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MANAGEMENT OF MODERATE PERIODONTITIS USING TEA TREE OIL GEL. A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

INTRODUCTION: Conventional periodontal therapy is an effective line of treatment for moderate periodontitis patients. Act of adjunctive use of other biomaterials assist in increasing the success of this therapy. One of these adjunctive treatments is the use of tea tree oil (TTO) as a locally delivered agent.

OBJECTIVE: The present work aims to assess clinically the effect of intra pocket application of TTO gel in patients with moderate periodontitis.

MATERIALS AND METHODS: this randomized controlled clinical trial was performed on a total number of thirty pockets in thirty patients with moderate periodontitis. They were classified into a control group which comprised fifteen patients treated with scaling and root planing SRP only and a test group which comprised fifteen patients treated with SRP and locally delivered TTO gel. The clinical parameters measured were: Probing pocket depth, clinical attachment level and bleeding upon probing. These were evaluated from baseline examination to three months follow-up.

RESULTS: The clinical parameters showed improvement in the test group when compared to control group.

CONCLUSION: The local delivery of TTO gel in conjunction with conventional periodontal treatment in moderate periodontitis is more effective than SRP therapy alone.

KEY WORDS: Clinical attachment level, local drug delivery, moderate periodontitis, scaling and root planning, Tea tree oil gel.

RUNNING TITLE: Locally delivered TTO gel in moderate periodontitis

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INTRODUCTION

Periodontitis is a chronic inflammation of the periodontium which may lead to loss of the periodontal attachment, increase of the periodontal probing pocket depth, and bone loss. It results from the homeostatic imbalance between the oral microbiota and the host modality to these microorganisms (1).

The proceedings of the World Workshop on the Classification of Periodontal and Peri-implant Diseases and Conditions classified periodontitis into four stages according to the severity and complexity of the treatment. The different stages are initial periodontitis, moderate periodontitis, severe periodontitis with potential for loss of teeth and part of dentition, and severe periodontitis which can lead to total loss of all the dentition. It also includes three grades which depend on the rate of progression and predicted treatment response. Grade A indicates slow progression, grade B moderate progression, and grade C rapid progression (2).

Accurate diagnosis can assess the severity and level of activity of periodontitis leading to the correct treatment plan. There are several diagnostic procedures such as periodontal probing pocket depth, assessment of mobility, bleeding upon probing, plaque index and using radiographs to assess alveolar bone level (3).

The important role of periodontal management is to prevent disease progression and to overcome and resolve inflammation (4). Mechanical debridement is the first approach, but many studies have proved that mechanical debridement alone cannot eliminate most of the causative micro-organisms and it is related to high recurrence rate (4,5).

The systemic use of antibiotics to treat moderate periodontitis, to prevent or kill periodontal pathogens can be used as an adjunct to conventional therapy of SRP (6).

However, side effects of systemic antibiotics such as toxicity, resistance, sensitivity, growth of opportunistic infection, and interaction with other medications were recorded (5). Therefore, the use of antimicrobials locally may provide a good solution to overcome those complications (7).

Locally delivered drugs result in high drug levels in the periodontal pocket, which can reach the periodontal

tissues as well. This dual effect on pocket micro flora may provide 100‑fold higher therapeutic doses of the agent in sub gingival areas than systemic therapy. It also results in enhancement of clinical parameters without systemic side effects (8).

Many pharmaceuticals used today are from natural products (9). Herbal medicines are tested for their effects on periodontitis, in addition to their antibacterial, anti‑inflammatory effects and their ability to regenerate periodontal tissue (10,11).

Tea tree oil (TTO) is a herbal drug that has antimicrobial, anti‑inflammatory, antifungal, antiviral, and antioxidant effects (12-15). Studies showed useful effects of local delivery of this product in the management of periodontal diseases (11,16,17).

The most important active components of TTO are 1,8-cineole and terpinen-4-ol. These components are common herbal essential oils similar to eucalyptus and fennel oil. 1,8-cineole has anti-inflammatory properties (16,18), and is able to penetrate human skin (19). Terpinen-4-ol has the same properties of 1,8-cineol as an anti-bacterial and anti-inflammatory (14,20-24).

