Comparative Clinical Efficacy of Murrayakoenigii Gel and Chlorhexidine Gluconate Gel for Improvement of Oral Health

Abstract:

Introduction: Gingivitis is a non-destructive, plaque induced disease that causes inflammation of the gums. Chlorhexidine is regarded as the gold standard agent due to its chemical substantivity and clinical efficacy in chemical plaque control. Nowadays, herbal products are widely substituting synthetic antimicrobials due to their minimal side effects and cost effectiveness. Murrayakoenigii (curry leaf) is an easily available green leaf in the Indian subcontinent, known for its antimicrobial, antioxidative, and cytotoxic activity.

Objective: This study was aimed to evaluate the effectiveness of M. koenigii gel in reduction of plaque and gingivitis when compared with commercially available Chlorhexidine (Hexigel) gel.

Materials and Method: This single center, randomized controlled clinical trial was carried out among 40 participants with moderate gingivitis. After scaling, they were divided into two groups: Group I (control) and Group II (Test) [n=20] and were instructed to use Chlorhexidine gel and M. koenigii gel respectively. Clinical parameters (PI & GI) were recorded on baseline and 15 days later. Student's paired t-test and independent-test were used for intra and intergroup comparison of clinical parameters.

Results: On intra-group comparison, both the groups showed a statistically significant difference (P = 0.001). Inter-group comparison, showed no statistically significant difference between the two groups. (P > 0.05)

Conclusion: M. koenigii gel is equally effective as Chlorhexidine gel, in treating plaque induced gingivitis.

Key-words: Gingivitis, Murrayakoenigii, Chlorhexidine gel.

Introduction:

Dental plaque is the major etiological factor for two common oral disease conditions, dental caries and periodontal diseases. Plaque control is considered as the cornerstone of good oral hygiene and it includes mechanical and chemical measure. However, even the most meticulous patient may not always be able to completely remove all plaque.

Chemical plaque control is an ideal adjunct to mechanical therapy in the treatment of gingivitis. Antibacterial chemicals such as chlorhexidine (CHX) have been successfully prescribed in the prevention and treatment of gingivitis. CHX is considered as the gold standard due to its chemical substantivity and clinical efficacy in chemical plaque control. However, compliance to CHX is diminished by various side effects; the most vital of those are discoloration of teeth and alteration of taste. Hence, there is a need of an alternate

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substitute that can provide a product which is well accepted within the Indian community and which could also be safe and economical for the everyday layman.

Murraya koenigii (curry leaf) is a green leafy vegetable, which is known for their antimicrobial, antiemetic, antidiabetic, antiulcer, antioxidative, cytotoxic, and phagocytic activity. Experimental studies have shown an effective reduction in levels of halitosis by orally chewing fresh curry leaves for 5 min and rinsing the mouth with water.

To the best of our knowledge, no other clinical study has reported evaluating the clinical efficacy of *M. koenigii* as a gel in the treatment of gingivitis. The objective of this study was to evaluate the effectiveness of 3% M. Koenigii gel in reduction of plaque & gingivitis and to compare with commercially available gold standard 1% Chlorhexidine gel.

Materials and Method:

This Single-centered randomized controlled clinical trial included a total of 40 subjects within the age group of 20–50 years who reported to the outpatient department of Periodontics, Pacific Dental College and Hospital, Udaipur, Debari from August 2019 to October 2019.The study protocol was approved by the ethical committee. The inclusion criteria for participants were as follows: Systemically healthy individuals and participants within the age group of 16–50 years, with minimum 20 teeth and subjects with moderate gingivitis (GI ≤ 2).The exclusion criteria for participants were as follows: patients using nonsteroidal anti-inflammatory drugs and antibiotics in the past 3 months, those who underwent scaling in the past 6 months, patients with prosthetic or orthodontic appliances and allergy to active ingredients.

The individuals were assigned to two groups:

1) **Group I** (Control, Hexigel): 20 subjects under went SRP and prescribed to use 1% CHX gel for 15 days.

2) **Group II**(Test, Murraya Koenigii Gel): 20 subjects under went SRP and prescribed to use 3% M. koenigiigel for 15 days.

A written informed consent was taken from all subjects in the study.

The preparation of *M. koenigii*gel was carried out at College of Pharmacy PAHER, Udaipur. The fresh curry leaves obtained, were first washed thoroughly to remove any dirt and the nair dried for 10 days and then crushed to get a fine powder. Then it was mixed with Carbopol 940 p (gelling agent) and distilled water. Methyl Paraben was added as a preservative along with a sweetening agent Sucralose (Sugar free™). The final gel prepared was 3%w/v.

*M. koenigii*gel was dispensed in plastic containers and weighted 30 gm each.Two tubes of the commercially available 1% CHX gel (Hexigel™) each weighing 15gm were given to each subject. So each subject, both in control and test received a bottle of 30 gm of gel.

