Comparison of the Efficacy of Locally Administered Curcumin as A Gel Versus A Pastille, as an Adjunct to Scaling, in the Management of Chronic Gingivitis

Dr. Susannah Thomas*, Dr. Asha Prabhu, Dr. Purvi Sampat, Dr. Kanchan Jadhav, Dr. Sweety Agarwal, Dr. Abha Hedao

*Department of Periodontology, Dr. G.D. Pol Foundation's Y. M.T Dental college, Kharghar, Navi Mumbai, India. *Corresponding Author

Aim: To clinically compare the efficacy of locally administered curcumin as a gel versus a pastille, as an adjunct to scaling, in the management of chronic gingivitis.

Materials and Method: A total of 52 subjects were divided into two groups: Group A (26 subjects) who were prescribed - Curcumin Oral gel (Curenex® oral gel/Abbot Pharmaceuticals) post scaling twice a day for 3 weeks. and Group B (26 subjects) who were prescribed - Curcumin pastille (Dennkur Soft Curcumin Pastilles/DenteksORTurmgel™ Turmeric Lozenges /Gelnova Laboratories) post scaling, twice a day for 3 weeks.

Clinical parameters included: (Evaluated at baseline (pre-scaling) and 14 & 21 days (post-scaling).) Plaque index (PI) (Loe H, 1967), Gingival Index (GI) (Loe H and Silness J, 1963), Sulcus Bleeding Index (SBI) (Muhlemann H.R and Son S, 1971). Visual examination of side effects was also assessed.

Results:
1. There was a statistically significant difference seen with intra group comparison of the variables at various time intervals for both group A and group B (p<0.05)
2. There was a statistically non-significant difference seen with intergroup comparison of all the variables (p>0.05). However, from 14 to 21 days there was a statistically significant reduction in gingival index of Group B as compared with Group A. (p= 0.014).
3. Greater patient compliance was seen in Group B and side effects like oral mucosal erosions or ulcerations and burning sensation were seen in 4 cases in Group A.

Conclusion: Group B (Curcumin Pastille) showed more favourable results as far as the anti-inflammatory effect and patient compliance and had less side effects when compared to Group A (Curcumin Gel).

Key words: Curcumin, Chronic Gingivitis, Scaling, Gel, Pastille

Date of Submission: 29-04-2020

Date of Acceptance: 13-05-2020

I. Introduction

Gingivitis is a form of periodontal disease that is prevalent in most children and adult populations. Bacterial plaque is the primary aetiological agent in gingivitis. Mechanical plaque control, like scaling and root planing (SRP), is the first recommended step in the management of gingivitis and periodontitis. Many chemical agents have been tested as adjuncts to mechanical methods which can reduce plaque-associated gingivitis. Chlorhexidine, Triclosan, Povidone iodine and various phenolic compounds have been used successfully as anti-plaque agents. However, side-effects such as allergy, discolouration of teeth and unpleasant taste can occur when these chemicals are used for an extended period of time. Discolouration can involve the tongue as well.
Hence, a need was felt for an alternative medicine which was not only safe and economical but could also provide a product readily available within the traditional Indian setup. Medicinal herbs have been used as a treatment modality since ages in many parts of the world and have been variedly used throughout the human history. Turmeric is indigenous to Southeast Asia and has been cultivated and used in India since 2500 years. Its Latin name, Curcuma longa, is derived from the Persian word, ‘kirkum’, which means saffron, in reference to the rhizomes vibrant yellow-orange color. Components of turmeric are named curcuminoinds. The active constituents of turmeric are the flavonoid curcumin (diferuloylmethane) which comprises 0.3-5.4% of raw turmeric and various volatile oils including tumerone, atlantone, and zingiberone. Other constituents include sugars, proteins, and resins. Curcumin has biological activities as a.a pro-oxidant and an antioxidative agent b. an anti-inflammatory agent c. an immunomodulator d. an anti-tumorogenic agent e. a healing agent f. an antimicrobial agent & g. a photosensitizer through its photodynamic effect To overcome the adverse effects caused by the presently used chemical agents, curcumin can be employed in the management of gingivitis. Because of curcumin’s rapid plasma clearance and conjugation, its therapeutic usefulness has been somewhat limited, leading researchers to investigate the benefits of complexing curcumin with other substances to increase systemic bioavailability. The two main forms that have been used are A. A Gel form and B. A Pastille form