Administration of TTO demonstrated the same antimicrobial properties as chlorhexidine (CHX), with different mechanisms of action. It also has the same antibacterial, antiviral and antifungal properties (21,24-27).

The current study was done to assess the effect of local application of TTO gel as an adjunctive treatment in the management of moderate periodontitis.

The null hypothesis of this research is that there is no superior benefit of topical application of TTO gel in management of moderate periodontitis in non-surgical treatment of periodontal pockets.

MATERIALS AND METHODS

Study overview (design)

The current study is a randomized clinical trial conducted according the CONSORT guidelines (28). (Figure 1)

It was performed on thirty patients, classified into two groups (test and control groups) with moderate periodontitis. The first group (control group) comprised fifteen patients treated with SRP only and the second group (test group) comprised fifteen patients treated with SRP and local delivered TTO gel.

All patients were diagnosed at the outpatient clinic in the Oral Medicine, Periodontology, Oral Diagnosis and Radiology Department, Faculty of Dentistry, Alexandria University, Egypt. All subjects agreed to participate in the clinical trial and signed a written informed consent. Ethical approval was obtained from the Research Ethics Committee at the Faculty of Dentistry, Alexandria University, Egypt (IRBNO: 00010556- IORG:0008839). Helsinki guidelines (2013) for conduct of clinical trials on humans were also followed (29,30).

Eligibility was determined by conducting periodontal evaluation at baseline screening visits to evaluate disease status, periodontal and medical treatment history. Subjects were diagnosed with moderate periodontitis, if they presented with periodontal pocket depth between ≥5 mm and ≤7 mm and CAL was between 3 and 4 mm). All cases showed bleeding on gentle probing (31).

The patients were not accepted in this study if they suffered from any systemic disease or were under any medications. Smokers, pregnant or lactating women were excluded from the study. Also, patients receiving chemotherapeutics during the past six months were excluded.

Preparation of the gel

The gel used as a local sub gingival application was prepared by the Department of Pharmaceutics, Faculty of Pharmacy, Alexandria University. The gel was prepared by soaking 1% Carbopol 940 in distilled water for 2 hours. TTO (Sigma Aldrich® Steinheim, Germany) was dissolved in an appropriate amount of propylene glycol mixed with the Carbopol dispersion. Methyl paraben 0.2% was dissolved in preheated water. The mixture was made from water which was then magnetically stirred for 30 minutes. The pH was controlled with 1N NaOH added drop wise with gentle stirring with a spatula until the desired pH value (6.5-7) was reached. The gel was sterilized by autoclaving at 110°C for 20 min.

Treatment procedure

At baseline examination and at three months follow-up evaluation, measurements of PPD, bleeding upon probing, and CAL were made (32).

Measurements were made at six points in each tooth:

Periodontal pocket depth was read by using a graduated periodontal probe. (Figure 2)

At the disto-buccal line angel, mesio-buccal line angel, mid buccal region, disto-lingual line angel mesio-lingual line angel and mid-lingual region. Scaling and root planing were done using manual and ultrasonic scalers and curettes in both groups (Figure 3).

Coronoplasty was done when required and a proper oral hygiene instructionsl were given to patients in both groups.

Application of the gel

After the isolation for the test quadrant, the gel was applied by a bent, blunt-ended needle syringe. The needle was carefully inserted in the periodontal pocket and the gel was injected to fill the selected pocket till the gingival margin and the excess gel was removed then periodontal pack was placed at test sites. (Figure 4)

Patient instructions

Patients were instructed to follow strict oral hygiene measures during the study period. They were also asked not to use the toothbrush at selected site after TTO gel application for 24 hours and not to chew hard or sticky foods at the gel placement sites.

On the subsequent recall visits, no adverse effects were recorded. No probing was made prior to three months in order not to disrupt healing.

Statistical method

Data were sent to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp).

