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EFFICACY OF CURCUMIN LOCAL DELIVERY GEL FOR THE TREATMENT OF STAGE II GRADE B PERIODONTITIS IN SMOKERS. RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Aim: The current study aimed to compare the efficacy of scaling and root planing (SRP) alone versus sub-gingival curcumin local delivery gel in combination with scaling and root planing in the treatment of stage II grade B periodontitis in smokers.

Subjects, materials and methods: In this double-blinded RCT, thirty smoker patients were treated with full-mouth nonsurgical SRP alone (control group) and full-mouth SRP followed by 2% local delivery curcumin gel (test group). Patients were observed at baseline, 30-day, and 45-day follow-ups to evaluate gingival index (GI), plaque index (PI) and clinical attachment level (CAL) parameters.

Results: One Way ANOVA followed by Tukey`s post hoc test was used to analyse the data and revealed that GI and PI measurements among both groups showed statistically significant improvements over time. However, CAL showed a statistically significant difference over time in the test group only. Independent t-test for comparison between both groups demonstrated that the SRP with curcumin group had better reduction in GI and PI (0.8000, 0.6000 respectively) compared to the control group (1.400, 1.200 respectively), with a statistically significant difference at 45-day. CAL measurements between groups showed significant differences at both the 30-day (p=0.0168) and 45-day (p=0.0030) assessments.

Conclusions Locally delivered curcumin gel improved the healing outcome of SRP in smokers, represented by a significant reduction in the gingival and plaque indices scores and a greater CAL gain compared to the mechanical debridement alone.

KEYWORDS: Curcumin, local delivery gel, periodontitis, smoking, SRP, clinical attachment loss

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INTRODUCTION

Periodontal disease severity is increased in smokers with less favourable response to the non-surgical periodontal therapy in contrast to non-smokers [1].

Smoking influences the onset and progression of periodontitis and has been correlated with higher attachment loss, deeper periodontal pockets, marked radiographic signs of furcation involvement, and enhanced alveolar bone destruction. Tobacco smoking negatively influences periodontal tissue via multiple factors including vasoconstriction in peripheral blood vessels and locally within gingival tissues, in addition to decreased gingival perfusion. Furthermore, it affects the circulating levels of immune-inflammatory cells in the crevicular fluid, and causes alterations in host bacterial interactions as the dysbiosis microbiota shows a higher prevalence of e.g., B. forsythus and P. gingivalis. It is also associated with impaired healing and fibroblast function [2, 3].

Non-surgical periodontal therapy remains the gold standard treatment for chronic periodontitis as it focuses on eliminating the main etiological factors of periodontal disease. Recently, several chemical agents used as an adjunct to mechanical methods. Curcumin is derived from the turmeric plant Curcuma longa L. which possesses potent antibacterial, antioxidant, and anti-inflammatory properties while causing minimal allergic reaction[4, 5, 6].

Meanwhile, clinical trials indicate that local delivery of curcumin enhances periodontal parameters of non-surgical periodontal treatment (NSPT) permitting greater concentrations at the diseased site while minimizing potential side effects associated with systemic administration [7, 8, 9].

The utilization of curcumin as a local adminstration in combination with NSPT plays a pivotal role in anti-inflammatory properties, as it works to inhibit pro-inflammatory cytokines, reducing the prostaglandin biosynthesis, inhibiting protein expression of cyclo-oxygenase-2 throughout suppression of NF-kB activation [10, 11]. In addition, curcumin can suppress the proliferation of A. actinomycetemcomitans, F. nucleatum, and P. gingivalis periodontal pathogens and the formation of dysbiotic biofilms [12].

To enhance the effectiveness of conventional periodontal therapy for smokers, numerous studies have suggested the incorporation of adjunctive treatment approaches, such as systemic or local antimicrobials and anti-inflammatory agents [13, 14]. Nevertheless, there are currently no published studies assessing the conventional use of locally administered curcumin gel in combination with scaling and root planning (SRP) demonstrating its effectiveness to enhance smokers' periodontal health. As a result, this trial aimed to compare scaling and root planing alone and subgingival curcumin local delivery in combination with scaling and root planning alone for managing stage II grade B periodontitis in current smokers.

SUBJECTS, MATERIAL AND METHODS

Study design

A uni-center, double blinded, randomized controlled clinical trial was the design of the current study. The study protocol was registered on ClinicalTrials.gov (ID: NCT06653231) and approved by Cairo University's Faculty of Dentistry's Ethics Committee of Scientific Research (521024).

