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Comparative evaluation of efficacy of sub-gingivally delivered 2% indigenously prepared curcumin gel and 1% commercially available hexigel as an adjunct to scaling and root planing in chronic periodontitis patients : A split mouth randomized controlled clinical trial.

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ABSTRACT: Aim: To evaluate and compare the clinical efficacy of subgingivally delivered curcumin gel and hexigel as an adjunct to scaling and root planing in chronic periodontitis patients.

Materials and method:A total of 12 subjects of age 18-55years were randomly selected for the study from the Out Patient Department. A total of 36 sites with pocket depths ≥5 mm were chosen as a split mouth design at three different sites in the same patient. After scaling and root planning, in Group I -2% curcumin gel, in Group II-Chlorhexidinegel(Hexigel) and in Group III-placebo gel (control)was placed sub-gingivally. Clinical parameters such as gingival index and plaque index were recorded at baseline, 7 days and 21 days. Pocket depth was checked at baseline, 21 and 45 days.

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Results:All the groups showed statistically significant reduction in gingival, plaque indices and pocket depth. Group I(curcumin)as a local delivery agent showedcomparable results in terms of pocket depth reduction as group II (Hexigel).

Conclusion:Curcumin gel showed effective results and thus, can be used as an alternate to chlorhexidine gel in management of chronic periodontitis patient without any side effects.

Keywords:Chlorhexidine , Chronic periodontitis, Curcumin, Gingival index, Plaque index.

1. INTRODUCTION

Periodontitis, a chronic inflammatory disease, is characterized by destruction of connective tissue and alveolar bone around teeth resulting in progressive destruction of the periodontal ligament and alveolar bone with periodontal pocket formation, gingival recession or both, eventually leading to tooth loss.[1,2] The microbial biofilm is the primary etiological agent for initiation and progression of periodontal disease.[3]Conventional periodontal therapy aims at disrupting the microbial biofilm. But however mechanical debridement alone cannot get rid of all microorganisms in deeper pockets.[4] The use of local drug delivery agents at target sites increases the concentration of drug at that site with no side-effects and the drug dosage can also be altered.[5]Systemic administration of drugs may cause certain side-effects such as hypersensitivity,resistant strain and super infection.[6]Moreover, systemic administration also reduces the bioavailability of drugs.

Chlorhexidine, a highly effective anti-microbial agent has been used effectively as a mouthrinse and a sub-gingival irritant.[7] Its usage has shown effectiveness in reducing periodontal probing depth, clinical attachment loss, and bleeding on probing.[8] However, its long term use may have detrimental effects like pigmentation of teeth and other intra-oral soft tissues, dulling of taste sensation, oral mucosal erosion.[5,9]

Turmeric has been used as ancient medicine since 7th century AD. Turmeric is derived from the plant Curcuminlonga, a herbaceous perennial plant belonging to Zingiberaceos family.[10]Turmeric contains a wide variety of phytochemicalsincluding curcumin,demethoxycurcumin,bisdemethoxycurcumin,zingiberene,curcumol,curcumenol,eugenol,tetrahydrocurcumin,triethylcurcumin,turmerin,turmerones and turmeronols.[11]Curcumin forms approximately 2-5 % of the herb which imparts the characteristic yellow color to turmeric and is responsible for most of its therapeutic effects.[12]Curcuminpossesses wide range of properties including anti-microbial, anti-oxidant, anti-inflammatory, anti-carcinogenic, anti-mutagenic, and wound healing.[13-15]Curcuminoids have been classified under “Generally Recognized As Safe” (GRAS) by US Food and Drug Administration (FDA). Good tolerability and safety profiles have been shown by clinical trials, at doses between 4000 and 8000 mg/day.[16,17] Doses up to 12,000 mg/day of 95% curcumin has been proven to be safe.[18]

Taking into consideration the beneficial properties of curcumin, it was hypothesized that curcumin, a natural product sans any side effects would provide comparable results as chlorhexidine, a well established highly effective anti microbial agent in treatment of chronic

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periodontitis patients. Thus, the present investigation was undertaken to evaluate the efficacy of 2% indigenously prepared curcumin gel and 1% commercially availablehexigel in patients with chronic periodontitis.