A Gel is defined as a semi rigid system in which the movement of the dispersing medium is restricted by an interlacing three-dimensional network of particles or solvated macromolecules of the dispersed phase. The rigidity of a gel arises from the presence of a network formed by the interlinking of the particle’s gelling agent. A Pastille is defined as, a gelatin-based sweetened and molded medication impregnated with a therapeutic substance intended to be sucked. A pastille has maximum absorption before it reaches the stomach, provides instant relief, buccal absorption bypasses the liver and no water is required for consumption.

Till date, no study had been published to clinically compare the efficacy of locally administered curcumin as a gel versus a pastille, as an adjunct to scaling, in the management of chronic gingivitis. Hence, the present study was conducted.

II. Materials and Method

Study design
This was a single-centre, longitudinal, randomised parallel arm study design.

Source of data
Subjects for the study were selected from those reporting to the Department of Periodontology, Dr. G.D. Pol foundation’s Y.M.T dental college and hospital, Navi Mumbai, India. Subjects for the study were selected from May 2017 to August 2018. Approval from the ethical committee of the institute was taken prior to conducting the study.

The subjects were selected on the basis of the following inclusion and exclusion criteria.

Inclusion criteria
1. Subjects, of either sex, within the age group of 18-55 years.
2. Systemically healthy and cooperative subjects.
3. Subjects with minimum of 20 teeth present in the dentition.
4. Subjects with moderate to severe gingivitis having probing depth ≤ 3mm. (Subjects with Gingival Index scores 2 or 3; according to Gingival Index by Loe and Silness J, 1963)

Exclusion criteria
1. Smokers and tobacco chewers (as per AHA guidelines).
2. Subjects who have taken antibiotics, anti-inflammatory drugs or nutritional supplements in the past 3 months or who are currently on any of these.
3. Pregnant and lactating women and those using oral contraceptive pills

DOI: 10.9790/0853-1905051624 www.iosrjournal.com 17 | Page
Comparison of the Efficacy of Locally Administered Curcumin as A Gel Versus A Pastille, as an...

4. Subjects with a history of periodontal therapy undertaken in the past 6 months.
5. Subjects with known hypersensitivity to curcumin.

Sample size
This was selected using the formula:

\[ n = \frac{2(Z_{\alpha} + Z_{\beta})^2 s^2}{d^2} \]

where \( Z_{\alpha} \) is the z variate of alpha error i.e. a constant with value 1.96, \( Z_{\beta} \) is the z variate of beta error i.e. a constant with value 0.84, \( s \) - standard deviation. \( d \) - size of the effect that is clinically worthwhile to detect.

Methodology
This study was conducted on subjects who give verbal and written consent after being informed about the study protocol. A case history of the subjects participating in the study was recorded. Appropriate tooth brushing technique and frequency of brushing was explained and demonstrated to all the subjects. Subjects were advised to use a similar soft toothbrush and a dentifrice. Ultrasonic scaling was done for all 52 subjects.

The 52 subjects were finally selected depending on the inclusion and exclusion criteria were randomly assigned by the lottery method into 2 groups:

**In Group A** (26 subjects) who were prescribed - **Curcumin Oral gel** (Curenext® oral gel/Abbot Pharmaceuticals) post scaling.

Subjects were advised to apply **Curcumin Oral gel** (Curenext® oral gel/Abbot Pharmaceuticals) on the gums twice a day for 3 weeks, after brushing. They were instructed to leave the gel in the mouth for at least 10 minutes after application and thereafter rinse with water to clear any residual medication.

The clinical parameters mentioned below were evaluated at baseline (pre scaling) and after the 14th and the 21st day (post scaling).

**In Group B** (26 subjects) who were prescribed - **Curcumin pastille**
(Denkkur Soft Curcumin Pastilles/Denteks) OR
(Turmgel™ Turmeric Lozenges®/Gelnova Laboratories) post scaling

Subjects were advised to suck slowly (not to chew) on a curcumin pastille (Denkkur Soft Curcumin Pastilles/Denteks) OR (Turmgel™ Turmeric Lozenges®/Gelnova Laboratories) twice a day for 3 weeks.

The clinical parameters mentioned below were evaluated at baseline (pre scaling) and after the 14th and the 21st day (post scaling).

The clinical parameters assessed were:

<table>
<thead>
<tr>
<th>Clinical parameter</th>
<th>Author /year</th>
<th>Timeline of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque Index (PI)</td>
<td>Loe H (1967)</td>
<td>Baseline (pre scaling) and on the 14th and 21st day (post scaling).</td>
</tr>
<tr>
<td>Gingival Index (GI)</td>
<td>Loe H and Silness J (1963)</td>
<td>Baseline (pre scaling) and on the 14th and 21st day (post scaling).</td>
</tr>
<tr>
<td>Sulcus Bleeding Index (SBI)</td>
<td>Muhlemann H.R and Son S (1971)</td>
<td>Baseline (pre scaling) and on the 14th and 21st day (post scaling).</td>
</tr>
</tbody>
</table>

A questionnaire was prepared and completed by the interviewer as an aid in evaluating patient compliance for both groups at the end of the study period. All the observations of the study were recorded by a single examiner. Visual examination of any side effects, such as, oral mucosal erosions or any allergic reaction, staining of teeth, discoloration of the tongue and an alteration of taste were also recorded at each follow up.

There was no conflict of interest related to this study.

Statistical procedures:
Data obtained was compiled on a MS Office Excel Sheet (v 2010). Data was subject to statistical analysis using Statistical package for social sciences (SPSS v 21.0, IBM). Normality of data was checked using Shapiro-Wilk test. Data followed a normal distribution hence parametric tests have been used for statistical comparisons. Comparison of numerical values between the 2 groups was done using t test. For intra group comparison repeated measures ANOVA had been used followed by Tukey’s Post Hoc test. Comparison of change in numerical values over time intervals from baseline or initial values between the 2 groups was done using t test. For all the statistical tests, \( p < 0.05 \) was considered to be statistically significant.
III. Results

Age:
On comparison of mean age between Group A (Gel) and Group B (Pastille) there was a statistically non significant difference seen for inter group comparison of mean age of the subjects (p>0.05). (Table 1)

Gender:
On comparison of frequencies of gender between Group A (Gel) and Group B (Pastille) there was a statistically non significant difference seen for frequencies of gender of the subjects (p>0.05) between the groups. (Table 2)

Plaque Index (PI)\(^2\):
In Group A, on intragroup comparison, there was a statistically significant reduction in PI scores over baseline, 14, 21 days (p<0.05). (Table 3)
In Group B, on intragroup comparison, there was a statistically highly significant reduction in PI scores over baseline, 14, 21 days (p<0.01). (Table 4)
On inter group comparison, at all time intervals there was a statistically non significant difference seen for the PI scores between the 2 groups. (p>0.05) (Table 5)

Gingival Index (GI)\(^2\):
In group A, on intragroup comparison, there was a statistically highly significant reduction in GI scores over baseline, 14, 21 days (p<0.01) (Table 6)
In group B, on intragroup comparison, there was a statistically highly significant reduction in GI scores over baseline, 14, 21 days (p<0.01). (Table 7)
On inter group comparison, at all time intervals there was a statistically non significant difference seen for the GI scores between the 2 groups. (p>0.05). (Table 8).
However, from 14 to 21 days there was a statistically significant reduction in gingival index of Group B as compared with Group A. (p= 0.014) (Table 9)