The Kolmogorov-Smirnov test was used to measure distribution and normality. Chi-square test for

categorical variables, to compare between different groups. Fisher's Exact Correction for chi-square when more than 20% of the cells have expected count less than 5. Student t-test for normally distributed quantitative variables, to compare between two studied groups. Mann Whitney test for abnormally distributed quantitative variables, to compare between two studied groups. Friedman test for abnormally distributed quantitative variables, to compare between more than two periods or stages and Post Hoc Test (Dunn's) for pairwise comparisons.

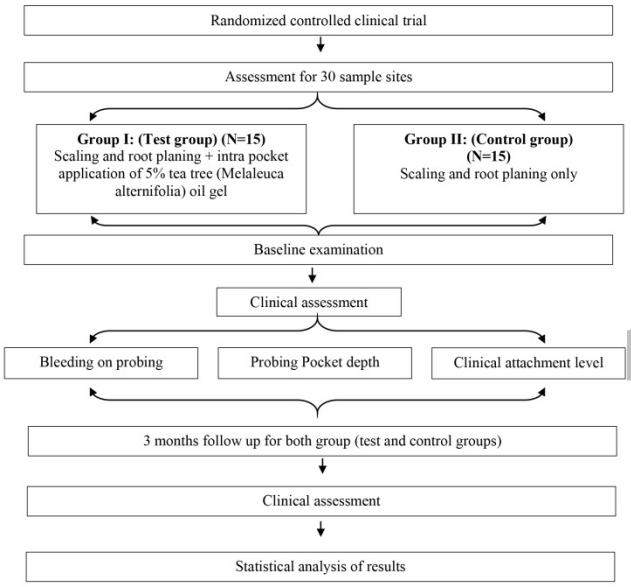

Figure (1): Consort Flow chart

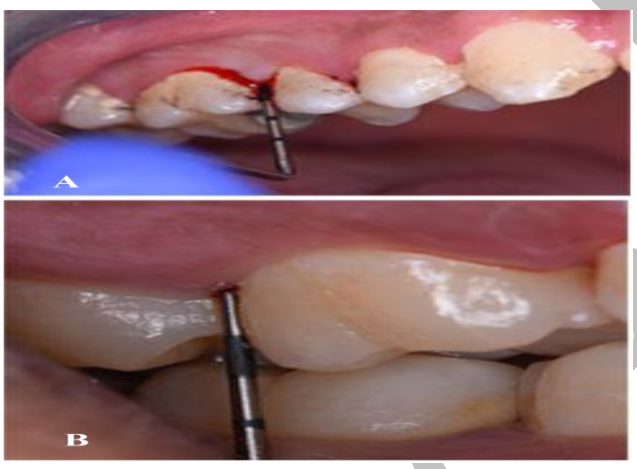

Figure (2): Clinical measurement of probing pocket depth by periodontal graduated probe (mm)

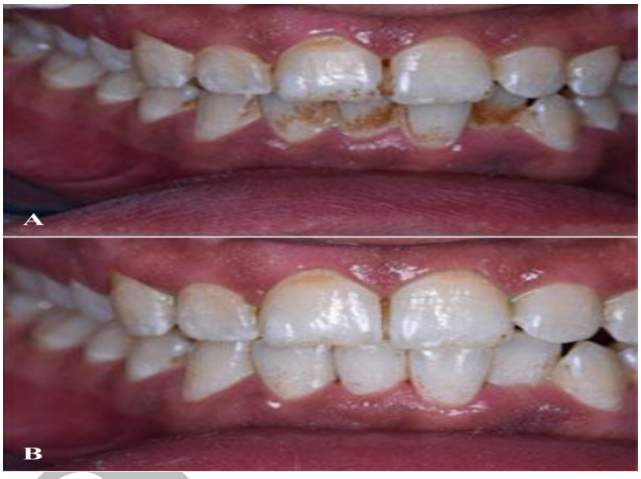

Figure (3): A case of moderate periodontitis before and after scaling and root planing.

