

**Evaluation of curcumin gel compared with chlorhexidine gel as an adjunct in the treatment of chronic gingivitis: A randomised controlled clinical trail**

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**Citation of this Article:** Dr. Soumya Mundhra, Dr. Raja Sridhar, Dr. Sudeep HM, Dr. Ela Shree Chatterjee, Dr. Wajeeh Khan, “Evaluation of curcumin gel compared with chlorhexidine gel as an adjunct in the treatment of chronic gingivitis: A randomised controlled clinical trail”, IJDSIR- February - 2022, Vol. – 5, Issue - 1, P. No. 427 – 433.

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**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

**Introduction**

Gingivitis is characterized by the presence of clinical signs of inflammation that are confined to the gingiva.<sup>1</sup> The biofilm nature of dental plaque provides a specialized environment for the microorganisms ensuring its vitality and pathogenicity.<sup>2</sup> Mechanical plaque control like scaling is the first and the foremost step in the management of gingivitis and periodontitis and is an indispensable phase of periodontal therapy.<sup>1</sup> Recolonization of the treated sites can occur, and thus pharmacological agents are nowadays used as adjuncts to mechanical therapy.<sup>2</sup> Chlorhexidine is an antiseptic that has a broad spectrum of antimicrobial activity and is safe and not toxic<sup>3</sup> and is regarded as gold standard in dentistry for the prevention of dental plaque.<sup>4</sup> Chlorhexidine though very effective also has certain side effects such as brown discoloration of the teeth, oral mucosal erosion, and bitter taste.<sup>2</sup> Hence, a requirement was felt of an alternative medicine that

could provide a product already enmeshed within the traditional Indian set-up and is also safe and economical.<sup>4</sup> Turmeric commonly known as “Haladi” is a popular spice frequently used in Indian foods and curry. Curcumin has been found to have anti-oxidant, anti-tumor, anti-inflammatory, antiviral, antibacterial, antifungal, analgesic, antiseptic properties, and thus has a potential against various diseases. The uses of gel as a delivery system enhance bioavailability of the drug by increasing the residence time of drugs on the skin<sup>5</sup>. Literature search reveals limited studies published to evaluate any additional benefits of CUM over only SRP as a topical chemotherapeutic agent for gingival disease. Thus, this study was intended to investigate any adjuvant superior effects of curcuma oral gel and chlorhexidine oral gel over Scaling and Root Planning in chronic gingivitis patients.

**Materials and methods**

This RCT included a total of 60 gingivitis subjects from the department of periodontics, Triveni Institute of

Dental Sciences hospital and Research Centre, Bilaspur, Chhattisgarh. This study was registered at the clinical trial registry under the aegis of Indian

Council of Medical Research (ICMR) at [www.ctri.nic.in](http://www.ctri.nic.in) with reference number REF/2019/05/025744.

#### **Inclusion criteria**

- Patients of age between 18 years and 55 years
- Subjects having at least 20 erupted teeth.
- Subjects with moderate gingivitis
- Probing depth < 3mm

#### **Exclusion criteria**

- Patients who are allergic to turmeric or chlorhexidine gluconate
- Participants with any adverse habits, such as smoking or tobacco chewing
- Patients with mouth breathing habit.
- Chronic periodontitis patients
- Patients with history of oral prophylaxis 6 months prior to the study.
- Medically compromised patients, Pregnant and lactating women.

Study was explained to the subjects and a written consent was taken from those who were interested to participate in the study.

A total of 60 subjects were chosen for the study diagnosed with mild to moderate gingivitis based upon the inclusion and exclusion criteria. Three groups were formed for the study:

- Group A comprised of 20 subjects diagnosed with Gingivitis and received Curcumin gel (cure next by A bott pharmaceuticals) as an adjunct to scaling and root planning.
- Group B comprised of 20 subjects diagnosed with Gingivitis and received Hexi gel as an adjunct to scaling and root planning.

- Group C comprised of 20 subjects diagnosed with Gingivitis and received Scaling and Root planning.

