CHAPTER-3

MATERIALS AND METHODS

A Randomized clinical trial with parallel study design was conducted to determine the effect of Green Tea on gingival and periodontal status.

ORGANIZING THE STUDY

1. Ethical clearance

The study proposal was submitted for approval and clearance from the Ethical review board of Pacific Dental College and Hospital, Debari, Udaipur prior to the start of the study from which the same was obtained. (Annexure-II)

2. Informed Consent

Study subjects were explained about the purpose of the study, the advantage and the disadvantage associated with the study and written informed consent was obtained before the examination. All the queries regarding the study were answered and no study subjects were forced to be part of the present study.

3. Preparation of Proforma

A pretested self designed format (Annexure -1), which consisted of two parts was used for the data collection. First part consisted of demographic information like name, age and informed written consent. Second part consisted of the Plaque Index (Silness and Loe), Papillary Bleeding Index (Muhlemann
The scoring system of indices pertaining to the study is as follows.

1. **Plaque index (Loe and Silness).**
2. **Papillary bleeding index.**
3. **Community periodontal index**

**PILOT STUDY**

In order to check the feasibility and validity of the study, pilot study was carried out. By standardizing all the material and methods, the study was conducted by considering a total of 15 participants who fulfilled the selection criteria by random selection. Pilot study assessments were utilized for proper planning and execution of the main study. A written informed consent was obtained from the subjects. The Plaque Index (PI), Papillary bleeding index and Community periodontal index were assessed. They were then divided into three groups each containing five
subjects randomly. The 3 groups were: Group A: professional scaling and root planing alone (SRP). Group B: (SRP+GT) will receive scaling and root planing at baseline along with green tea. Group C: green tea alone (GT). Based on the observations of pilot study certain modifications were done for the main study. The participants included in the pilot study were not included in the main study.

TRAINING AND CALIBRATION

Prior to the study intra examiner validation had been carried out. The method of examination and scoring was standardized in the Department of Public Health Dentistry of Pacific Dental College and Hospital Debari, Udaipur. The kappa coefficient values for inter-examiner variability with respect to Plaque index, Papillary bleeding index and Community periodontal index were 0.89, 0.97 and 0.95 respectively. This value reflects a high degree of conformity in the observational judgment of the examiners. All the examinations were carried out by a single examiner (i.e., investigator). On a given day the investigator was assigned to examine and record the findings in the prepared format on specific number of subjects. Ten percent of the subjects were randomly selected for repeated examination by the investigator on the same day. The data so obtained in the first and second examinations done on 10% of the selected subjects was subjected to kappa statistical analysis to check the consistency in judgments. The kappa (k) coefficient values for intra-examiner variability with respect to Plaque index,
Papillary bleeding index and Community periodontal index were 0.90, 0.94 and 0.96 respectively showing a high level of conformity in observational judgment. All the examinations were recorded by an alert and co-operative recording clerk. The recording clerk was given clear instructions about recording data on the assessment form (Proforma) prior to the examination. The constant flow of subjects to the examiner without crowding was maintained, throughout the examination.
STUDY DESIGN

A double blinded, randomized clinical trial with parallel study design was done, to reduce the bias. Blinding was done so that the examiner and study participants were unaware of the group they were allotted to.

SAMPLE SIZE DETERMINATION

Sample size (N) was calculated by using following formula:

\[ N = \frac{Z^2 PQ}{e^2} \]

P = Anticipated population proportion = 80%
Confidence interval = 95%
Relative precision = 5%
Q = Free of gingivitis (100-P) = 20%
Z = Point of normal distribution (as per table of area under normal curve for the given confidence level of 95%) = 1.96

\[ N = \frac{(1.96)^2 \times 0.80 \times 0.20}{(0.05)^2} = 10 \text{ samples in each group} \]
Sample size was inflated to 40 subjects keeping in mind the dropout rate.