Sulcus Bleeding Index (SBI)\(^2\),\(^4\),\(^25\),\(^26\):
In group A, on intragroup comparison, there was a statistically highly significant reduction in SBI scores over baseline, 14, 21 days (p<0.01). (Table 10)
In group B, on intragroup comparison, there was a statistically highly significant reduction in SBI scores over baseline, 14, 21 days (p<0.01). (Table 11)
On inter group comparison, at all time intervals there was a statistically non significant difference seen for the SBI scores between the 2 groups. (p>0.05) (Table 12)

Visual examination/Side effects:

Group A- Curcumin Gel:
1. Oral mucosal erosions or ulcerations were seen in 4 subjects in Group A (Gel) during the study period
2. One subject reported severe burning sensation after initial usage of the gel and was lost to follow up, hence excluded from the study.
3. No staining of teeth, discolouration of tongue or alteration of taste was observed.

Group B- Curcumin Pastille:
1. No report of ulcerations due to usage of pastille was observed.
2. No burning sensation reported.
3. No staining of teeth, discolouration of tongue or alteration of taste was observed.

Questionnaire:
Palatability: Overall, both the curcumin gel (Group A) and the curcumin pastille (Group B) were palatable except for 2 subjects in each group.
Compliance: Overall, greater compliance was observed in the curcumin pastille (Group B) compared to the curcumin gel (Group A).
Feeling of freshness: Overall, greater feeling of freshness was reported in the curcumin pastille (Group B) compared to the curcumin gel (Group A). Six subjects in the curcumin pastille group (Group B) reported strong flavour of the pastille.
Difficulties experienced: Nine subjects in the curcumin gel (Group A) reported difficulty in spreading or lack of adherence of the gel over their gums.
Comparison of the Efficacy of Locally Administered Curcumin as A Gel Versus A Pastille, as an...

Tables:

- **Age:** Table 1 - Comparison of mean age between Group A (Gel) and Group B (Pastille).

<table>
<thead>
<tr>
<th></th>
<th>Groups</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>T value</th>
<th>p value of t test</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (Gel)</td>
<td>26</td>
<td>22.50</td>
<td>2.354</td>
<td>.462</td>
<td>0.385</td>
<td>0.702#</td>
<td></td>
</tr>
<tr>
<td>B (Pastille)</td>
<td>26</td>
<td>22.27</td>
<td>1.951</td>
<td>.383</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# = non significant difference (p>0.05)

- **Gender:** Table 2 - Comparison of frequencies of gender between Group A (Gel) and Group B (Pastille).

<table>
<thead>
<tr>
<th></th>
<th>Groups</th>
<th>A(Gel)</th>
<th>B(Pastille)</th>
<th>Total</th>
<th>Chi square value</th>
<th>p value of chi square test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Females</td>
<td>19</td>
<td>18</td>
<td>37</td>
<td>0.994</td>
<td>0.760#</td>
</tr>
<tr>
<td></td>
<td>Males</td>
<td>7</td>
<td>8</td>
<td>15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# = non significant difference (p>0.05)

- **Plaque Index (PI):**

  - **Table 3** - Plaque Index - Intra group comparison for Group A (Curcumin Gel Group) at baseline, 14 and 21 days.