#### **Assessment of clinical parameters**

The following Clinical parameters were recorded:

- Gingival index (Loe and Silness,1963)
- Plaque index (Ture sky Gilmore Glickman Modification of Quigley Hein Plaque,1970)
- Modified sulcus bleeding index (Mombelli, Van Oosten and S. Church et al,1987)
- Probing Pocket depth

#### **Results**

Table1 shows the Intra-group comparison for measuring PI, GI, BOP and PPD scores from baseline to 3weeks in all the three groups (Group A, Group B, Group C). Results reveal consistent decrease in the PI, GI, BOP and PPD from baseline upto 3weeks with a significant reduction ( $p=0.001$ ) seen from Baseline to One week, and three weeks for all the 3 groups.

Table 2 and 3 shows the Inter group comparison of clinical parameters between Groups A, B and C. Baseline scores of all the clinical parameters examined (PI, GI, BOP, PPD) did not show any significant difference between the 3 groups.

Among the 3 groups, group C subjects who underwent only scaling and root planning had higher mean PI scores as compared to the mean PI scores of Group A and Group B subjects at 1 week and the difference was statistically significant ( $P=0.03$ ). However, pairwise comparison between the groups at 1 week confirmed a higher PI score for only Group C that was statistically significant ( $P=0.038$ ) when compared with subjects having received Curcumin gel i.e., Group A (Table 3). Also no significant difference existed between Curcumin group (Group A) and Chlorhexidine Group (Group B). For GI, among the 3 groups, group C subjects had higher mean GI scores as compared to the mean GI scores of

Group A and Group B subjects at 1 week and 3 weeks and the difference was statistically significant. ( $p=0.02$  and  $p=0.001$  respectively) (Table 2). However, pairwise comparison again revealed higher Gingival inflammation with only SRP subjects i.e., Group C when compared to subjects having received Curcumin gel i.e., Group A and was statistically significant both at 1 week and at 3 weeks ( $p=0.018$  and  $p=0.001$  respectively) (Table 3).

### Discussion

Gingivitis is a form of periodontal disease, when left untreated, it usually progresses to periodontitis leading to destruction of the soft tissue and resorption of alveolar bone eventually leading to loss of teeth. Mechanical therapy viz Scaling and Root Planning (SRP) is undoubtedly the first line of treatment for plaque induced gingival inflammation. Comprehensive mechanical debridement of sites with deep periodontal pockets is difficult to accomplish as it fails to eliminate the pathogenic microflora because of their location within deeper gingival and dental tissues or in other areas inaccessible to periodontal instruments.<sup>6</sup> This has led to the adjunctive use of antimicrobial agents delivered either systemically or locally.

Decrease in gingival inflammation is of primordial importance in the treatment of gingivitis adjuncts such as mouthwashes, gels or patches that are directly applied on to the gingiva are commonly and widely used agents in the treatment of gingivitis. These agents act as astringents causing shrinkage and contraction of tissues by constricting small blood vessels, water extraction from tissues, or by protein extraction. Another important concern in the treatment of periodontal inflammation is recolonization of treated sites with microbes. Research reveals an abrupt reduction in the subgingival microbiota at 1–2 weeks after SRP, followed by gradual bacterial

re-establishment towards pretreatment levels over 3 weeks.<sup>7</sup> Locally delivered agents are routinely used to control the re-growth of bacteria following SRP.<sup>8</sup> Hence, the recall visits for subjects in the present study were kept up to 3 weeks to evaluate the efficacy of test materials.

The present study utilized 2 agents delivered in the form of gels viz CHX and Curcumin as an adjunct in the treatment of gingivitis.