2. MATERIALS AND METHODOLOGY

A total of 36 sites in12 patients aged (18-55)years each comprising 3 non adjacent test sites with probing pocket depth >5mm diagnosed with generalizedmild to moderate chronic periodontitis were selected for the study. Patients were randomly selected from the out-patient Department of Periodontology, A.M.E's Dental college, Raichur. Among them 10 were males and 2 females.Sample size was determined on the basis of previously conducted studies.[5]The study protocol was approved by institutional Ethical committee.Patients were duly informed about the study and written consent was obtained for their participation in the study.

Subject selection

Inclusion criteria

Patients within age group of 18-55 years, with ≥5mm of probing pocket depth (PPD) in at least three non adjacent sites in different quadrants of mouth formed the study population. Systemically healthy patients with ≥ 20 teeth, not on systemic antibiotics for the past 6 months were included in the study.

Exclusion criteria

Patients with history of deleterious habits including use of tobacco or alcohol were not included in the study. Pregnant and lactating mothers, patients with history of allergy to chlorhexidine and patients on antibiotic therapy from the past 1 month were also excluded from the study.

Preparation of curcumin gel

500mg finely powdered carbopol-934 was accurately weighed anddispersed in 10 ml ofdeionized water using a vortex mixer. The volume of dispersion was raised to 50 ml, accurately weighed quantity of curcumin was dispersed and sonicated for 90 seconds until clear transparent dispersion was obtained. The dispersion was neutralized to attain the desired pH by adding triethanolamine until a clear transparent gel loaded with curcumin was obtained. The gel was refrigerated for 24 hours to achieve full deaeration and hydration.

Chlorhexidine gel

Commercially available chlorhexidine gel (Hexigel) with a 1.0%w/w chlorhexidinegluconate was used in the study.

Preparation of placebo gel

500mg finely powdered carbopol-934 was accurately weighed anddispersed in 10 ml ofdeionized water using a vortex mixer. The volume of dispersion was raised to 50 ml and

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sonicated for 90 seconds until clear solution was obtained. The solution was then neutralized to attain the desired pH by adding triethanolamine slowly until a clear transparent gel was obtained. The gel was refrigerated for 24 hours to achieve full deaeration and hydration.

Clinical parameters

Gingival and plaque indices (GI, PI) were recorded as per the guidelines given by Loe and Silnes (1963) and Turskey-Gilmore-Glickman modification of Quigley-Hein(1970)respectively.[19,20] PPD was measured using Williams periodontal probe by inserting a probe into the gingival sulcus and readings were taken from gingival margin to base of pocket.

3. METHODOLOGY

All the participants were explained about the need, design of study and its potential benefits. Informed written consent was obtained from patients.Clinical case history was recorded for the patients. All the clinical parameters were recorded at baseline.Each patient underwent ultrasonic scaling and root planingby a single operator. It was a single blind study,wherein three non-adjacent sites in three different quadrants were randomly selected, divided into three different groups and treated using split mouth design. The study sites were randomly assigned to either chlorhexidine or curcumin groups using fair coin tossing method. The three groups were Group I: individuals who received 2% turmeric gel, Group II: individuals who received 1% chlorhexidine gel (Hexigel), and Group III: patients who received placebo gel (control). All the gels were delivered into the selected sites using a syringe with a needle attached to it (Figures 1 and 2). Patients were instructed to continue with the regular oral hygiene measures. A standardized brushing technique was advised to all the patients.They were recalled after 1 week, and GI, PI was measured. At the end of 21 days (3weeks)probing pocket depth (PPD) ,GI and PI were recorded. After 45 days, PPD was again measured to check for long term effects of the medicaments.

Statistical analysis

Descriptive and inferential statistical analyses were carried out. Results on continuous measurements were presented on Mean ± SD. Level of significance was fixed at p=0.05 and any value less than or equal to 0.05 was considered to be statistically significant.Student t tests (two tailed, paired) was used to find the significance of study parameters on continuous scale within the group at different time intervals.Repeated measures Analysis of variance (ANOVA) was used to find the significance of study parameters within the group at different time intervals. Further Bonferroni's post hoc analysis was carried out if the values of ANOVA test were significant.The Statistical software IBM SPSS statistics 20.0 (IBM Corporation, Armonk, NY, USA) was used for the analyses of data.

