# A Herbal Approach In Healing Of Oral Traumatic Ulcer – A Randomized Control Trial

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# **ABSTRACT**

In recent times, focus on plant research has got an immense popularity due to highly efficient potential of medicinal plant used in traditional medicine. an attempt is made in the current study to evaluate the effect of *Ocimum Sanctum* by preparing a paste on healing of oral traumatic ulcers.

Methods: The current study is a Randomized Controlled Trial, conducted with an aim to assess the efficacy of *Ocimum Sanctum* in healing oral traumatic Ulcer. The study consisted of Three groups (group A- Tulsi ghee, B-plain ghee and C- control). The study subjects were randomly allocated to these groups employing lottery method. Baseline pain score was recorded by using Visual Analogue Scale and baseline ulcer diameter was measured using Vernier caliper.

Results: There was mean reduction and statistically significant results of decrease in ulcer dimension at 3, 5 and 7 days. Mean reduction in ulcer dimension was significantly larger in group 1 at 3,5 and 7 days as compared to group 2 and group 3.

Conclusion: *Ocimum Sanctum* is found in majority of Indian courtyards, and the preparation done is very easy which can be simulated at the domestic level.

#### **KEYWORDS**

AI-driven recruitment, Algorithmic bias, Candidate experience, Ethical AI in recruitment, Hiring Ocimum Sanctum, tulsi, oral ulcer

# 1. INTRODUCTION

In recent times, focus on plant research has got an immense popularity due to highly efficient potential of medicinal plant used in traditional medicine. Use of plant and plant products can be traced as far back as beginning of ancient civilization. The medicinal plants are rich in secondary metabolites and essential oils of therapeutic importance. Importance of medicinal plants was based mainly on their safety besides being economical effective and easy availability. <sup>1,2,</sup>

Among them *Ocimum* species belonging to family *Lameaciae* are very important for their therapeutical use. *Ocimum sanctum L*. (Family *Lamiaceae*) commonly known as Tulsi in India and Holy Basil in Western countries is a small herb seen throughout India. *Ocimum sanctum L*. have been recommended for the treatment of bronchitis, bronchial asthma, malaria, diarrhoea, dysentery, skin diseases, arthritis, painful eye diseases, chronic fever, insect bite etc-<sup>3</sup>

Laksmana Rao Bathala et alshowed efficacy of *Osimum Sanctum* in releaving stress amongst rats. <sup>4</sup> Devanand Gupta et al showed effectiveness of *Ocimum Sanctum* mouth wash on Plaque and Gingival Inflammation. <sup>5</sup> Rajesh Ramesh Hosadurga, Sudarshan Narayan Rao, and Shashidhara Raju used *Ocimum Sanctum* gel in treatment of experimental periodontitis and got significant result. <sup>6</sup>

Ocimum Sanctum at a dose of 100mg/kg was found to be effective antiulcer agent. Anti-ulcer effect of Ocimum Sanctum has found to be due to cytoprotective effect rather than antisecretory activity. Literature review revealed no study done to assess the effect of Ocimum Sanctum on healing of oral traumatic ulcer. Thus an attempt is made in the current study to evaluate the effect of Ocimum Sanctum by preparing a paste on healing of oral traumatic ulcers.

#### 2. MATERIALS

The current study is a Randomized Controlled Trial, conducted with an aim to assess the efficacy of *Ocimum Sanctum* in healing oral traumatic Ulcer conducted in month of April from 1<sup>st</sup> to 28<sup>th</sup> may 2015. It was conducted among the patients undergoing orthodontic treatment at Narsinhbhai Patel Dental college and who developed oral traumatic ulcer in the first week of treatment.

Ethical clearance was obtained from IRB Narsinhbhai Patel Dental College and Hospital, Visnagar (Gujarat)

After explaining complete procedure, written Informed consent was obtained from the patients. Thirty patients were randomly included in the study with

Inclusion criteria-patients having ulcer due to trauma caused by orthodontic treatment. Exclusion criteria:-

1. Cause of Ulcer other than trauma

2. Patients who where allergic to any of products used in the preparation.

The study consisted of Three groups (group A- Tulsi ghee, B- plain ghee and C- control). The study subjects were randomly allocated to these groups employing lottery method.

#### 2.1 Tulsi-ghee paste preparation

500 gms of fresh leaves of *Ocimum Sanctum* was obtained from locally grown plants in Visnagar(Gujarat). 250gms of which was utilized to prepare juice by adding one liter of water. The left over tulsi leaves were converted into paste.

To this one Kg (Kilogram) of warm ghee was added followed by adding the tulsi juice. On low flame the mixture was boiled until it had becomes thick, followed by adding one litter of water. The mixture was again re-boiled on low flame. The preparation was confirmed by evaporation of entire water, bright color and pleasant smell of tulsi. The mixture was filtered and was placed in packed sterilized bottles.

# 2.2 Ghee paste preparation

One kilogram of cow ghee was boiled until it became one fourth of its concentration.

#### 2.3 Packing

The study materials where packed in opaque bottles covered with adhesive tapes. The assignment of study material was done randomly by an individual who was not involved in the study.

The preparation was dispatched in bottles of same colored and size. Baseline pain score was recorded by using Visual Analogue Scale and baseline ulcer diameter was measured using Vernier caliper. All the examination was performed by a single trained and calibrated examiner at department of Public Health Dentistry (who was blinded regarding to which group the patient belongs to.). After collection of baseline data the participants were instructed to apply a pea sized paste of the respective preparation on the ulcer site using their index finger, 2 times a day for seven days (morning after brushing & night after brushing). Once applied they were not suppose to spit or rinse for 10 minutes, after which they can spit but not rinse. No restriction was implied to their diet and oral hygiene measures. Clinical examination were again repeated on 3,5 and 7 day.

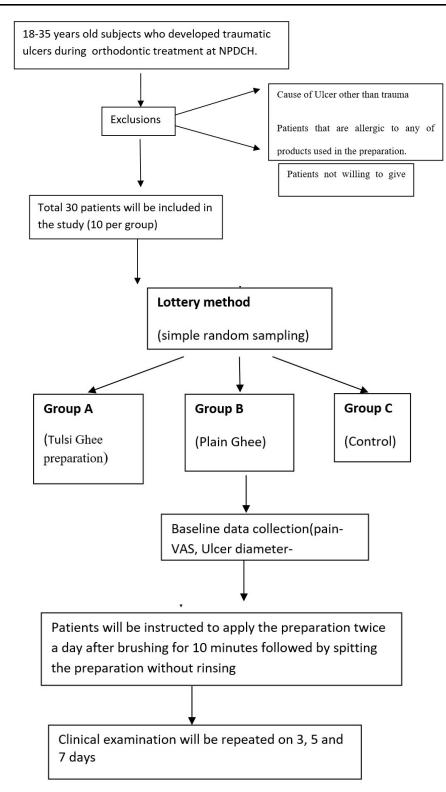


Figure: 1. Allocation of Participants in study

The compliance of participants was enhanced by reminding them personally to use the allotted product by phone call every day.

# 2.4 Statistical Analysis

The statistical analysis was performed using SPSS version 20. Chi–square and ANOVA test was employed for assessment of Difference in pain score and ulcer diameter between between groups respectively.

#### 2.5 Results

The present study was conducted to assess the effect of tulsi (Ocimum sanctum) on healing of oral traumatic ulcer.

Total of 30 patients (14 males and 16 females)(10 per group) were examined for reduction in diameter of ulcer and for pain score on 3,5 and 7 days.

Table – 1- Depicts mean reduction and statistically significant results of decrease in ulcer dimension at 3, 5 and 7 days Mean reduction in ulcer dimension was significantly larger in group 1 at 3,5 and 7 days as compared to group 2 and group 3.

Table- 2: Multiple comparisons of reduction in ulcer dimension between and within groups On day third post-hoc test revealed that group 1 shows significant reduction with group 3 but there was no significant reduction between group 1 and group 2 and between group 3 and group 2.

On fifth and seventh day there was significant reduction in ulcer dimension between group 1 and group 2 and between group 1 and group 3 but there was no significant reduction between group 3 and group 2.

#### 3. PAIN SCORE ANALYSIS

# Table – 3 describes pain score analysis using Kruskal Wallis Test. The result show significant relationship within and between the groups.

Pain score analysis done using Post Hoc test Test shows significant relationship of pain score reduction in group 1 when compared to group 2 and 3 on 3,5 and 7 days. There is no significant relation amongst group 2 when compared to group 3 on 3,5 and 7 day.

Post Hoc analysis showed significant reduction in pain score between group 1 when compared to group 2 and 3 on 3,5 and 7 days. There was no significant reduction in pain amongst group 2 when compared to group 3 on 3,5 and 7 days.

#### 3.1 Discussion

Plants are one of the most important sources of medicines. Amongst the plants known for medical value, is the plants of genus *Ocimum* belonging to the family of *Labiatae*. Two types of *Ocimum Sanctum L* are cultivated in Indian gardens 1) Tulsi plant with green leaves are known as "Sri tulsi". 2) Tulsi plant with purple leaves are called as "Krishna tulsi".  $^{7.8}$ 

Tulsi has its implication to combat against various ailments<sup>7-11</sup> Tulsi is also effective against Oral Problems like are Oral infections<sup>12</sup>, tooth ache<sup>13</sup>, periodontal disorders<sup>12,13</sup>, anticariogentic agent<sup>12</sup>, candidiasis<sup>14</sup>, lichen planus<sup>15</sup>, leukoplakia and OSMF<sup>16,17</sup>, phemphigus<sup>18</sup>, apthous ulceration<sup>19</sup>, and as a important nutrient source<sup>20</sup>. It has also shown to posses antiulcer properties against alcohol, histamine, reserpine, serotonin, and stress. <sup>21</sup>.

Literature review revealed no studies appraising the effect of Tulsi on traumatic ulcer. Thus the present study was conducted with an aim, To assess the efficacy of *Osimum Sanctum* in healing Oral Traumatic Ulcer.

In the present study the subjects were randomized into three groups, group 1(tulsi with ghee), group 2(ghee) and group 3(control).

Tulsi was mixed with ghee so that it can form a paste like consistency for easy application on ulcer site. Second group (ghee) acted as negative control.

Tulsi paste was mixed with ghee to extract its oil soluble components and tulsi juice was prepared to extract its water soluble components.

The results of Current study reveals better healing of Oral Traumatic Ulcer among subjects using tulsi-ghee paste which was evaluated by measuring the ulcer dimension and pain scale (visual analog scale) as compared to other group. This difference between the groups was statistically significant.

There was no difference between ghee and control group which clears that ghee does not poses healing property. Thus the effect seen in group 1(tulsi+ghee) can be totally attributed to tulsi. The probable reason can be due to its cytoprotective effect rather than antisecretory effect. The aling is a complex process that involves combination of wound retraction and re-epithelialization. It also involves other factors, such as, growth factors and angiogenesis. *Ocimum sanctum* (OS) significantly reduced the size of ulcer after 10 days of treatment. Furthermore, after 20 days of treatment, complete regeneration of the mucosal glandular structure was seen through histological studies of ulcer base. The ulcer healing property of *OS* seems to be based on its mucoprotective activity and its antisecretory effect. The ulcer base may have healed quickly because the basic fibroblast growth factor was protected from acid, which is considered to be chiefly responsible for epithelial regeneration. *O.S.* fixed oil may be considered to be a drug of natural origin which possesses both anti-inflammatory and antiulcer activity.<sup>22</sup>

The comparison of the study results is limited due to lack of literature. A study done by Dharmani P in 2004 showed that *Ocimum Sanctum* at dose of 100mg/kg was found to be effective antiulcer agent for Apthous Ulcer<sup>19</sup>.

The limitation of study is smaller sample size. A study with larger sample size would strengthen the evidence. In present study *Ocimum Sanctum* has proved in reducing the discomfort and accelerate the healing of oral traumatic ulcer. *Ocimum Sanctum* is found in majority of Indian courtyards, and the preparation done is very easy which can be simulated at the domestic level. Thus it can be advised to apply this lotion to patients who develops ulcer following Ortho treatment.

# 3.2 Consent to Participate declaration

Written informed consent was obtained from each participants.

# 3.3 Funding Declaration

No finding was available for the study.

#### 3.4 Data Availability declaration

All data are available for the study.

#### 3.5 Competing Interest declaration

Nil

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# **5. DESCRIPTIVE STATISTICS**

Table – 1- depicts mean reduction and statistically significant results of decrease in ulcer dimension at 3. 5 and 7 days

uicer dimension at 5, 5 and 7 days								
Size of ulcer	Group	N	MEAN(SD)	F	Sig.			
Reduction in ulcer dimension at second visit	Group 1 Group 2 Group 3	10 10 10	1.58(0.827) 0.81(0.319) 0.51(0.197)	11.063	<0.001			
Reduction in ulcer dimension at third visit	Group 1 Group 2 Group 3	10 10 10	3.5310(1.28849) 1.5990(0.38086) 0.9490(0.28282)	28.701	<0.001			
Reduction in ulcer dimension at forth visit	Group 1 Group 2 Group 3	10 10 10	4.8890(1.18583) 2.5610(0.78968) 1.4660(0.35725)	42.490	<0.001			

Mean reduction In ulcer dimension was comparitively larger in group 1 at 3,5 and 7 days as compared to group 2 and group 3, when ANNOVA was applied the dimensons also showed statistically significant results.

Table- 2. POSTHOC TESTS, Multiple comparisons Tukey HSD

Days	GROUPS COMPARED		MEAND DIFFERENCE	SIG.
3rd day	GROUP 1	GROUP 2	0.77*	0.08
	GROUP 1	GROUP 3	1.07*	< 0.01
	GROUP 3	GROUP 2	0.30	0.414
5 <sup>th</sup> day	GROUP 1	GROUP 2	1.9320*	< 0.01
	GROUP 1	GROUP 3	2.5820*	< 0.01
	GROUP 3	GROUP 2	0.6500	0.178
7 <sup>th</sup> day	GROUP 1	GROUP 2	2.3820*	< 0.01
	GROUP 1	GROUP 3	3.4230*	< 0.01
	GROUP 3	GROUP 2	1.0950*	0.20

<sup>\*</sup>The mean difference is significant at the 0.05 level.

As ANNOVA shows highly significant relationship pair wise comparison was done using POSTHOC Test at 3,5 and 7 days.

Table 3: PAIN SCORE ANALYSIS-+

Table 5. I AIN SCORE ANALISIS-1									
Groups	N ( value of 3 days)	Mean (value of 3 days)	Std deviation	Test results X <sup>2</sup>	P value				
Group 1	30	1.47	0.819	18.816	< 0.01				
Group 2	30	2.93	1.337						
Group 3	30	3.70	1.343						

Table 3 shows pain score analysis using Kruskal Wallis Test. The result show significant relationship within and between the groups.