A prospective randomised, placebo controlled clinical trial to evaluate & compare the efficacy and safety of Gum Tone gel in the management of patients suffering from periodontal diseases

Hemant Dhusia, Archanà Dhusia, Chitra Ayyar

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Address for correspondence & reprint request to Charak Pharma Pvt. Ltd.

ABSTRACT:
Periodontal disease is a chronic infection that slowly attacks and destroys the gums and bones supporting the teeth. In India, periodontal diseases are on a rise. The article studies the safety and efficacy of Gum Tone gel, a polyherbal formulation in patients suffering from periodontal diseases.

INTRODUCTION:
The prevalence and severity of periodontal disease increases with age, beginning approximately at 5 years of age.

In India, the habits of the population such as pan chewing, smoking bidi, cigarette etc contribute significantly to etiopathogenesis of gingival and periodontal disease. Since a large percentage of rural population resides in rural region, the awareness regarding dental health or dental care is lacking and also due to low socio economic condition, they avoid dental treatment because of the high cost.

In periodontal disease, anaerobic bacteria are considered to be predominant causative factors. The management of periodontal diseases mainly consists of scaling and polishing accompanied with antibiotics and anti-inflammatory drugs. The drug treatment is not devoid of adverse effects. The prevention of periodontal diseases, stresses on maintenance of oral hygiene. Drugs like metronidazole play a preventive role, but has adverse effects when taken for a long duration. Hence, emphasis is laid on herbal drugs, which can aid oral hygiene, treat and prevent periodontal diseases. In addition, herbal drugs have fewer side effects than the existing drugs.

One such polyherbal formulation, Gum Tone gel, containing extracts of Acacia arabica, Barleria prionitis, Mimusops elengi, Emblica officinalis, Terminalia bellerica, Terminalia chebula, and Emblica ribes as main ingredients, was evaluated in the present study for efficacy and tolerability of the formulation in treatment of periodontal diseases. Gum Tone gel has ingredients which possess astringent, antibacterial, analgesic, demuculent, anti-inflammatory and mouth freshening actions, hence beneficial in periodontal diseases.

AIM:
To evaluate and compare the safety and efficacy of Gum Tone gel in patients suffering from periodontal diseases.

STUDY DESIGN
Randomised, open trial design. The duration of the study was 6 months.

STATISTICAL ANALYSIS
The efficacy and safety parameters were analysed using appropriate parametric test i.e. unpaired and paired 't' test and non parametric test i.e. chi square test and Wilcoxon rank sum test.

METHOD
The study was conducted in a total of 100 patients. One patient was lost to follow-up. Hence, evaluation was done in 99 patients.

They were started on Gum Tone gel after doing initial scaling and polishing.
Fig. 1: 35 patients had severe degree of plaque at start of trial. At end of trial, none of the patients showed presence of plaque.

Fig. 2: A total of 99 patients showed moderate to severe gingivitis at start of trial. At end of trial, 77 showed no inflammation and 22 had only mild inflammation.

Fig. 3: Symptoms of pain were 3.9 ± 1.2 on visual analog scale, which reduced to 0.3 at end of study.

Fig. 4

Fig. 5: Physician's evaluation rated Gum Tone gel as good in 79% patients, and a fair response in 21%. 1% patient rated Gum Tone gel as excellent, 74% as good response and 25% as fair response.

**METHOD OF APPLICATION**
Gum Tone gel was applied twice a day with a toothbrush/finger at the affected area for a period of 4 weeks. The patients were advised not to rinse or wash off for at least 15 minutes after application of gel.

**Advice to patient:** No change in oral hygiene habit should be made.

**INCLUSION CRITERIA:**
1. Patient of either sex, age between 12-60 years.
2. Patients ready for study procedure and follow-up.
3. Gingivitis in more than 2 teeth with presence of at least 1 periodontal pocket (≥ 6mm)
4. No history of antibiotic use in the past 2 weeks.

**EXCLUSION CRITERIA**
1. Pregnant or nursing mother.

2. Patients with history of psychiatric illness, epilepsy, suicide risk in the patient.
3. A/o alcoholism and drug dependence.
4. History of any major medical disorder or surgical operation in the past 15 days.
5. Known hypersensitivity to one of the components of the investigational products.
6. Patients with history of active liver or kidney diseases or renal insufficiency; severe life threatening conditions requiring hospitalization.
7. Patients who are chronic tobacco chewers.

**DEMOGRAPHIC PROFILE: (TABLE 1)**

<table>
<thead>
<tr>
<th>Age (yrs) (Mean ± SD)</th>
<th>38.3 ± 9.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male / Female (%)</td>
<td>62 / 37 (63% / 37%)</td>
</tr>
</tbody>
</table>
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PERSONAL HISTORY: (TABLE 2)

<table>
<thead>
<tr>
<th>Veg / Non Veg (n %)</th>
<th>9 / 90 (9% / 91%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking (Yes / No) (n %)</td>
<td>35 / 64 (35% / 65%)</td>
</tr>
<tr>
<td>Alcohol (Yes / No) (n %)</td>
<td>47 / 52 (47% / 53%)</td>
</tr>
<tr>
<td>Paan or Gutkha (Yes / No) (n %)</td>
<td>38 / 61 (38% / 62%)</td>
</tr>
<tr>
<td>No. of patients brushed once a day (n %)</td>
<td>98 (99%)</td>
</tr>
<tr>
<td>No. of patients using Toothbrush/Finger/Both</td>
<td>79/18/2 (80%/18%/2%)</td>
</tr>
<tr>
<td>No. of patients using mouthwash</td>
<td>None</td>
</tr>
</tbody>
</table>

METHODOLOGY
1) Demographic information including age, sex, smoking history, consumption of alcohol, height, weight, family history and past history of illness/surgery.
2) Current medical history and dental history
3) Concomitant medication
4) Complete general and systemic examination findings.
5) Dental parameters i.e. efficacy parameter recordings.