<table>
<thead>
<tr>
<th>Time</th>
<th>N</th>
<th>Mean PI</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>Error</th>
<th>F value</th>
<th>p value of Repeated measures ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Baseline</td>
<td>26</td>
<td>.96</td>
<td>.529</td>
<td>.104</td>
<td>4.265</td>
<td>.018*</td>
<td></td>
</tr>
<tr>
<td>14 Days</td>
<td>26</td>
<td>.67</td>
<td>.394</td>
<td>.077</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Days</td>
<td>26</td>
<td>.63</td>
<td>.383</td>
<td>.075</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* = statistically significant difference (p<0.05)

- **Table 4** - Plaque Index - Intra group comparison for Group B (Curcumin Pastille Group) at baseline, 14 and 21 days

<table>
<thead>
<tr>
<th>Time</th>
<th>N</th>
<th>Mean PI</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>Error</th>
<th>F value</th>
<th>p value of Repeated measures ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Baseline</td>
<td>26</td>
<td>1.04</td>
<td>.454</td>
<td>.089</td>
<td>6.707</td>
<td>.002**</td>
<td></td>
</tr>
<tr>
<td>14 Days</td>
<td>26</td>
<td>.68</td>
<td>.382</td>
<td>.075</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Days</td>
<td>26</td>
<td>.68</td>
<td>.397</td>
<td>.078</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** = statistically highly significant difference (p<0.01)

- **Table 5** - Plaque Index – Inter group comparison at baseline, after 14 and 21 days

<table>
<thead>
<tr>
<th>Time interval</th>
<th>Groups</th>
<th>N</th>
<th>Mean PI</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>T value</th>
<th>p value of t test</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Baseline</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>.96</td>
<td>.529</td>
<td>.104</td>
<td>-0.606</td>
<td>0.547#</td>
</tr>
<tr>
<td></td>
<td>Group B(Pastille)</td>
<td>26</td>
<td>1.04</td>
<td>.454</td>
<td>.089</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI 14 Days</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>.67</td>
<td>.394</td>
<td>.077</td>
<td>-0.061</td>
<td>0.952#</td>
</tr>
<tr>
<td></td>
<td>Group B(Pastille)</td>
<td>26</td>
<td>.68</td>
<td>.382</td>
<td>.075</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI 21 Days</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>.63</td>
<td>.383</td>
<td>.075</td>
<td>-0.438</td>
<td>0.664#</td>
</tr>
<tr>
<td></td>
<td>Group B(Pastille)</td>
<td>26</td>
<td>.68</td>
<td>.397</td>
<td>.078</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# = non significant difference (p>0.05)

- **Gingival index (GI):**

  - **Table 6** - Gingival Index - Intra group comparison for Group A (Curcumin Gel Group) at baseline, 14 and 21 days

<table>
<thead>
<tr>
<th>Time</th>
<th>N</th>
<th>Mean GI</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>Error</th>
<th>F value</th>
<th>p value of Repeated measures ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI Baseline</td>
<td>26</td>
<td>1.45</td>
<td>.466</td>
<td>.091</td>
<td>82.260</td>
<td>.000**</td>
<td></td>
</tr>
<tr>
<td>14 Days</td>
<td>26</td>
<td>.39</td>
<td>.357</td>
<td>.070</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Days</td>
<td>26</td>
<td>.23</td>
<td>.269</td>
<td>.053</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DOI: 10.9790/0853-1905051624  www.iosrjournal
**Comparison of the Efficacy of Locally Administered Curcumin as A Gel Versus A Pastille, as an ..**

** = statistically highly significant difference (p<0.01)

Table 7- Gingival Index - Intra group comparison for Group B (Curcumin Pastille Group) at baseline, 14 and 21 days

<table>
<thead>
<tr>
<th>Time</th>
<th>N</th>
<th>Mean GI</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>F value</th>
<th>p value of Repeated measures ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>26</td>
<td>1.38</td>
<td>.261</td>
<td>.051</td>
<td>130.309</td>
<td>.000**</td>
</tr>
<tr>
<td>14 Days</td>
<td>26</td>
<td>.30</td>
<td>.274</td>
<td>.054</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Days</td>
<td>26</td>
<td>.29</td>
<td>.305</td>
<td>.060</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** = statistically highly significant difference (p<0.01)

Table 8– Gingival Index - Inter group comparison at baseline, after 14 and 21 days