Individuals were instructed to use a pea size dab of the gels twice daily,half an hour after brushing and were instructed not to consume food or water for 30 min after using the prescribed gels. The data were recorded in a case history proforma. The clinical parameters assessed were PI and GI.They were recorded at baseline and on the 15th day after using the prescribed Oral Gels.

Gingival Index:

One of the most commonly used indices for assessing the status of gingival health or inflammation is the Gingival Index (G.I.) by Loe and Silness (Table 1). While all the indices published prior to 1963 were based on the single tooth as a unit, the GI was the first index to evaluate every single tooth surface. Each of the buccal, mesial, lingual and distal surfaces of the gingival tissues is given a score of 0-3. This then constitutes the GI for the area, and scores from the 4 areas of the tooth are added and divided by four to give the GI for the tooth. Scores for individual teeth may be grouped to designate the GI for the group of teeth such as incisors, pre molars and molars. The scores may be added and divided by the number of teeth examined to derive the GI for the individual. Usually, all tooth surfaces are included or designated and single tooth surfaces may be selected. GI has gained wide acceptance as a simple, accurate and reproducible method for evaluating gingival health or disease in epidemiological and clinical research, therefore it was used in the current study.

Table 1. The Gingival Index of Loe and Silness.[7]

0 = Normal gingiva.
1 = Mild inflammation -- slight change in color, slightedema. No bleeding on probing.
2 = Moderate inflammation -- redness, edema and glazing.Bleeding on probing.
3 = Severe inflammation -- marked redness and edema. Ulceration. Tendency to spontaneous bleed.

Plaque Index[8]

The Plaque Index was described by Silness P. and Loe H. in 1964 (Table 2). This index was originally described by Silness and Loe and more fully described by Loe in 1967.In this index plaque thickness is given an important consideration. It is one among the most widely used indices to measure plaque. The evaluation or scoring is done on the entire dentition or on selected teeth. Only plaque of the cervical third of the tooth is evaluated. The surfaces examined are four gingival areas of tooth i.e. disto- facial, facial, mesio- facial and lingual surfaces. The lingual surface is considered as one unit.

Teeth examined are-

Maxillary left first molar 16

Maxillary right lateral incisor 12

Maxillary left first bicuspid 24

Mandibular left first molar 36

Mandibular left lateral incisor 32

Mandibular right first Bicuspid 44

If any tooth is missing there is no substitution and the index has to be done on a fullmouth basis. The tooth is dried and examined visually with the help of mouth mirror and explorer. When no plaque is visible an explorer is used to test the surface. The explorer is passed across the tooth surface in the cervical third and near the entrance to the sulcus. When no plaque adheres to the point of the explorer, the area is considered to have a 0 score. When plaque adheres a score of 1 is assigned. Plaque that is on the surface of calculus deposits and on dental restorations of all types in the cervical third is evaluated.

Table 2. The Plaque Index of Silness P. and Loe H.[8]

0- This score is given when the gingival area of the tooth surface is literally free of plaque. The surface is tested by running a pointed probe across the tooth surface at the entrance of the gingival crevice after the tooth has been properly dried and if no soft matter adheres to the point of the probe, the area is considered clean.
1- This score is given when no plaque can be observed in situ by the unarmed eye, but when plaque is made visible on the point of the probe after this has been moved across the tooth surface at the entrance of the gingival crevice. Disclosing solution has not been used.
2- This score is given when the gingival area is covered with a thin to moderately thick layer of plaque. The deposit is visible to the naked eye.
3- Heavy accumulation of soft matter, the thickness of which fills out the niche produced by the gingival margin and the tooth surface. The inter dental area is stuffed with soft debris

Calculation:

For Area-Each area disto- facial, facial, mesio- facial and lingual is assigned a score from 0-3. This is plaque index for the area.

For A Tooth-The scores of the four areas of tooth are added and are divided by four. This gives the plaque index for tooth.

For Groups of Teeth-The scores for individual teeth may be grouped and added and divided by the number of teeth examined. This gives the plaque score for groups of teeth.

For Individual-The indices for each of the teeth are added and then divided by the number of teeth examined. This gives the plaque index for the individual. The score ranges from 0-3

Advantages and Uses:

This index is the most widely used and recognized among plaque indices that have demonstrated good validity and reliability.

Can be scored on all surfaces of all or selected teeth or for selected surfaces of all or selected teeth.

The plaque index may be used in large scale epidemiological studies as well as for smaller groups or within the dentition of an individual.

The only index that measures plaque thickness:

The use of disclosing solution is very helpful especially for in experienced investigators.

Can be applied to longitudinal studies and clinical trials.