Study settings

Thirty smokers between the ages of 28 and 50 participated in this study were recruited from outpatient clinic of Periodontology Department, Faculty of Dentistry. Modern University for Technology and Information, Cairo, Egypt.

Inclusion criteria were: 1) Patients diagnosed with stage II grade B periodontitis. 2) Current smoker less than 10 cigarettes/day. Exclusion criteria were: 1) No surgical or nonsurgical periodontal therapy within the last 6 months. 2) Presence of

overhanging restorations. 3) Endo-perio lesions. 4) Treatment with antibiotics throughout the last three months. 5) Systemic disease history, cardiovascular diseases, diabetes mellitus, hypertension, bleeding disorders, hyperparathyroidism, compromised medical conditions, pregnancy and lactation.

Before the commencement of the research, all participants received explanations on the study procedure, expected hazards, intervention benefits, and follow-up period and requested to sign an informed consent.

Randomization and Masking

Eligible patients that were recruited were randomly divided in equal proportions (1:1) into the control group (fifteen patients received full-mouth SRP only) and study group (fifteen patients received full-mouth SRP followed by local delivery of curcumin gel). Allocation "sequence generation" was done by using a software program to divide patients randomly. Patients and the clinical examiners evaluating the outcomes were masked to the treatment allocation.

Interventions

The control group of fifteen periodontitis patients were treated with full-mouth supragingival and subgingival SRP only. The regular self-performed oral hygiene instructions for plaque control were advised to use a regular flossing, soft toothbrush twice daily by 'roll-on brushing technique' for a minimum of 2 minutes.

The test group of fifteen patients received full-mouth supragingival and subgingival SRP followed by local delivery of 2% curcumin gel.

Curcumin gel preparation was carried out at Ain Shams University's Faculty of Pharmacy, Pharmacology Department. The curcumin gel was prepared using the simple dispersion approach. Overnight, Carbopol 940 was submerged in filtered water that contained 0.2% w/v sodium benzoate. Using a tissue homogeniser, a solution of hydroxypropyl methylcellulose (HPMC) was combined with propylene glycol for local medication delivery.

Curcumin gel was locally administered in the periodontal sites using a disposable wide port needle syringe after the test site was totally isolated with cotton rolls to prevent saliva from contaminating the drug [15, 16].

Weekly follow-up recalls were conducted after gel application to reinforce oral hygiene measurements following gel administration. The locally administrated curcumin gel was applied once after completing SRP at the baseline visit.

Periodontal assessment

Clinical attachment level (CAL): The distance between the CEJ and the pocket base was used to calculate the CAL. The UNC-15 (Hufriedy-USA) periodontal probe was utilised to record the reading to the closest millimetre [17]. The CAL in the control and study groups were recorded at baseline and again checked at 30th and 45th day.

Gingival Index (GI): Each patient's gingival status was assessed and recorded from the six sites (mesiobuccal, midbuccal, distobuccal, mesiolingual, midlingual and distolingual) per tooth using a UNC-15 periodontal probe (Hu-Friedy, Chicago, IL, USA).

Regarding the gingival index, the assessment of bleeding was acheved by gently probing the soft tissue wall of the gingival sulcus. The following factors are used to determine the GI score: Score 0 (normal gingiva and no inflammation), 1 (mild inflammation with a slight change in colour, oedema, and no bleeding on probing), 2 (moderate inflammation with redness, oedema, glazing or bleeding on probing), and 3 (severe inflammation with marked redness, hypertrophy and a tendency toward spontaneous bleeding and ulceration). [18]

Plaque index (PI): PI was used to evaluate plaque accumulation. The PI received the following

scores : Score 0 indicates the absence of plaque, Score 1 indicates a thin film of plaque that adheres to the free gingival margin and adjacent area of the tooth, which is only visible with the use of disclosing solution or probe, Score 2 indicates a moderate buildup of soft deposits in the gingival pocket, on the gingival margin and/or tooth surface, that is visible to the naked eye, Score 3 indicates an abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin. [19]

A UNC 15 periodontal probe (PCPUNC-15, Hu-Friedy, Chicago, IL, USA) was used to assess each periodontal measurement separately for the entire mouth. Clinical parameters were carried out by a single periodontist who was blinded to control and test groups, blinded to the therapies, and clinical parameters assessments at baseline and posttreatment follow-up. GI and PI were evaluated at baseline before the local drug delivery (T0), and reevaluated at 30 days (T1), and 45 days (T2).