CHX, regarded as the gold standard, is one of the most effective topical agents, long been used as an effective antimicrobial agent. It is an antiseptic, which adheres to organic matter and demonstrates low toxicity when applied topically. Chlorhexidine though very effective also has certain side effects such as brown discoloration of the teeth, oral mucosal erosion, and bitter taste. Hence, a requirement was felt of an alternative medicine that could provide a product already enmeshed within the traditional Indian set-up and is also safe and economical.<sup>7</sup>

Currently, the use of herbal products in dentistry is ever increasing. That is attributed to their easy availability, low cost and lesser side effects. Curcuma longa is a member of ginger family, is indigenous to Southeast Asia, and as long been of about 2,500 y cultivated and used in India. According to Ayurvedic pharmacological properties turmeric is Tridosahara (alleviates vata, pitta and Kapha doshas) in nature. Because of its Lekhaniya (reducing corpulence) and anti-Kapha property, turmeric prevents plaque formation and capable of removing the plaques. This could propose the detachment of plaque biofilms and inhibits co-aggregation thus exhibiting the anti-plaque effect. Due to Katu Rasa, it has an anti-inflammatory action that helps in gingivitis. Its anti-Vata property helps in reducing the pain.<sup>9</sup>

Research protocols testing efficacy of any 2 groups have emphasized the importance of having a control group in Randomised controlled clinical trials. Studies, similar to the present study are published comparing the test agents but without a control group.<sup>5,7,10</sup> Literature search till date reveals only two pilot study conducted by Jaswal R et al<sup>11</sup> and Muglikar Set al<sup>12</sup> using CUM and CHX in gel form and comparing it with a control group of SRP alone. Accordingly, the results revealed significant better plaque control for the curcumin group and significantly better reduction in gingival inflammation for both the curcumin (Group A) and chlorhexidine group (Group B) as compared to the only SRP group (Group C).

Subjects in group A and B were asked to massage the gingiva with CUM/ CHX gels respectively that were provided to them. None of the study subjects reported any kind of adverse effects with the use of CUM or CHX. All the three treatment modalities made a significant impact on the reduction of plaque scores from baseline to 21 days. The maximum decrease in Plaque score at 3 weeks was seen for CHX group and least for the SRP group (Table 1).

Singh V<sup>4</sup> et al in their study to evaluate the adjunctive benefits of turmeric and chlorhexidine gluconate gel on gingivitis subjects demonstrated significant reduction in the PI scores with the use of CUM and CHX. Roopa DA<sup>1</sup> et al too found positive results with Curcumin group over the SRP group in gingivitis subjects. The present study failed to prove the Superior effects of CHX over the SRP group. Such inconsistencies in the results may be overcome with a larger sample size. The efficacy of CUM and CHX were equal in reducing the plaque scores with no significant difference was obtained between them for the entire duration of the present study. Similar result was obtained for Divya et al<sup>13</sup> too. The result for PI scores in the present study

definitely proves that the beneficial activity of CUM was in par with CHX.

Striking results were obtained for gingival inflammation in the present study demonstrating the positive actions of CUM and CHX. All the three groups individually showed significant improvement in GI and BOP over 3 weeks (Table 1). As stated previously primordial importance in the treatment of Chronic gingivitis is elimination of local factors and decreasing gingival inflammation. Though mechanical therapy alone favored reduction in gingival inflammation by reducing GI and BOP scores, there was no consistent reduction for the same during the 2-week time interval as significant reduction was obtained only for the first one week for GI and upto 3 weeks for BOP (Table1). Both the test agents significantly decreased GI scores and BOP for the entire treatment time interval (Table 1). The present study could not detect any significant difference between the groups for BOP. Though CHX fared better than CUM in reducing BOP, overall, both the agents had equal superior effects in reducing gingival inflammation as also shown in studies by Chatterjee A et al<sup>14</sup>, wag mare PF et al<sup>15</sup>, V Anitha et al<sup>2</sup>, Kandwal A et al<sup>16</sup>. The anti-inflammatory mechanism of action of CUM could be due to the blockage of arachidonic acid metabolism, namely, (1) selective inhibition in the synthesis of prostaglandin E2 and thromboxane occurs without altering the production of prostacyclin;(2) inhibition of arachidonic acid metabolism through lipoxygenase and scavenging of free-radicals generated in this pathway; and (3) decreased expression of inflammatory cytokines interleukin (IL)-1b, IL-6, and tumor necrosis factor-alpha.<sup>5</sup>

the additional benefits of CUM and CHX as against mechanical therapy in reducing the probing depth is better than SRP though not significant.

Patients can be extremely apprehensive for any kind of dental treatment including even a simple hand or ultrasonic scaling. It's important to address the problems of such patients including the post operative symptoms which they may experience. Common post operative sequelae even after ultrasonic scaling/ surgery is hypersensitivity, bleeding, pain or discomfort at the diseased sites especially in the first one week. Use of agents such as CUM or CHX in form of gels can alleviate patients of these post operative symptoms to a great extent. Also patients generally fear and avoid brushing over the treated sites after perio surgery, owing to the loosening of sutures or bleeding from the surgical site. CUM/CHX gel when applied over these sites, help patients to maintain better oral health by keeping the area free from plaque and gingival inflammation. Overall, both CUM and CHX did prove to be effective in reducing plaque and gingival inflammation and also showing some superior benefits over only SRP. CUM is easily available and most commonly used in India with no reported adverse effects. It can be indigenously used as an adjuvant in periodontal therapy and as a safe alternative to CHX owing to the many side effects of CHX as previously mentioned. The possible shortcomings of the present study are that a modest sample size of 20 subjects was considered in the present study. Also, the effect of curcumin on the periodontal microorganisms was not performed, further long-term studies with a larger sample size are required to analyze the clinical and microbiological and to evaluate the adjunctive use of the gels as an adjunct to scaling and root planning alone in chronic gingivitis patients.

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**Legend Tables**

Table 1: Intragroup comparison of Plaque Index (PI), Gingival index (GI), Bleeding on Probing (BOP), Probing Pocket Depth (PPD) for measuring change across the three weeks' time by repeated measured ANOVA.										
	GROUP A			GROUP B			GROUP C			SIG.
	Baseline	1 week	3 week	Baseline	1 week	3 week	Baseline	1 Week	3 week	
	Estimated Marginal means (Adjusted analysis-ANCOVA)									
PI	1.513	1.090	1.057	1.546	1.141	1.089	1.626	1.286	1.240	S, 0.001
GI	1.46	1.04	0.95	1.55	1.17	1.12	1.58	1.24	1.54	S, 0.001
BOP	1.486	1.127	1.060	1.396	1.047	.990	1.440	1.167	1.136	S, 0.001
PPD	2.854	2.345	2.2.97	3.027	2.454	2.386	2.614	2.225	2.215	S, 0.001

Table 2: Intergroup comparison of Plaque Index (PI), Gingival index (GI), Bleeding on Probing (BOP), Probing Pocket Depth (PPD) for measuring change across the three weeks' time by repeated measured ANOVA.

	BASELINE			1 WEEK			3 WEEKS		
	Group A	Group B	Group C	Group A	Group B	Group C	Group A	Group B	Group C
	Estimated Marginal means (Adjusted analysis-ANCOVA)								
PI	1.51	1.55	1.63	1.09	1.14	1.29	1.06	1.09	1.24
significant	0.47 (N.S)			0.03 (S)			0.07(N.S.)		
GI	1.46	1.55	1.58	1.04	1.17	1.24	0.95	1.12	1.54
significant	0.31 (N.S)			0.02 (S)			0.001(S)		
BOP	1.49	1.40	1.44	1.13	1.05	1.17	1.06	0.99	1.14
significant	0.59(N. S)			0.34(N. S)			0.22(N.S.)		
PPD	2.85	3.03	2.61	2.35	2.45	2.32	2.30	2.39	2.18
significant	0.16 (NS)			0.56 (NS)			0.61 (NS)		

Table 3: Intergroup Pairwise comparison between the groups by post hoc Bonferroni test\*

Comparison groups		Mean difference	p-value	Significance
Group A	Group B	-0.05	1.000	NS
	Group C	-0.196*	0.038	S
Group B	Group C	-0.15	0.186	NS
Group A	Group B	-0.13	0.219	NS
	Group C	-0.203	0.018	S
Group B	Group C	-0.07	0.933	NS
Group A	Group B	-0.17	0.864	NS
	Group C	-0.59*	0.001	S
Group B	Group C	-0.42	0.030	S