4. RESULTS

A statistically significant reduction in the mean values of gingival and plaque indices were seen from the baseline to 7th to 21st day (Table 1 and table 2). Mean GI recorded at the baseline was 4.64±1.80, which reduced to 2.34±0.98 on the 7th day. The value had further

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gone down to 1.08±0.66 on the 21st day. Similarly, a reduction in plaque index was seen from 4.69±1.09 (baseline value) to 1.38±0.47 on the 21st day. Post hoc Bonferroni's test showed significant values.

Intra-group comparison

Curcumin: Table 3 shows comparison of PPD values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test. There was a statistically significant difference observed (p value: <0.001). Further using Bonferroni's post hoc analysis significant difference was observed between baseline and 21 days (p value: <0.001) and between baseline and 45 days (p value: <0.001). No significant difference was observed between 21 days and 45 days (p value: 0.498)

Hexigel : Table 4 shows comparison of PPD values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test which shows a statistically significant difference. Bonferroni's post hoc analysis showed significant differencebetween baseline and 21 days (p value: <0.001) and between baseline and 45 days (p value: <0.001). However, no significant difference was observed between 21 days and 45 days.

Placebo : Table 5 shows comparison of PPD valuesusing repeated measures ANOVA test, wherein statistically significant difference was observed (p value: <0.001). Bonferroni's post hoc analysis showed significant difference between baseline and 21 days (p value: <0.001) and between baseline and 45 days (p value: <0.001). However, no significant difference was observed between 21 days and 45 days (p value: NA) (Values were same).

Intergroup comparison

Table 6 shows comparison of PPD values at baseline among the 3 groups using ANOVA test, which showed a statistically significant difference(p value: 0.037). Tukey's post hoc analysis done showed significant difference between curcumin and placebo. No significant difference was observed between curcumin and hexigel (p value: 0.737) and between hexigel and placebo (p value: 0.163).

Table 7 shows comparison of PPD values at 21 days among the 3 groups using ANOVA test. There was a statistically significant difference observed between the groups (p value: <0.001). Further using Tukey's post hoc analysis, significant difference was observed between curcumin and placebo (p value: <0.001) and between hexigel and placebo (p value: 0.012). No significant difference was observed between curcumin and hexigel (p value: 0.662).

Table 8 shows PPD comparisonat 45 daysamongst the three groups using ANOVA test, which showed a statistically significant differencebetween the groups (p value: <0.001). Further using Tukey's post hoc analysis, significant difference was observed between curcumin and placebo (p value: <0.001) and between hexigel and placebo (p value: <0.001). However,significant difference was observed between curcumin and hexigel (p value: 0.134).

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Comparison of Mean Difference

Table 9 shows comparison of mean difference of PPD values (Baseline - 21 days) in terms of {Mean (SD)} among all the 3 groups using ANOVA test. There was a statistically significant difference observed between the groups (p value: <0.001).Tukey's post hoc analysis showed significant difference between curcumin and placebo (p value: <0.001) and between hexigel and placebo (p value: <0.001). No significant difference was observed between curcumin and hexigel (p value: 0.184).

Table 10 shows comparison of mean difference of PPD values (Baseline - 45 days) in terms of {Mean (SD)} among all the 3 groups using ANOVA test, which showed a statistically significant difference(p value: <0.001). Further, Tukey's post hoc analysis showed significant difference between curcumin and placebo (p value: <0.001) and between hexigel and placebo (p value: <0.001). However, no significant difference was observed between curcumin and hexigel (p value: 0.154).

Table 1: Comparison of gingival index values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test

Group	***N***	***Mean***	***Std. Deviation***	***Wilk's Lambda value***	***P value***
Baseline	12	4.6400	1.80387	**18.361**	**<0.001****
7 days	12	2.3425	0.98163		
21 days	12	1.0750	0.66333		

p< 0.001 - Highly significant**

Table 2: Comparison of plaque index values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test

Group	***N***	***Mean***	***Std. Deviation***	***Wilk's Lambda value***	***P value***
Baseline	12	4.6867	1.08749	**39.535**	**<0.001****
7 days	12	1.9983	0.73792		
21 days	12	1.3767	0.47433		

p< 0.001 - Highly significant**

Table 3: Comparison of PPD values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test (Curcumin)

Group	***N***	***Mean***	***Std. Deviation***	***Wilk's Lambda value***	***P value***
Baseline	12	5.58	0.669	**120.172**	**<0.001****
21 days	12	3.17	0.389		
45 days	12	3.00	0.000		

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(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Bonferroni's post hoc analysis)