Data analyses

Sample Size Calculation

Depending on a prior study by **Abdel-Fatah et al.,** [20] as a reference, the sample size was calculated. To evaluate the effect of curcumin gel in addition to scaling and root planing on the smoker patients in two main groups (Group I and Group II) at three measurement points (Baseline, 30 days, and 45 days), One-way analysis of variance (ANOVA), a post hoc test, or an equivalent non-parametric test were used to statistically analyse the results. The Pearson's correlation coefficient (r) test was performed to correlate various parameters.

With a power (1-β=0.90), a minimum of 30 samples were required to detect the effect size of 0.25, with a power analysis (1-β=0.90) at a significant probability level of $p \leq 0.05$ to compare the different clinical parameters in the two studied groups. According to sample size calculations, there is a 90% chance of correctly rejecting the null hypothesis of no significant effect if 15 samples represent each group. In accordance with G*Power software version 3.1.9.7, the sample size was determined.

Statistical Analysis

1. **Shapiro-Wilk Test**: This is generally preferred for smaller sample sizes (n<50) like this study with 15 participants per group. It tests the null hypothesis that the data is normally distributed. The null hypothesis, according to which the data is regularly distributed, is tested.
2. **One-Way Analysis of Variance (ANOVA)**: Used to evaluate differences in gingival index, plaque index, and clinical attachment loss within each group across different time points (baseline, 30 days, and 45 days).
3. **Tukey's Post Hoc Test**: After an ANOVA, Tukey's Post Hoc Test was used to determine which specific time points significantly differed from each other within each treatment group (indicated by letters A, B, and C in the tables).
4. **Independent t-test**: Used to compare differences and variations between the control group (SRP alone) and test group (SRP + curcumin) at each measurement time point.

RESULTS

The baseline characteristics demonstrate that both the SRP control group and SRP + Curcumin test group were well-matched demographically. With mean ages of 40.07 and 40.13 years respectively, there was essentially no meaningful age difference between groups. Gender distribution showed a strong male predominance in both groups (93.33% in control vs. 86.66% in test), with only minimal female representation. This demographic similarity is important as it reduces the risk of confounding variables influencing the treatment outcomes, allowing for more reliable conclusions about the effectiveness of the curcumin intervention. **(Table 1)**

Table 2 reveals important trends in gingival index (GI) measurements across both groups. At baseline, both groups started with comparable

GI scores (2.600vs. 2.400, p=0.5868), indicating similar levels of gingival inflammation before treatment. As treatment progressed, both groups displayed statistically significant improvements over time (p<0.0001 for both groups). However, the key finding appears at the 45-day mark, where the test group (SRP + Curcumin) demonstrated a significantly better reduction in GI (0.8000) compared to the control group (1.400), with a statistically significant difference (p=0.0027). This suggests that the addition of curcumin gel provided enhanced anti-inflammatory effects on gingival tissues compared to SRP alone, particularly in the longer term. **(Figure.1)**

In **Table 3**, the analysis of plaque index data follows a pattern similar to the gingival index. Both groups started with comparable baseline plaque scores (2.800 vs. 2.600, p=0.5611) and showed significant improvements over the period of the trial (p<0.0001 for both groups). While differences at 30 days approached but did not reach significance (p=0.0596), by day 45, the test group demonstrated significantly lower plaque accumulation (0.6000) compared to the control group (1.200), with a p-value of 0.0019. This suggests that the curcumin gel may provide additional benefits in plaque control beyond what mechanical debridement alone can achieve, possibly through its antimicrobial properties or by modifying the oral environment to be less conducive to plaque formation. **(Figure.1)**

In **Table 4**, the clinical attachment loss (CAL) data reveals interesting differences in treatment response patterns. While both groups started with comparable baseline CAL values (3.600 vs. 3.400, p=0.5929), the test group shown an improvement over time that was statistically significant (p<0.0001), whereas the control group's improvement over time was not statistically significant (p=0.0126, marked as NS). Additionally, significant differences between groups emerged at both the 30-day (p=0.0168) and 45-day (p=0.0030) assessments, with the test group showing better outcomes. **(Figure.1)** This suggests that curcumin gel may provide meaningful benefits for periodontal attachment, potentially through enhanced tissue healing or reduced inflammation, which is particularly noteworthy as CAL improvements are generally more challenging to achieve than improvements in more superficial parameters like GI or plaque index.