In optimal conditions with chair side assistance scoring of all teeth requires approximately 5 minutes.

Is a reliable technique for evaluating both mechanical antiplaque procedures and chemical agents.

Due to the above advantages, PI was used in this study.

The primary outcome variable was the difference in mean reduction of GI scores from baseline to the 15th day. The secondary outcome variables were the differences in mean reduction of PI scores from baseline to the 15th day.

The following methods of statistical analysis were used in this study. The data collected were entered in Microsoft Excel, and statistical analyses were performed using SPSS version 10.5 software (Mission Hills, California, United States).Student's Paired t-test and Independent t-test were used for inter and intra group comparison of the clinical parameters. In the above-used tests, $P \leq 0.05$ was considered as statistically significant.

Results:

A total number of 40 subjects were assessed and included in the study based on the inclusion and exclusion criteria. Demographic data were recorded such as Name, Age, Sex, Occupation, Address and contact details. The mean age of the study population was 30 years with an age range of 20-50 years. Almost all subjects were from Udaipur district of Rajasthan and surrounding areas. The clinical parameter

recorded were gingival index (GI) and plaque index(PI) and it was recorded at baseline and 15th day post SRP.

On intragroup comparison, the mean baseline GI and PI score for the control group (Hexigel) was 1.45±0.13 and 1.30±0.17 respectively. And the mean GI and PI score on the 15th day for the control group was 0.84 ± 0.11 and 0.80 ± 0.11 respectively. The mean difference in scores within the control group was statistically significant (P < 0.001). (Table 3)

On intragroup comparison, the mean baseline GI and PI score for the test group (Murraya Koenigii) was 1.48 ± 0.13 and 1.33 ± 0.20 respectively. And the mean GI and PI score on the 15th day for the test group was 0.81 ± 0.12 and 0.79 ± 0.18 respectively. The mean difference in scores within the test group was statistically significant (P < 0.001). (Table 3)

On intergroup comparison, the mean baseline GI in both Control and Test group was 1.45 ± 0.13 and 1.48 ± 0.13. The mean difference in the GI score on baseline between the two groups was 0.03 and was not statistically significant (P > 0.001). (Table 4)

The mean baseline GI score on the 15th day in both Control and Test group was 0.84 ± 0.11 and 0.81 ± 0.12 respectively. The mean difference in the GI score on the 15th day between the two groups was 0.03 and was not statistically significant (P > 0.001). (Table 4)

On intergroup comparison, the mean baseline PI in both Control and Test group was 1.30 ± 0.17 and 1.33 ± 0.20 respectively. The mean difference in the PI score on baseline between the two groups was 0.03 and was not statistically significant (P > 0.001). (Table 4)

The mean baseline PI score on the 15th day in both Control and Test group was 0.80 ± 0.11 and 0.79 ± 0.18 respectively. The mean difference in the PI score on the 15th day between the two groups was 0.01 and was not statistically significant (P > 0.001). (Table 4)

Comparison of GI and PI before and after application of respective gel

Groups	Interval	N	Mean ± SD	Difference	t value	p value
Hexigel	Baseline GI	20	1.45 ± 0.13	0.61	16.697	0.001*
	15 day GI	20	0.84 ± 0.11			
	Baseline PI	20	1.30 ± 0.17	0.50	10.381	0.001*
	15 day PI	20	0.80 ± 0.11			
MK gel	Baseline GI	20	1.48 ± 0.13	0.67	17.767	0.001*
	15 day GI	20	0.81 ± 0.12			
	Baseline PI	20	1.33 ± 0.20	0.54	9.931	0.001*
	15 day PI	20	0.79 ± 0.18			