	Baseline	***21 days***	***45 days***
Baseline	-	**<0.001****	**<0.001****
21 days	**<0.001****	-	0.498
45 days	**<0.001****	0.498	-

Table 4: Comparison of PPD values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test (Hexigel)

Group	***N***	***Mean***	***Std. Deviation***	***Wilk's Lambda value***	***P value***
Baseline	12	5.42	0.669	**90.625**	**<0.001****
21 days	12	3.33	0.651		
45 days	12	3.25	0.452		

(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Bonferroni's post hoc analysis)

	Baseline	***21 days***	***45 days***
Baseline	-	**<0.001****	**<0.001****
21 days	**<0.001****	-	1.000
45 days	**<0.001****	1.000	-

Table 5: Comparison of PPD values in terms of {Mean (SD)} at different time intervals using repeated measures ANOVA test (Placebo)

Group	***N***	***Mean***	***Std. Deviation***	***Wilk's Lambda value***	***P value***
Baseline	12	5.00	0.000	**169.00**	**<0.001****
21 days	12	3.92	0.289		
45 days	12	3.92	0.289		

(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Bonferroni's post hoc analysis)

	Baseline	***21 days***	***45 days***
Baseline	-	**<0.001****	**<0.001****
21 days	**<0.001****	-	NA
45 days	**<0.001****	NA	-

(NA: Not applicable)

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Table 6: Comparison of PPD values at baseline in terms of {Mean (SD)} among all the 3 groups using ANOVA test

Groups	***N***	***Mean***	***Std. Deviation***	***F value***	***P value***
Curcumin	12	5.58	0.669	**3.636**	**0.037***
Hexigel	12	5.42	0.669		
Placebo	12	5.00	0.000		
Total	36	5.33	0.586		

(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Tukey's post hoc analysis)

	Curcumin	***Hexigel***	***Placebo***
Curcumin	-	0.737	**0.035***
Hexigel	0.737	-	0.163
Placebo	**0.035***	0.163	-

Table 7: Comparison of PPD values at 21 days in terms of {Mean (SD)} among all the 3 groups using ANOVA test

Groups	***N***	***Mean***	***Std. Deviation***	***F value***	***P value***
Curcumin	12	3.17	0.389	**8.471**	**<0.001****
Hexigel	12	3.33	0.651		
Placebo	12	3.92	0.289		
Total	36	3.47	0.560		

(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Tukey's post hoc analysis)

	Curcumin	***Hexigel***	***Placebo***
Curcumin	-	0.662	**<0.001****
Hexigel	0.662	-	**0.012***
Placebo	**<0.001****	**0.012***	-

Table 8: Comparison of PPD values at 45 days in terms of {Mean (SD)} among all the 3 groups using ANOVA test

Groups	***N***	***Mean***	***Std. Deviation***	***F value***	***P value***
Curcumin	12	3.00	0.000	**28.079**	**<0.001****
Hexigel	12	3.25	0.452		
Placebo	12	3.92	0.289		
Total	36	3.39	0.494		

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(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Tukey's post hoc analysis)

	Curcumin	***Hexigel***	***Placebo***
Curcumin	-	0.134	**<0.001****
Hexigel	0.134	-	**<0.001****
Placebo	**<0.001****	**<0.001****	-

Table 9: Comparison of mean difference of PPD values (Baseline - 21 days) in terms of {Mean (SD)} among all the 3 groups using ANOVA test

Groups	***N***	***Mean***	***Std. Deviation***	***F value***	***P value***
Curcumin	12	2.4167	0.51493	**28.247**	**<0.001****
Hexigel	12	2.0833	0.51493		
Placebo	12	1.0833	0.28868		
Total	36	1.8611	0.72320		

(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Tukey's post hoc analysis)

	Curcumin	***Hexigel***	***Placebo***
Curcumin	-	0.184	**<0.001****
Hexigel	0.184	-	**<0.001****
Placebo	**<0.001****	**<0.001****	-

Table 10: Comparison of mean difference of PPD values(Baseline - 45 days) in terms of {Mean (SD)} among all the 3 groups using ANOVA test

Groups	***N***	***Mean***	***Std. Deviation***	***F value***	***P value***
Curcumin	12	2.5833	0.66856	**24.991**	**<0.001****
Hexigel	12	2.1667	0.57735		
Placebo	12	1.0833	0.28868		
Total	36	1.9444	0.82616		

(p< 0.05 - Significant*, p < 0.001 - Highly significant)**

(Tukey's post hoc analysis)

	Curcumin	***Hexigel***	***Placebo***
Curcumin	-	0.154	**<0.001****
Hexigel	0.154	-	**<0.001****
Placebo	**<0.001****	**<0.001****	-

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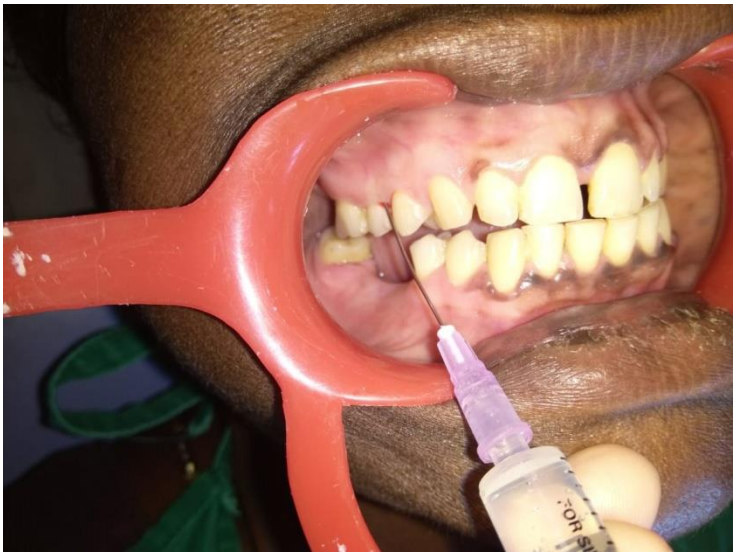

Figure 1: Placement of 1% hexigel sub-gingivally.

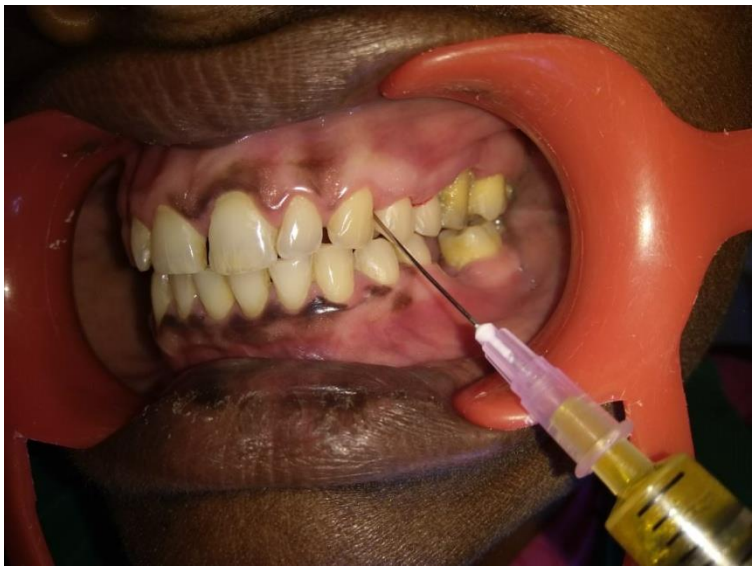

Figure 2 :Placement of curcumin gel sub-gingivally.

5. DISCUSSION

Periodontal disease encompasses several pathological conditions affecting the tooth supporting structures, and the role of bacteria in its etiology is indisputable. Conventional treatment for periodontal disease includes mechanical debridement to disrupt the subgingival flora, which usually provides satisfactory results.[21] But difficulty in reaching the bottom of the pocket may result in treatment failure, which makes supplementary treatment a necessity.[22] Moreover, scaling and root planing is a technique sensitive method, the outcome of which is dependent on several factors including time spent on therapy, number of sites that require instrumentation, and experience of the clinician.[23]Furthermore, some bacterial species cannot be eradicated only by mechanical debridement, thereby constraining the use of anti-microbial agents as an adjunct to improve the treatment outcomes.[5]

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Chlorhexidine, available as mouthwash, topical gel and biodegradable chips for local delivery, has been considered the gold standard for chemical plaque control aid.[24]Chlorhexidinegluconate, a cationic molecule binds to negatively charged surfaces such as teeth surface, dental pellicle and bacterial cell wall, resulting in bacterial cell wall lysis.[25]Chlorhexidine is a well established effective agent in plaque inhibition, and has added advantage of substantivity, safety, ease of use and economical.[26,27] However, various side effects of chlorhexidine have been documented like brown discoloration of teeth, dulling of taste sensation and oral mucosal erosion.[5]Therefore there was a need felt for antimicrobial agent which is safe and economical and with no side effects. Thus, the present study was conducted to evaluate the efficacy of naturally occurring curcumin in periodontal treatment as an adjunct to scaling and root planing.