TABLE (1) Baseline characteristics of age and gender:

		Group A SRP alone (Control Group)	Group B SRP +Curcumin local delivery (Test Group)
Age (M±SD)		40.07±6.871	40.13±7.019
Gender	Male	14 (93.33%)	13 (86.66%)

TABLE (2) One Way ANOVA analysis of baseline, 30 and 45 days follow up of gingival index followed by Independent t-test between control and test groups:

	Group A SRP alone (Control Group)	Group B SRP +Curcumin local delivery (Test Group)	P-value 2
Baseline	2.600±0.5071 A	2.400±0.5071 A	0.5868 NS
30 Days	1.800±0.4140 B	1.400±0.5071 B	0.0716 NS
45 Days	1.400±0.5071 B	0.8000±0.4140 C	0.0027*
P-value 1	<0.0001*	<0.0001*	

M; Mean, SD; Standard Deviation, P1; Using One Way ANOVA, P2; Using Independent t-test
Means with same letters in the same column were insignificant different using Tukey's post hoc test
Means with different letters in the same column were significant different using Tukey's post hoc test
NS; Insignificant difference *; significant difference

TABLE (3) One Way ANOVA analysis of baseline, 30 and 45 days follow up of plaque index followed by Independent t-test between control and test groups:

	Group A SRP alone (Control Group)	**Group B SRP +Curcumin local delivery (Test Group)**	**P-value 2**
Baseline	2.800±0.4140 A	2.600±0.5071 A	0.5611 NS
30 Days	1.800±0.4140 B	1.400±0.5071 B	0.0596 NS
45 Days	1.200±0.4140 C	0.6000±0.5071 C	0.0019*
P-value 1	**<0.0001***	**<0.0001***	

M; Mean, SD; Standard Deviation, P1; Using One Way ANOVA, P2; Using Independent t-test
Means with same letters in the same column were insignificant different using Tukey's post hoc test
Means with different letters in the same column were significant different using Tukey's post hoc test
NS; Insignificant difference
****; significant difference***

TABLE (4) One Way ANOVA analysis of baseline, 30 and 45 days follow up of clinical attachment loss followed by Independent t-test between control and test groups:

	Group A SRP alone (Control Group)	**Group B SRP +Curcumin local delivery (Test Group)**	**P-value 2**
Baseline	3.600±0.5071 A	3.400±0.5071 A	**0.5929 NS**
30 Days	3.100±0.5071 B	2.600±0.3873 B	**0.0168***
45 Days	3.100±0.5071 B	2.500±0.4629 B	**0.0030***
P-value 1	**0.0126 NS**	**<0.0001***	

M; Mean, SD; Standard Deviation, P1; Using One Way ANOVA, P2; Using Independent t-test
Means with same letters in the same column were insignificant different using Tukey's post hoc test
Means with different letters in the same column were significant different using Tukey's post hoc test
NS; Insignificant difference ****; significant difference***

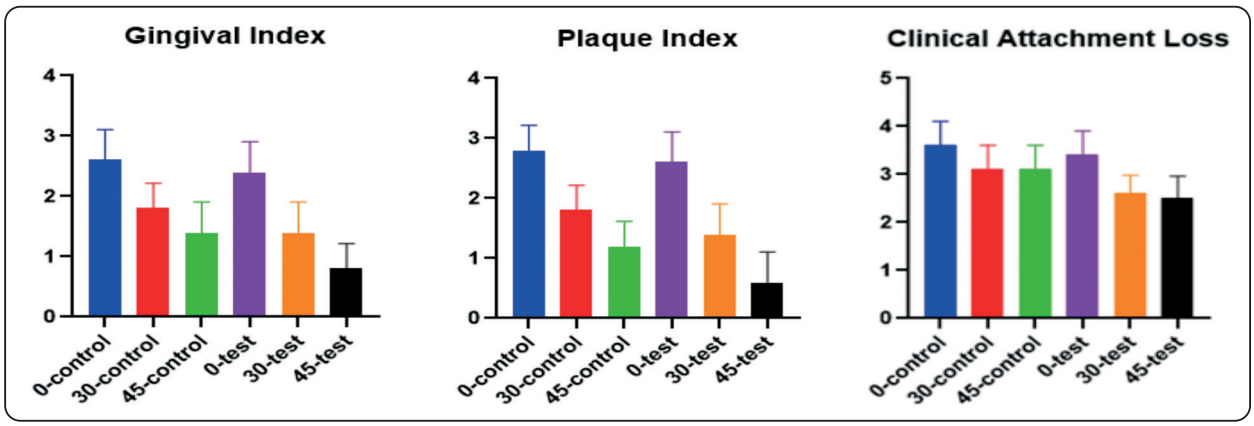

Fig. (1) Bar Charts of gingival index, plaque index and clinical attachment loss between control and test groups

DISCUSSION

Several systematic reviews [5, 11, 21, 22] aimed to investigate the effectiveness of curcumin and demonstrated an effective reduction in most clinical indices following curcumin + SRP. However, there was no information available regarding its effect on smoker patients.