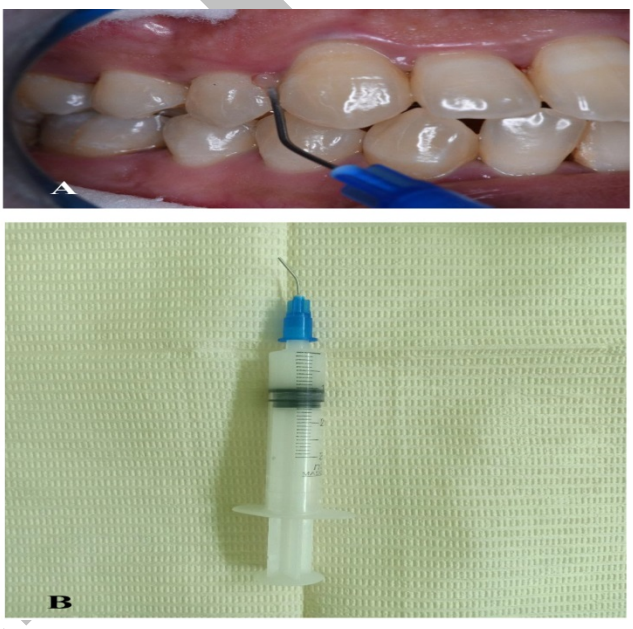

Figure (4): Sub gingival local delivery of tea tree oil gel after SRP in a periodontal pocket (mm).

RESULTS

Probing pocket depth (in mm)

No statistically significant difference was seen among the two groups at both baseline examination and after three months at follow up period (P=0.775, P=0.137)

The mean PPD was reduced during the test period in both groups and showed significant decrease (P_1=0.002, P_1=0.016). (Table 1, Figure 5).

Clinical attachment loss (in mm)

No statistically significant difference was seen between the two groups at both baseline examination and after three months (P=0.539, P=0.174).

The mean CAL was reduced from baseline examination to three months follow up and the difference was statistically significant (P_1<0.001, P_1=0.001). (Table 1, Figure 5)

Bleeding on probing (BOP)

There was no statistically significant difference between the two groups at baseline examination (p=0.318) but it became statically significant when we followed the candidates at three months follow up. (P=0.005) (Figure 5)

Bleeding on probing was reduced during the test period and showed significant decrease in test group more than control group. (P_1<0.001). (Table 1, Figure 5)

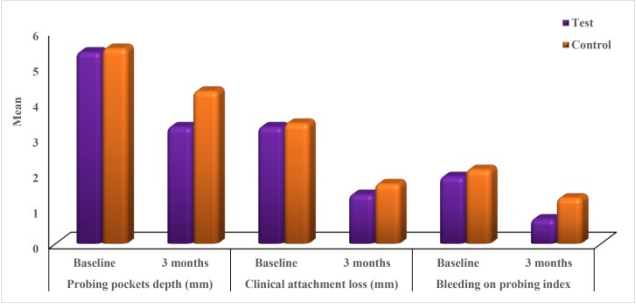

Figure (5): Comparison between the two groups based on the different clinical measurements

Table (1): Comparison between the two groups according to clinical measurements

		Test (n = 15)	Control (n = 15)	Test of Sig.	
Probing pockets depth	Baseline				
	Mean ± SD.	5.4 ± 1.1	5.5 ± 1.1	U = 105.5	.775
	Median (Min. – Max.)	6 (3 – 6)	6 (3 – 6)		
	3 months				
	Mean ± SD.	3.3 ±0.6	3.3 ±1.5	U = 76.50	.137
	Median (Min. – Max.)	3 (2 – 4)	4 (2 – 6)		
	^{z}p	0.002*	0.016*		
Clinical attachment loss (mm)	Baseline				
	Mean ± SD.	3.3 ±0.5	3.4 ±0.5	U = 97.50	.539
	Median (Min. – Max.)	3 (3 – 4)	3 (3 – 4)		
	3 months				
	Mean ± SD.	1.4 ±0.5	1.7 ±0.6	U = 79.50	.174
	Median (Min. – Max.)	1 (1 – 2)	1 (1 – 3)		
	^{z}p	< 0.001*	0.001*		
Bleeding on probing	Baseline				
	Mean ± SD.	1.9 ± 0.6	1 ± 0.5	t = 1.016	.318
	Median (Min. – Max.)	2 (1 –2.8)	2 (1.1 – 2.8)		
	3 months				
	Mean ± SD.	0.7 ± 0.5	1.3 ± 0.4	t = 3.083*	.005*
	Median (Min. – Max.)	0.8 (0 – 1.8)	1.2 (0.5 –2)		
	^{t}p	< 0.001*	<0.001*		