<table>
<thead>
<tr>
<th>Time interval</th>
<th>Groups</th>
<th>N</th>
<th>Mean GI</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>T value</th>
<th>p value of t test</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI Baseline</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>1.45</td>
<td>.466</td>
<td>.091</td>
<td>0.701</td>
<td>0.487#</td>
</tr>
<tr>
<td></td>
<td>Group B (Pastille)</td>
<td>26</td>
<td>1.38</td>
<td>.261</td>
<td>.051</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI 14 Days</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>.39</td>
<td>.357</td>
<td>.070</td>
<td>1.077</td>
<td>0.287#</td>
</tr>
<tr>
<td></td>
<td>Group B (Pastille)</td>
<td>26</td>
<td>.30</td>
<td>.274</td>
<td>.054</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI 21 Days</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>.23</td>
<td>.269</td>
<td>.053</td>
<td>-0.665</td>
<td>0.509#</td>
</tr>
<tr>
<td></td>
<td>Group B (Pastille)</td>
<td>26</td>
<td>.29</td>
<td>.305</td>
<td>.060</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# = non significant difference (p>0.05)

Table 9– Gingival Index- Inter group comparison change in variables from baseline to 14 and 21 days

<table>
<thead>
<tr>
<th>Time interval</th>
<th>Groups</th>
<th>N</th>
<th>Mean GI</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>T value</th>
<th>p value of t test</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI Baseline-14D</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>1.06</td>
<td>.233</td>
<td>.046</td>
<td>-0.263</td>
<td>0.793#</td>
</tr>
<tr>
<td></td>
<td>Group B (Pastille)</td>
<td>26</td>
<td>1.08</td>
<td>.346</td>
<td>.068</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI Baseline-21D</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>1.22</td>
<td>.305</td>
<td>.060</td>
<td>1.286</td>
<td>0.204#</td>
</tr>
<tr>
<td></td>
<td>Group B (Pastille)</td>
<td>26</td>
<td>1.09</td>
<td>.399</td>
<td>.078</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI 14-21 D</td>
<td>Group A (Gel)</td>
<td>26</td>
<td>.16</td>
<td>.221</td>
<td>.043</td>
<td>2.098</td>
<td>0.014*</td>
</tr>
<tr>
<td></td>
<td>Group B (Pastille)</td>
<td>26</td>
<td>.01</td>
<td>.284</td>
<td>.056</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* = statistically significant difference (p<0.05)

# = non significant difference (p>0.05); D- Days

Sulcus bleeding index (SBI):

Table 10- Sulcus Bleeding Index - Intra group comparison for Group A (Curcumin Gel Group) at baseline, 14 and 21 days

<table>
<thead>
<tr>
<th>Time</th>
<th>N</th>
<th>Mean SBI</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>F value</th>
<th>p value of Repeated measures ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>26</td>
<td>.80</td>
<td>1.075</td>
<td>.211</td>
<td>8.702</td>
<td>.000**</td>
</tr>
<tr>
<td>14 Days</td>
<td>26</td>
<td>.17</td>
<td>.228</td>
<td>.045</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Days</td>
<td>26</td>
<td>.13</td>
<td>.201</td>
<td>.039</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** = statistically highly significant difference (p<0.01)

Table 11- Sulcus Bleeding Index - Intra group comparison for Group B (Curcumin Pastille Group) at baseline, 14 and 21 days

<table>
<thead>
<tr>
<th>Time</th>
<th>N</th>
<th>Mean SBI</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
<th>F value</th>
<th>p value of Repeated measures ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>26</td>
<td>.74</td>
<td>.658</td>
<td>.129</td>
<td>18.337</td>
<td>.000**</td>
</tr>
<tr>
<td>14 Days</td>
<td>26</td>
<td>.16</td>
<td>.256</td>
<td>.050</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Days</td>
<td>26</td>
<td>.11</td>
<td>.102</td>
<td>.020</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

** = statistically highly significant difference (p<0.01)
Till date, there is no published study stating the effects of curcumin pastille in the use of gingivitis and periodontitis. However, Maha M. A. Nasraetal (2017) in their study stated that curcumin in its novel drug delivery system is an excellent candidate for periodontal disease treatment but shows lower significance where plaque reduction is considered.

Till date, there is no published study stating the effects of curcumin pastille in the use of gingivitis and periodontitis.

Intragroup Comparison

The plaque inhibitory action of curcumin gel noted in the present study, is in accordance with its efficacy in various studies of gingivitis and periodontitis over different time intervals reported by Dave DHetal (2018)27, Roopa DAetal (2016)28; Hugar SSetal (2016)29; Sharma V, Kalsi DS (2016)30; Farjana HNetal (2014)1.

However, Mishra Aetal (2015)32 concluded that further studies with a larger sample size are required to attribute the effect of topical gel application on gingival status.

IV. Discussion

Plaque Index (PI)22:

Intragroup Comparison

The plaque inhibitory action of curcumin gel noted in the present study, is in accordance with its efficacy in various studies of gingivitis and periodontitis over different time intervals reported by Dave DHetal (2018)27, Roopa DAetal (2016)28; Hugar SSetal (2016)29; Sharma V, Kalsi DS (2016)30; Farjana HNetal (2014)1.

However, Maha M. A. Nasraetal (2017)31 in their study stated that curcumin in its novel drug delivery system is an excellent candidate for periodontal disease treatment but shows lower significance where plaque reduction is considered.

Till date, there is no published study stating the effects of curcumin pastille in the use of gingivitis and periodontitis.

Intergroup Comparison

Till date, no study has been published to clinically compare the efficacy of locally administered curcumin as a gel versus a pastille, as an adjunct to scaling, in the management of chronic gingivitis and/or periodontitis.

Gingival Index (GI)22:

Intragroup Comparison

The anti-inflammatory action of curcumin gel noted in the present study, is in accordance with its efficacy in various studies of gingivitis and periodontitis reported by Roopa DA etal (2016)28; Hugar SS etal (2016)29; Sharma V, Kalsi DS (2016)30; Farjana HN etal (2014)1, and a review article by Jurenka JS (2009)11.

However, Mishra A etal (2015)32 concluded that further studies with a larger sample size are required to attribute the effect of topical gel application on gingival status.

Till date, there is no published study stating the effects of curcumin pastille in the use of gingivitis and periodontitis.

Intergroup Comparison

From 14 to 21 days there was a statistically significant reduction in gingival index of Group B as compared with Group A. (p= 0.014).

In Group A (Curcumin Gel) post brushing subjects were instructed to leave the gel in the mouth for at least 10 minutes after application and thereafter rinse with water to clear any residual medication. It was observed that this routine could be disrupted if the subject was having a hectic day or in a hurry to leave his/her house for work.

In Group B (Curcumin Pastille) the curcumin pastille could be carried along with the subject as per his/her work schedule and sucked slowly during the day. This could probably be the reason for greater compliance and statistically significant reduction in gingival index of Group B as compared with Group A from 14–21 days.

Till date, no study has been published to clinically compare the efficacy of locally administered curcumin as a gel versus a pastille, as an adjunct to scaling, in the management of chronic gingivitis and/or periodontitis.

Sulcus Bleeding Index (SBI)24,25,26:

Intragroup Comparison

The anti-inflammatory action of curcumin gel noted in the present study, is in accordance with its efficacy in various studies of gingivitis and periodontitis reported by Dave DH etal (2018)27; Roopa DA etal (2016)28; Hugar SS etal (2016)29; Sharma V, Kalsi DS (2016)30; Farjana HN etal (2014)1 and a review article by Jurenka JS (2009)11. However, Mishra A etal (2015)32 concluded that further studies with a larger sample size are required to attribute the effect of topical gel application on gingival status.

Till date, there is no published study stating the effects of curcumin pastille in the use of gingivitis and periodontitis.
Comparison of the Efficacy of Locally Administered Curcumin as a Gel Versus a Pastille, as an Adjunct to Scaling, in the Management of Chronic Gingivitis and/or Periodontitis

Intergroup Comparison
Till date, no study has been published to clinically compare the efficacy of locally administered curcumin as a gel versus a pastille, as an adjunct to scaling, in the management of chronic gingivitis and/or periodontitis.

Visual examination:
Group A - Curcumin Gel-
Oral mucosal erosions or ulcers were seen in 4 subjects in Group A (Gel) during the study period. One subject reported severe burning sensation after initial usage of the gel and was lost to follow up, hence excluded from the study. These results are not in conjunction with studies by Kaur et al. (2018) and Roopa DA et al. (2016) who stated that experimental gel did not show adverse reactions.

Group B - Curcumin Pastille-
Till date, there is no published study stating the side effects of curcumin pastille in the use of gingivitis and periodontitis.

Chattopadhyay et al. (2004) in their article stated that the safety of curcumin and its various forms has been studied with positive results. It has been observed that very high doses of curcumin of upto 400 mg/kg and longer duration of upto 8 weeks did not cause any adverse effects in rats but lead to reduction in the TNF-α and IL-6 levels in rats.

Livada Retal (2017) in their review article stated that, furthermore, allergic reactions to curcumin such as rash or urticaria have been reported and patients with allergies to plants in the ginger family or curcuma genus are most susceptible to these side effects. Patients who are allergic to yellow food coloring, which is often derived from turmeric, should also avoid curcumin.

Questionnaire:
Till date, no study has been published to clinically compare the efficacy of locally administered curcumin as a gel versus a pastille, as an adjunct to scaling, in the management of chronic gingivitis and/or periodontitis. In this study the following was noted:

Palatability- Overall, both the curcumin gel (Group A) and the curcumin pastille (Group B) were palatable except for 2 subjects in each group.

Compliance- Overall, greater compliance was observed in the curcumin pastille (Group B) compared to the curcumin gel (Group A). The curcumin pastille could be carried along with the subject as per his/her work schedule and sucked slowly during the day. This could probably be the reason for greater compliance seen in Group B (Curcumin Pastille).

Feeling of freshness- Overall, greater feeling of freshness was reported in the curcumin pastille (Group B) compared to the curcumin gel (Group A). This could be because of the spearmint oil ingredient present in the pastille.

Difficulties experienced- Nine subjects in the curcumin gel (Group A) reported difficulty in spreading or lack of adherence of the gel over their gums. These results are not in conjunction with studies by Roopa DA et al. (2016) and Farjana HN et al. (2014) who stated that experimental gel had a good patient acceptance.

Possible Limitations of the study are:
There is an individual variation and person-specific plaque development and viscosity of saliva. An ideal study should include a cross-over design in the same individual with adequate washout period.

V. Conclusion
Therefore, on the basis of this study we conclude that Group B (Curcumin Pastille) showed more favourable results as far as the anti-inflammatory effect, patient compliance and minimal side effects were considered.

Definitive conclusions on the effectiveness of locally administered curcumin as a gel versus a pastille, as an adjunct to mechanical plaque control will have to come from well-designed interventional studies with a larger sample size. Measures should be taken to reduce the side effects and improvise the material properties and compliance of the Curcumin preparations. The sample size of the study is less and further studies with a larger sample size including patients diagnosed with chronic periodontitis needs to be carried out to reach a definitive conclusion.

References

DOI: 10.9790/0853-1905051624    www.iosrjournal.org  23 | Page
Comparison of the Efficacy of Locally Administered Curcumin as A Gel Versus A Pastille, as an Adjunct to Scaling, in the Management of Chronic Gingivitis.

Dr. Susannah Thomas, et. al. "Comparison of the Efficacy of Locally Administered Curcumin as A Gel Versus A Pastille, as an Adjunct to Scaling, in the Management of Chronic Gingivitis." IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), 19(5), 2020, pp. 16-24.