This clinical trial assessed the impact of curcumin on the improvement of surrogate variables such as gingival indices and clinical attachment level after non-surgical management of periodontal disease in smokers with periodontitis. The true outcome variable, such as tooth loss is not assessed and is not a feasible variable in short-term clinical trials [6].

In this study, our hypothesis tested smoking as it is the main risk factor for periodontitis and a major reason for the increase in tooth loss rates [23]. It is also included in the periodontitis classification, and periodontitis grade is directly modified by the smoking status and the number of daily cigarettes used [24]. Compared to non-smokers, smokers are more likely to experience the progression of periodontal disease and typically react less favourably to non-surgical periodontal treatment [25, 26].

In the current research, grade B periodontitis was selected because there is usually a dose-response relationship between the cigarette consumption and its detrimental effects on periodontal disease.

The results of the present trial demonstrated that locally delivered curcumin gel used as an adjunct to mechanical non-surgical debridement in the treatment of periodontitis offered more improvement in the treatment outcome and showed statistically significant difference compared to mechanical debridement alone.

In the current study, gingival index outcome within the SRP control group and among the SPP followed by the curcumin group showed statistically significant improvements over time, this can be attributed to the meticulous mechanical debridement during initial therapy, and the reinforcement of oral hygiene measurements that was provided repeatedly in the regular recalls [27]. This is in line with previous studies that demonstrated significant reduction from baseline to 45 days [10, 28].

In the present study, gingival index score reduction was better in the curcumin group in contrast to the SRP group at all the follow-up periods but statistically significant GI reduction was found in 45 days between groups. This is because curcumin inhibits inflammatory mediators on gingiva, particularly the release of thromboxane and prostaglandin E2 [12]. Similar findings have been reported by multiple studies [15, 29-31] that were observed statistically significant difference with curcumin with SRP as compared to SRP alone. However other studies showed contrasting results, [32] non-statistically significant reduction was remarkable in GI at baseline and 30 days or baseline on 45 days.

Also, **Guru et al** [28] revealed non-significant difference in the intergroup comparison in clinical scores compared at baseline and 21 and 45 days. Moreover, **Rahalkar et al.** [10] that shows greater reduction in the values of GI, but statistically insignificant in curcumin group than in SRP group on 30th day post treatment.

In this trial, plaque index reduction was better in the curcumin gel group as compared to solely conventional phase I therapy group during all the follow-up periods, this was similarly observed in previous studies by **Dave et al., Ravishankar et al. and Pandey et al** [31, 33, 34]. The greater significant reduction of PI score with curcumin use than SRP alone in our study could be due to the anti-plaque and anti-biofilm properties of curcumin; as curcumin inhibits formation and disperses of the dysbiotic biofilm.

In the current study, differences in PI at 30 days did not reach significance; however, by day 45, the test group revealed statistically significantly

lower plaque accumulation (0.6000) compared to the control group (1.200). This result was contrary to **Raghava et al.,** [30] who stated a statistically significant decrease in PI after 30 days of curcumin application. Findings are also not in agreement with **Rahalkar et al** [10] whose results displayed a statistically significant difference in PI at the 30th day post-treatment (P = 0.007), implying that LDD with curcumin is more effective in plaque reduction compared to SRP alone.

In the current study, CAL in the curcumin and SRP group, showed statistically significant improvement over time, rather than the SRP alone group which showed improvement over time that is non-statistically significant. This could be due to that curcumin application helps accelerate wound healing [5]. Also, this study's results coincided with **Fulbel et al., Raghava et al., and Ravishankar et al.,** [4, 30, 34] that showed CAL was significant in intra-curcumin group. On the contrary, **Guru et al.,** [28] did not show statistical significance.

The efficacy of 2% curcumin local delivery gel can be employed to reduce the impact of smoking on periodontitis. However, further studies are necessary to investigate the use of curcumin with a larger sample size, longer follow-ups, frequent application, different concentrations and various drug delivery routes.

CONCLUSIONS

Within this study's limitations, it could be concluded that smoker patients who received local delivery of 2% curcumin gel in conjunction with SRP in periodontitis Stage II grade B patients showed additional clinical improvement as measured by GI, PI, and CAL compared with patients who did not receive a curcumin gel.

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