Paired t test; * indicates significant at p≤0.05

Comparison of GI and PI in between both the groups at each interval

Interval	Groups	N	Mean	Difference	t value	p value
Baseline GI	HXG	20	1.45 ± 0.13	0.03	-0.646	0.522 (NS)
	MKG	20	1.48 ± 0.13			
15 day GI	HXG	20	0.84 ± .10	0.03	0.866	0.392 (NS)
	MKG	20	0.81 ± 0.13			
Baseline PI	HXG	20	1.30 ± 0.17	0.03	-0.448	0.656 (NS)
	MKG	20	1.33 ± 0.20			
15 day PI	HXG	20	0.80 ± 0.11	0.01	0.322	0.750 (NS)
	MKG	20	0.79 ± 0.18			
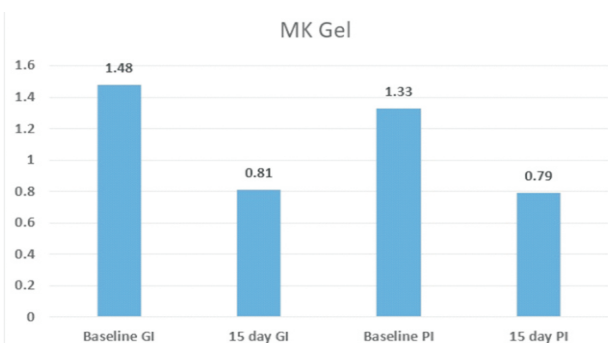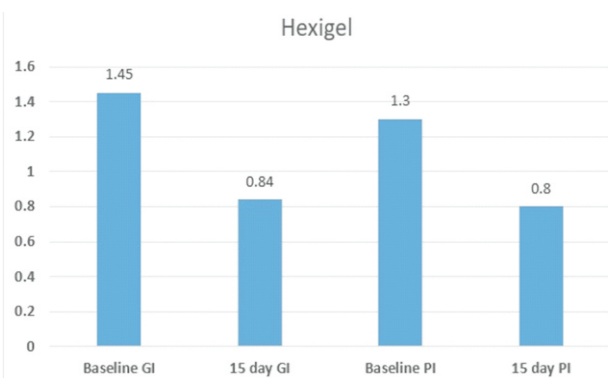
Hexigel

MK Gel

On intragroup comparison, both the groups showed a statistically significant difference with p ≤ 0.05. On intergroup comparison, Group I (control) and Group II (test) showed no statistically significant difference.

Discussion:

Herbal products are widely substituting chemicals for the management of various diseases including periodontal diseases, because of their clinical effectiveness and minimal reported adverse effects. M. koenigiiis a green leafy vegetable grown all over the Indian subcontinent, used daily as a key spice in Indian cuisine. Fresh curry leaves contain 2.6% volatile essential oils such as sesquiterpenes and monoterpenes that are water soluble and have broad anti-microbial effects on S. mutans and S. sanguinis.[9] Curry leaves are known for their anti-microbial, anti-emetic, anti-diabetic, anti-ulcer, anti-oxidative, cytotoxic, and phagocytic activity. It has anti-cancer and hepatoprotective properties too.[10]

The commercially available CHX is regarded as one of the most effective antiplaque agents in dentistry. However, its usage for a longer period is not recommended because of reported side effects, such as teeth discolouration and taste alteration, which affects the patient's compliance. Herbal products can be used to replace them to overcome these unwanted effects. Hence, the current study was designed to evaluate the effectiveness of *M. koenigii* gelin the reduction of plaque and gingivitis and to its effectiveness with CHX gel.

The minimum inhibitory concentration (MIC) of ethanolic extracts of *M. koenigii* was estimated based on an *in vitro* study conducted by Nithya *et al.*, against periodontal pathogens such as *P.gingivalis* and *P.intermedia,* and MIC was estimated as 0.8 mg/ml. 9 serial dilutions of *M. koenigii* extracts were made as 0.2, 0.4, 0.8, 1.6, 3.12, 6.25, 12.5, 25, 50, and 100 mg/ml. To each dilution, specific concentration of the cultured microorganism specimens was added and checked for turbidity. Except 0.2 and 0.4 mg/ml of extract, all other dilutions of extracts showed sensitivity against the cultured specimens. Based on these observations, the concentration of *M. koenigii* needed for the preparation of the gel was calculated as 3 mg/ml (3%).[11]

Sunitha *et al*[12] assessed MIC of ethanolic and aqueous extracts of *M. koenigii* against *S. mutans*. The mean diameter of inhibition zone was 16 and 13.05 mm, respectively. Chandrashekar *et al*[13] determined MIC of combination of *Vachellianilotica*, *M. koenigii*, *Eucalyptus hybrid*, and *Psidium guajava* extracts on *S. mutans*, *Lactobacillus acidophilus*, *S. sanguis*, *S. salivarius*, *F. nucleatum*, and *P. gingivalis*. The formulation inhibited all microorganisms at low concentrations.

In the current study, the mean reduction in GI and PIscores on the 15th day was statistically significant in the two groups. However, the difference was not significant on intergroup comparison which is in accordance to the study conducted by Varghese et al[14].This indicates comparable efficacy of *M. koenigii* with CHX in inhibiting gingival inflammation.

The small sample size and the lack of microbiological confirmation of the results can be considered as limitations of the study. Long-term trials with a larger sample size are necessary to validate the results.

Curry leaves grinded into a fine powder.

Test gel stored in containers weighing 30 gm each.

Control Gel (CHX).

Fresh Curry Leaves.

Air-dried Curry leaves.

Conclusion:

In the present study, *M. koenigii* gel was found to be equally effective in reducing plaque and gingivitis. These findings throw light upon the fact that herbal products are easily available, economical, socially acceptable and report minimal adverse effects compared to commercially available chemical products. Hence, it opens up a new natural method for the maintenance of periodontal health.

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