Curcumin blocks nuclear factor kappa-B (NF-κB) activation, which regulates the activation of tumor necrosis factor(TNFα), which acts a major mediator of inflammation.[28,29]It also down regulates the expression of cyclooxygenase 2 (COX 2), an enzyme that results in synthesis of prostaglandins and is linked to most forms of inflammation including periodontitis.[30]Present investigation showed that curcumin group showed significant improvement in GI, PI and PPD, comparable to that of chlorhexidine group, and hence can be used effectively as an alternative to chlorhexidineas a local drug delivery agent in management of periodontal diseases. It would prove advantageous in individuals who are allergic to chlorhexidine or show adverse staining of teeth, taste alteration, dry mouth or unpleasant taste sensations in mouth. The added advantages are that it is a natural product with no side effects, has an acceptable taste and is also affordable. Similar results whereincurcumin and chlorhexidine showed comparable results were reported by Jaswal et al, Behal et al.[5,6]Hugar et al reported curcumin gel to be more effective than chlorhexidine gel in treatment of mild to moderate periodontal pockets with a significant reduction in the indices scores when compared to the baseline values, a finding not similar to ours.[31]

Anitha et al evaluated the efficacy of curcumin in the management of chronic periodontitis as local drug delivery in comparison to chlorhexidine. They found significant reduction of the clinical parameters (PPD, Clinical Attachment Level) and microbiological parameters [Colony Forming Unit (CFU)] at 15 and 30 days for both the groups. However, curcumin group showed greater reduction in the clinical parameters when compared with chlorhexidine group. Our findings were in concordance with this study.[32]

Bhatia et al assessed the clinical and microbiological efficacy of locally delivered 1% curcumin gel as an adjunct to scaling and root planing in the treatment of chronic periodontitis, and reported 1% curcumin gel to provide significant improvements in clinical parameters with reduction of microbiological counts ofPorphyromonasgingivalis, Prevotellaintermedia, Fusobacteriumnucleatum and Capnocytophaga at the test sites after six months when compared with that of control sites.[33]

Sreedhar et al compared curcumin and curcumin photodynamic therapy (PDT)as an adjunct to conventional SRPwith SRP alone in the treatment of patients with chronic

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periodontitis, and concluded that curcumin photodynamic therapy provided better resultsagainst pathogens likeAggregatibacteractinomycetemcomitans, Porphyromonasgingivalis, and Prevotellaintermedia, and the effects were found to be further enhanced by multiple applications of PDT.[13]

Singh et al evaluated and compared the effect of chlorhexidine chip and turmeric chip as a local drug delivery agent in treatment of patients with chronic periodontitis, and reported both the treatment modalities to show equally beneficial results.[34]Madaan et al compared the effects of two different local drug delivery systems incorporating green tea and turmeric extracts as an adjunct to SRP in the treatment of chronic periodontitis, and reported thatboth the agents were equally beneficial and showed a reduction in the clinical parameters which was statistically significant.[35]

Kandwal et al conducted a comparative evaluation of turmeric gel with 2% chlorhexidine gel for treatment of plaque induced gingivitis using vacupress trays, and concluded that both the groups showed comparable reduction in PI and GI. However, turmeric gel was better accepted by patients due to its pleasant odor and no staining properties, whereas patients reported bitter taste and staining of teeth with chlorhexidine gel.[36]

The limitations of the present study were small sample size, absence of microbiological examination and biochemical investigations. Further longitudinal studies are required in larger samples for longer duration to evaluate the effect of curcumin gel (herbal agent) as a local drug delivery agent in treatment of periodontal diseases.

6. CONCLUSION

Within the limitations of the study it can be concluded that 2%curcumin gel can be used as an alternate to chlorhexidine gel in treating chronic periodontitis patient without any side effects since it is economic, easy to prepare and has no side effects.

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