**SAMPLING METHODOLOGY**

After the pilot study, the necessary changes in the proforma were done and study period was scheduled. The study subjects fulfilling the inclusion criteria were selected randomly and those who were interested and gave informed consent were included in the study. The inclusion and exclusion criteria was based to reduce the bias. The calibration and study was carried out in the Department of Public Health Dentistry, Pacific Dental College and Hospital, Debari, Udaipur.

**Inclusion criteria:**

40 patients (20 females and 20 males) with chronic periodontitis with minimum of 20 teeth from the outpatient department of the faculty was selected.

**Exclusion Criteria:**

The patients with history of smoking in past 1 year, Scaling and Root Planning (SRP) for 12 months prior to baseline, as well as pregnant and lactating mothers will be excluded from the study.

**Method of Examination:**

Using simple random sampling the study subjects were selected, purpose of the study was explained to them and their written informed consent was obtained.
Demographic details were recorded. The selected 40 patients will randomly be divided into three groups using block randomization method. The assignment of the participants to the groups was performed by a person not involved in the examination. The first group will receive professional scaling and root planning alone (SRP). The second group (SRP+GT) will receive scaling and root planning at baseline along with green tea for a period of 6 months. The third group will receive only green tea (GT) for a period of 6 months without any professional SRP.

The Plaque Index (Silness and Loe), Papillary Bleeding Index (Muhlemann and Son), and Community Periodontal Index will be recorded at baseline, 3 months, 6 months to evaluate the effect of dietary intake of green tea on dental plaque, gingival inflammation, and periodontal disease, respectively.

The professional for performing the SRP as well as examiner for recording the data will be blinded of the different groups in the study. The same professional will be deployed for performing SRP in all the patients. The single calibrated examiner will be used to reduce any examiner bias. The statistician performing analysis will also be blinded. Duration for the study will be of six months.

Green tea (Camellia sinensis) without any additional flavors like lemon or mint will be used in the study. The green tea will be provided to the subjects in the form of tea bags, each weighing 1.75 g. This is in accordance with the MIC (minimum inhibitory concentration) of Green tea. The patients shall be asked to have four
cups of green tea per day. No attempt will be made to quantify the type of additives as sugar or honey as the main focus of the study will be to study the effect of green tea on the periodontal status.

Green tea should be handled tenderly, just as you would fresh green leafy vegetables. Spring water is the ideal choice for brewing tea, followed by filtered water. Distilled water should never be used; the brew it produces will be flat as the minerals removed from it are essential to bringing out the tea’s flavor. Use 3 g of tea to 5 ounces of water if brewing tea in a small teapot.

Although heartily boiling water is used to brew and oolong teas, green tea needs much lower temperatures (160–170°F; 79–85°C), and should be brewed for a lesser time. Let the water barely reach the boiling point to liberate its oxygen, then allow it to cool slightly before pouring over the tea.

The recorder was made to sit close to the examiner so that instructions and codes could be easily heard and the examiner could see the findings recorded correctly.

**BLINDING**

Examination was done by a single examiner. Examiner was blinded regarding the groups to minimize the selection bias.

The statistician also blinded with regard to the groups thereby ensuring a double blinded study.
ARMAMENTARIUM

The instruments used for the clinical examinations were:

1. Plain mouth mirrors,
2. Hufriedy’s Williams graduated periodontal probes,
3. Tweezers,
4. Kidney tray,
5. Disposable gloves,
6. Sterile Head caps,
7. Disposable mouth masks,
8. Cotton and Gauze,
9. Patient’s drape,
10. Depen-dish
11. Data recording sheets, pencils and pen.

DATA COMPILATION AND PRESENTATION

The obtained data was compiled systematically. A master table was prepared and the dataset was subdivided and distributed meaningfully and presented as individual tables along with graphs.
STATISTICAL ANALYSIS

Data collected was coded, computerized and analyzed using Statistical package for Social Sciences (SPSS version 19.0).