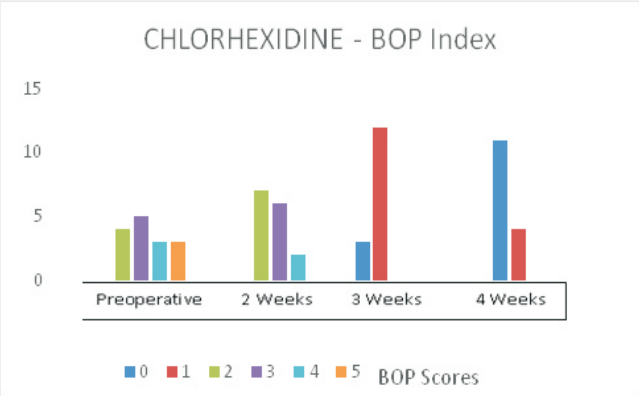

Figure 6: BOP Index in Group A- CHX mouthwash at different time intervals.

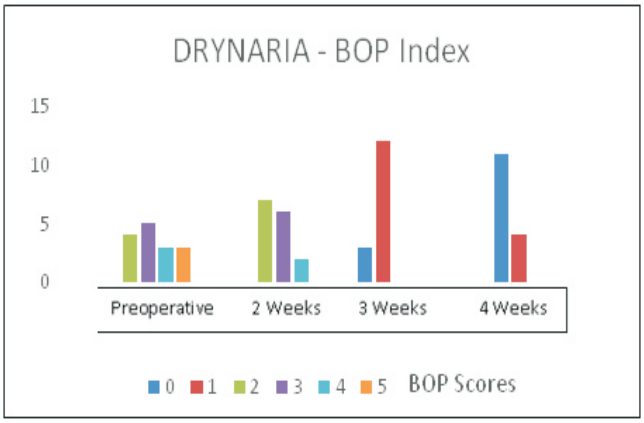

Figure 7: BOP Index in Group B- Drynaria Herbal mouthwash.

The pair wise comparison was performed using Post hoc test which showed significant difference among all the pairs.

Discussion:

Indian medicine's Ayurveda system (Ayu means "life" and Veda means "science") has been successfully applied to treat a wide range of systemic and dental pathologic diseases. Ayurveda places a strong emphasis on the use of plant-based medications, which can effectively treat systemic illness problems and also serve as a good alternative to conventional treatment methods due to their inherent phytochemicals.[17]

A thorough exploration of the available literature revealed few studies in which different herbal mouthwashes were compared with chlorhexidine mouthwash. The sample size, design, the study period, the indices and the technique used in those studies highly varied from one study to another study. A sincere attempt has been made to compare the available results wherever possible maintaining the validity of the comparisons to the possible extent. The current study was designed to determine effectiveness of Drynaria mouthwash in reducing gingival inflammation in individuals with gingivitis in comparison with the gold standard Chlorhexidine mouthwash.

Chlorhexidine served as a positive control in this study, since it is the antiplaque agent of choice and showed statistically significant results at all the time intervals in all the 3 clinical parameters assessed. The PI score which was 2.12 ± 0.64 at baseline improved to be 0.54± 0.36 after 4 weeks; the GI score which was 2.00 ± 0.78 at baseline, improved to be 0.21 ± 0.29 after 4 weeks. The BOP score also reduced significantly with the use of chlorhexidine mouthwash. Though, CHX demonstrated to be more successful at controlling plaque than placebo mouthwash, a few adverse effects of its use for long term therapy has been limited or not actively recommended.[18]Instead, herbal remedies may be more effective with fewer drawbacks. Numerous research have been done on mouthrinses containing CHX; however, only a small number of studies have compared the effectiveness of CHX and other herbal mouthwashes in treating gingivitis.[5]

Drynaria herbal mouthwash which was the test group in this study showed statistically significant results at all the time intervals in all the 3 clinical parameters assessed. The PI score which was 2.12 ± 0.66 at baseline improved to be 0.46 ± 0.32 after 4 weeks; the GI score which was 1.98 ± 0.70 at baseline, improved to be 0.18 ± 0.29 after 4 weeks. The BOP score also reduced significantly with the use of Drynaria mouth wash.

Our study of comparison between Chlorhexidine mouthwash with Drynaria herbal mouthwash resulted with non-significant difference between the two, and both were equally efficient in reducing gingivitis. Fewer researches have been conducted with somewhat positive outcomes, as demonstrated by herbal mouthrinses. Similar to our study, study conducted by Varghese et al[17] showed that Murraya koenigii mouthwash is just as successful as CHX in treating gingivitis. Naiktari et al[19] concluded that Herbal mouthwash with Triphala is an efficient antiplaque substance, in controlling periodontal disease. Triphala reduced inflammatory markers, which improved gingivitis.[5] Additionally, it is affordable, readily accessible, and acceptable and free of reported adverse consequences. Chatterjee et al[20] concluded that Curcumin mouthwash has demonstrated gingivitis and plaque prevention qualities comparable to CHX mouthwash. Akca et al[21] suggested that Propolis treatment at suitable concentrations may have an impact on oral bacteria, and may be used as an alternative natural and trustworthy antimicrobial mouth rinse. Bhat et al[22] concluded that the efficacy of Hiora Herbal mouthwash (Himalaya drug company) was equally successful in decreasing gingivitis and plaque as chlorhexidine. But it contains natural chemicals of no known negative effects , other than a minor burning feeling, whereas the study conducted by Bhate et al[23] contradicted to other studies, by concluding that in addition to reducing plaque scores, chlorhexidine also had a statistically significant effect on the clinical symptoms of plaque-induced gingivitis, compared to the Hiora herbal rinse.

The limitations of our study which can be the scope for further research include the substantivity of herbal mouth rinses and their antimicrobial analysis of associated microorganisms need to be investigated. Future research should consider the following recommendations: (1) Increase the study population to encompass a wider range of age groups and illness status (2) Extend the study period by six months; (3) Include calculus indices and stains.

Conclusion:

The results of this clinical trial showed that Drynaria mouthwash was just as successful as the gold standard of Chlorexidine in lowering gingivitis and plaque. This trial highlights the fact that, in comparison to chemical products sold in stores, herbal products are readily accessible, reasonably priced, socially acceptable, and have less reported adverse effects. Thus, it ushers in a new era of natural remedies for maintaining periodontal health.

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