DENTAL HISTORY:
Five types of dental history were noted in these patients
1) Swelling over gums
2) Bleeding gums
3) Hypersensitivity of Teeth
4) Foul breath smell
5) Pain over gums.

The details are shown as below:

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swelling over gums</td>
<td>22</td>
</tr>
<tr>
<td>Bleeding gums</td>
<td>23</td>
</tr>
<tr>
<td>Swelling over gums &amp; bleeding gums</td>
<td>17</td>
</tr>
<tr>
<td>Hypersensitivity of teeth</td>
<td>1</td>
</tr>
<tr>
<td>Swelling over gums &amp; hypersensitivity of teeth</td>
<td>2</td>
</tr>
<tr>
<td>Bleeding gums &amp; hypersensitivity of teeth</td>
<td>4</td>
</tr>
<tr>
<td>Swelling over gums &amp; bleeding gums &amp; hypersensitivity of teeth</td>
<td>1</td>
</tr>
<tr>
<td>Foul breath smell</td>
<td>1</td>
</tr>
<tr>
<td>Swelling over gums &amp; foul breath smelling</td>
<td>5</td>
</tr>
<tr>
<td>Bleeding gums &amp; foul breath smelling</td>
<td>8</td>
</tr>
<tr>
<td>Swelling over gums &amp; bleeding gums &amp; foul breath smelling</td>
<td>1</td>
</tr>
<tr>
<td>Pain over gums</td>
<td>1</td>
</tr>
<tr>
<td>Swelling over gums &amp; pain over gums</td>
<td>4</td>
</tr>
<tr>
<td>Bleeding gums &amp; pain over gums</td>
<td>2</td>
</tr>
<tr>
<td>Pain over gums &amp; hypersensitivity of yeeth</td>
<td>5</td>
</tr>
<tr>
<td>Bleeding gums &amp; pain over gums &amp; foul breath smelling</td>
<td>1</td>
</tr>
<tr>
<td>Pain over gums &amp; foul breath smelling</td>
<td>1</td>
</tr>
</tbody>
</table>

BASE LINE INVESTIGATIONS
The following baseline investigations were done during initial enrollment of patient:
1. Hb, CBC, Urine (Routine/Microscopic)
   There was no significant finding in the enrolled patients.

EFFICACY, EVALUATION AND RESULTS
Efficacy parameters evaluated were as follows:
1. Oral hygiene: This was graded as poor, fair and good.
2. Halitosis: This was recorded as present/absent. None of the patients showed presence of halitosis at the end of treatment.
3. Plaque Index: (Fig.1): This was scored as follows:
   0. No plaque in gingival area
   1. A film of plaque adhering to free gingival margin and adjacent area of tooth surface visible to the naked eye.
   2. Moderate accumulation of soft deposits within the gingival pocket and on the gingival margin and on the adjacent tooth surface that can be seen by the naked eye.
   3. Adherence of soft matter within the gingival pocket and/or the gingival margin and adjacent tooth surface.

4. Gingival Index: This was scored as follows: (Fig. 2)
   0. Normal gingiva
   1. Mild inflammation, slight change in colour, slight edema, no bleeding on palpation
   2. Moderate inflammation, redness, edema and glazing bleeding on probing.
   3. Severe inflammation, redness, edema and glazing bleeding on probing.
5. Pain scale: Pain was scored on the Visual Analogue Scale (VAS). (Fig. 3)
6. Teeth sensitivity: (Fig. 4)

OTHER PARAMETERS
1. Patient's evaluation of treatment - at the end of 30 days patients were asked to grade their treatment tolerability as fair, good and excellent.
2. Doctor's evaluation of treatment - at the end of 30 days the treating dentist graded the overall efficacy and tolerability of the treatment as fair, good and excellent.

DISCUSSION:
Periodontal disease is a chronic infection that slowly attacks and destroys the gums and bone that support the teeth. Healthy gums are pale pink, firm and look speckled. Gingivitis is the condition where gums become inflamed and swollen.
Untreated gingivitis can advance to periodontitis. The bacterial toxins in plaques can irritate the gums, causing further damage. Pockets (spaces between teeth and gums) may be formed, which can become infected. Eventually, the teeth can become loose, may fall off and may have to be removed.
A wide range of products are commercially available, but interest is shifting to natural products.
One such newly launched polyherbal formulation Gum Tone gel containing extracts of Acacia arabica, Barleria prionitis, Minusops elengi, Emblica officinalis, Terminalia belerica, Terminalia chebula, and Emblica ribes as main ingredients was shown to be very effective in the treatment of periodontal diseases. Gum Tone gel has ingredients which possess astrigent, antibacterial, analgesic, styptic, demulcent, anti-inflammatory and mouth freshening actions hence beneficial in periodontal diseases.
In this study, it can be clearly demonstrated that Gum Tone gel acts as an effective dentifrice formulation, which aids in the control of plaque and gingivitis.

CONCLUSION
Gum Tone gel acts as a good astrigent, anti-inflammatory agent and dentifrice, which can be given alone to control gingivitis. Gum Tone gel should be used as a first line treatment in treating gingivitis along with scaling.
Gum Tone gel is an ideal formulation for routine oral hygiene to prevent plaque formation and halitosis. Regular use of Gum Tone gel is recommended for its multi action profile.
It can be concluded that Gum Tone gel should be tried as a first line treatment in spongy & bleeding gums and arrest bleeding. The gel form makes it convenient to use by the patients and will ensure compliance.

REFERENCES: