

# TITLE

## EFFICACY OF 4% TULSI DENTIFRICE ON SALIVARY STREPTOCOCCUS MUTANS COUNTS AMONG 14-15-YEAR-OLD SCHOOL CHILDREN IN DAVANGERE CITY, INDIA – A TRIPLE BLIND PLACEBO CONTROLLED CONCURRENT TRIAL

### INTRODUCTION

A clinical trial showed the antibacterial efficacy of tulsi against streptococcus mutans, when used as a mouthrinse<sup>3</sup>

### AIM OF THE STUDY

To evaluate the efficacy of 4% Tulsi extract dentifrice, commercially available fluoridated dentifrice, and placebo dentifrice on salivary Streptococcus mutans counts among 14-15-year-old school children in Davangere city.



**Streptococcus mutans** – one of the main culprits

Shortcomings of mechanical plaque control include compliance, dexterity, and inadequate cleaning in inaccessible areas

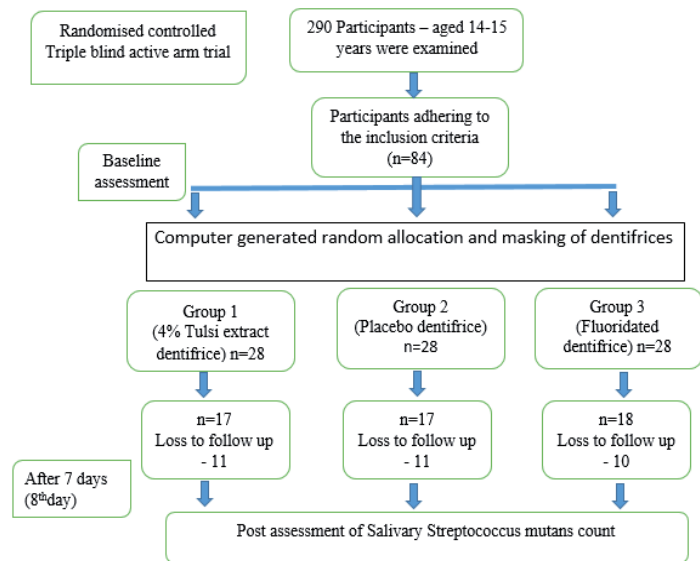
Increased bacterial resistance is one of the undesirable side effects of chemotherapeutic agents

#### TULSI (OSCIMUM SANCTUM)

- Is a holy herb easily available in courtyard
- It possess antibacterial, antioxidant, and anti-inflammatory properties

Thorough literature search revealed, no studies assessing the antibacterial efficacy of Tulsi dentifrice against salivary Streptococcus mutans.

### FLOWCHART OF THE STUDY



### METHODOLOGY

**Tulsi extract toothpaste**

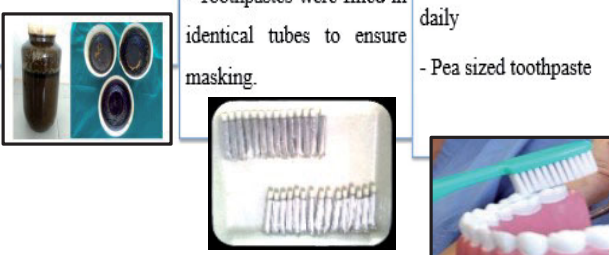
- 4% Tulsi extract toothpaste was prepared by cold maceration technique.<sup>3</sup>

**Standardization of brushing technique**

- Toothpaste and soft bristle toothbrush were provided
- Refrain from other oral hygiene aids
- Toothpastes were filled in identical tubes to ensure masking.

**Demonstration of brushing technique**

- Modified Bass brushing technique
- 4-5 minutes twice daily
- Pea sized toothpaste



### NULL HYPOTHESES

There is no difference in the antibacterial efficacy of 4% Tulsi extract, and commercially available fluoridated and placebo dentifrices among school-going children aged 14-15 years in Davangere city

- The trial was registered with the clinical trial registry in India; trial no **CTRI/2017/12/010749**.
- The study was designed, analysed, and interpreted according to the **CONSORT extension for herbal intervention**.
- Sample size was calculated scientifically using GPower with  $\alpha = 0.05$  &  $\beta = 0.20$ , and 20% drop out was anticipated.
- Children with **at least one cavitated active caries lesion<sup>4</sup>** (clinical selection criteria) and a **salivary streptococcus mutans count equal to or more than  $10^5$  colony-forming units (CFU)/ml** of saliva (microbiological criteria – pre test) were included in the study.
- Subjects with a history of hypersensitivity to any products used in the study, suffering from any systemic disease that may affect the salivary flow rate, having a history of antibiotic therapy in the month preceding the start of the study, and subjects undergoing orthodontic treatments were excluded.

### DISCUSSION

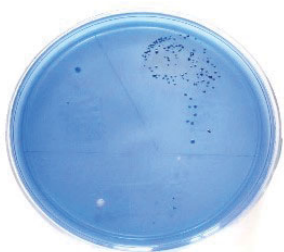
To the researcher's best knowledge, this is the first study of its kind to assess and compare the antibacterial efficacy of 4% Tulsi extract incorporated in the form of dentifrice.

### RESULTS

- Tulsi dentifrice had a significant inhibitory effect against salivary streptococcus mutans as compared to placebo dentifrice.
- The clinical effect size ( $\bar{d}$ ) was calculated for the Tulsi dentifrice and showed a moderate effect of 0.34 for antimicrobial action

- The antibacterial efficacy of tulsi is attributed to its compounds like Carracrol and Tetpene.

Streptococcus mutans colonies seen on Mitis Salivarius Agar



Baseline



Post assessment

**Table 1: Mean rank comparison of baseline and post test values between groups using Kruskal Wallis ANOVA**

S.N	Analysis	Groups	Mean rank	Chi square	p value
1.	Baseline values	Tulsi (TD)	37.95	2.102	0.350
		Placebo (PD)	38.66		
		Fluoridated(FD)	36.57		
2.	Average Score analysis	Tulsi (TD)	25.27	6.266	0.044*
		Placebo (PD)	32.91		
		Fluoridated(FD)	29.64		

**r = calculated effect size**

**Post hoc analysis**  
**TD&PD (p=0.026\*), r = 0.34**  
**TD&FD (p=0.040\*), r = 0.31**

- At least one cavitated active carious lesion was selected because S. mutans count  $>10^5$  CFU/ml of saliva is related to higher caries risk.

- The strengths of the study include the block randomisation method, concealed random allocation, and triple blinding. These methods reduced selection bias, allocation bias, and confounder bias. The oral hygiene technique was standardised for all the participants. Tulsi extract was used as dentifrice for brushing, which is a routine behaviour universally performed.

### CONCLUSION

**4% Tulsi dentifrice showed significant reduction in the salivary Streptococcus mutans counts as compared to the Fluoridated and Placebo dentifrices.**

### ACKNOWLEDGEMENT

We duly acknowledge Bapuji Pharmacy College for the preparation of Tulsi extract dentifrice, placebo dentifrice, and the principals, teachers, parents and students of the three schools for their cooperation. I extend my gratitude to Dr. Mahesh (Public Health Dentist) for statistical assistance, Dr. Chandrabhaga (post graduate - Public Health Dentistry) for concealed randomisation and Dr. Mukund (post graduate – Oral Pathology and Microbiology) for microbiological assistance.

- The compliance was assessed directly through the checklist and indirectly by assessing the dentifrice tubes of each participant.

### REFERENCES

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