U: Mann Whitney test **t: Student t-test**
p: p value for comparing between the studied groups
^{z}p: p value for **Wilcoxon signed ranks test** for comparing between **before** and **3months**
^{t}p: p value for **Paired t-test** for comparing between **before** and **3months**
*: Statistically significant at p ≤ 0.05

DISCUSSION

In the current study, locally delivered TTO gel showed to be an effective agent in the treatment of moderate periodontitis. Patients did not report any complications during the study period except for the bad taste of the tea tree oil which was the only complaint from the patients. All patients received conventional periodontal therapy. The test group received intra pocket application of TTO gel in addition to nonsurgical periodontal therapy.

The current study showed a statistically significant decrease in bleeding upon probing and gingival inflammation, which was maintained through the study period in a test group. All groups should show reduction in BP due to SRP and good maintenance. At three months test group may be due to the anti-inflammatory and antibacterial effect of TTO gel. TTO disrupts the microbial membrane structures by changing their permeability (26).

The TTO gel formulation in the present study is similar to the gel preparation in the study by Elgendy et al. (17), which was performed to assess tea tree oil effect on chronic periodontitis. The gel significantly reduced inflammation and bleeding of the gingiva in people with chronic periodontitis. These results are consistent with our current study.

The TTO gel used in the present study also had sustained release properties.

These results are in line with the study conducted in by Soukoulis and Hirsch (11). In the before mentioned work TTO gel was used two times as a dentifrice per day. Gingival inflammation and bleeding index were reduced in patients with severe gingivitis and in those with moderate periodontitis.

In addition, improvement in gingival inflammation due to the anti-inflammatory activity of TTO has been also reported in other studies (14,20). Furthermore, the anti-inflammatory action of TTO

function is to promote superoxide production by human monocytes (14).

Decrease in PPD and improvement in CAL were especially noted in the test group because of reduction in inflammation due to alteration in the sub gingival bacteria (33). In addition the reduction of local factors by scaling may also enhance a local and systemic host response that would aid in promoting the healing process (34).

However, there was no statistically significant difference in PPD between the test and control group in our results at both baseline examination and after three months follow up (P=0.775, P=0.137) with respect to which variable. The mean PPD was reduced significantly from baseline examination to three months follow-up in individual groups. The reduction in probing pocket depth could be because of the proper oral hygiene measures after SRP. This is in contrast with the study conducted by Arweiler et al. (35), who demonstrated reduction of plaque formation after using tea tree oil in a mouthwash. They found that PPD in the group treated by TTO gel did not differ significantly from patients treated with SRP only during the study period.

In the current study, the mean PPD and CAL were significantly reduced, but this improvement was recorded as higher in the test group in comparison to the control group at three months follow up. Arweiler et al. (35), and Saxer et al. (36), found that TTO had an effect in reducing the oral micro biota. Furthermore, the component of TTO has lipophilic properties that diffuse through epithelium it is proved the anti-inflammatory effect of TTO (19).

CONCLUSIONS

The results of the study demonstrate that locally delivered TTO gel provides better therapeutic effects than SRP alone. It also proves the efficacy of TTO as an anti-inflammatory agent, which reduces the pro-inflammatory process and enhances the healing process of periodontal tissues.

Conflict of Interest

The authors declare that they have no conflict of interest.

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