Chapter - 5

METHODOLOGY
From the time immemorial, man is in search of better and better options for improving the quality of his life. He was always very much conscious and eager about his own health and its care. The alterations in the lifestyle and also the working conditions contributed to the manifestation of many a disease. Not a few of them were not responding as expected, with the then available medicines. That turned his attention to research for greater piece of knowledge. Even though the modern research techniques are not fully athletic to the Ayurvedic system of medicine, evidence based studies are very much essential for the global acceptance of the science.

In any form of research, the methodology is the key component. In this study, the selected drug was tried for the efficacy with the commonest drug in practice, Omeprazole in Functional dyspepsia. The design used was a Randomized Controlled Clinical Trial. The selected patients were allocated into two groups using a system generated random number table after receiving proper written consent.
MATERIALS AND METHODS

Aims and Objectives

1. To evaluate the role of Mahatiktakam kwatham Tablet in Amlapitta with special reference to Functional Dyspepsia
2. To compare the efficacy of Mahtiktakam kwatham Tablet with Omeprazole in Amlapitta with special reference to Functional Dyspepsia.

Research Question

Is there any significant difference in the efficacy of Mahatiktakam kwatham tablet when compared with the Allopathic drug, Omeprazole in reducing the symptoms of Amlapitta with special reference to Functional Dyspepsia when administered continuously for 30 days.

Null Hypothesis

There is no significant difference in the role of Mahatiktakam kwatham tablet when compared with Omeprazole in Amlapitta with special reference to Functional dyspepsia.

Alternate Hypothesis

There is significant difference in the role of Mahatiktakam kwatham tablet when compared with Omeprazole in Amlapitta with special reference to Functional dyspepsia.

Materials

Patients/ Drugs/ Case Record Form / Written consent form
Drugs

Study drug

Mahatiktakam Kwatham tablet
prepared from Arya Vaidya Sala, Kottakkal with batch number
123/ 1/ 2013.

1 gm of the medicine of active ingredients of the respective
kwatham was there in each of the tablets.

Dosage and duration

2 tablets thrice daily, to be administered, with warm water, 1 hour
before food, continuously for 30 days.

Control drug

Omeprazole - 20 mg capsule, sufficient in quantity was purchased
from Micro labs limited, Solan district, Himachal Pradesh with batch no.
OMADO05/ 06/ 2013

Dosage and duration

One capsule daily 1 hour before lunch, continuously for 30 days.

Study Design

Randomized Controlled Clinical Trial

Randomization was done by the random number table of 200 subjects
which was created using the Random number generator software.

The protocol was submitted for clearance and approved by the research
committee of the Tilak Maharashtra Vidyapeeth, Pune.
Sample Size

**Calculation of sample size:** The sample size was calculated assuming the prevalence rate of the disease as 15% of the population, with a probability for type I error fixed at 5% ($Z_{\alpha} = 1.96$) and an effect size of 5%. The calculated sample size was 195. Expecting a dropout of 5%, the final sample size calculated was 200 which were equally divided, among the 2 groups. The samples in each group were allocated according to the computer generated random number table. (Appendix X)

**Duration of the study**

24 months from June 2012 onwards

**Setting**

OPD and IPD of Kayachikitsa Department and the Gastroenterology OPD, Vaidyaratnam P S Varier Ayurveda College, Kottakkal.

**Diagnostic Criteria**

I. **Features of Amlapitta**

1. Daha
2. Amlodgara
3. Chardi
4. Avipaka
5. Soola

Atleast 3 symptoms from the duration of more than 3 months included

II. **Functional Dyspepsia**

ROME III DIAGNOSTIC CRITERIA
Those with the following:

a. Bothersome postprandial fullness
b. Early satiation
c. Epigastric pain
d. Epigastric burning

AND

- No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms
- Criteria fulfilled for the last 3 months with the symptom onset at least 6 months prior to the diagnosis

**Inclusion Criteria**

- Participants fulfilling the proposed diagnostic criteria
- Upper GI Endoscopy negative for structural changes
- Age: 20 - 50 years
- No discrimination of sex, caste, religion and economic status
- Participants from whom the written consent is obtained

**Exclusion Criteria**

- Those with the endoscopic findings of peptic ulcer or gastritis
- Endocrine disorders - DM, Thyroid disorders etc.
- Other systemic disorders- CAD, HT, Bronchial asthma, Dyslipidaemia etc.
- Those on NSAID’s, antibiotics or other long-term and continuous medication
- Pregnant women and lactating mothers
Assessment Criteria

- Changes in the Gastrointestinal Symptom Rating Scale (GSRS)
- Changes in the Amlapitta rating scale

Assessment

There were three assessments throughout the study after the baseline evaluation

- Before starting the medication
- 15 days after starting the medication
- After completion of 30 days of the medication
- After 45 days from the commencement of the medication

Those who were positive in the Rapid Urease Test for the H pylori were also given the respective medicine, as per the randomization. After full course of intervention and on the 60th day of the commencement, they were advised to perform the post test, ie. Immunocomb II Helicobacter pylori IgG kit and the results were observed and recorded.

Observations and analysis

The observations were recorded in both the groups and was compared at the baseline and at the end of 15 days, 30 days and 45 days of assessment for the GSRS score as well as the Amlapitta rating scale, using the selected statistical tests - unpaired t test between groups, one way ANOVA for comparing within groups, Tuckey Kramer test for multiple comparison, Chi square test for association between the various factors. Also the correlation and regression test were done accordingly. Insta Graph pad 1.0 version and Microsoft Excel 07 were used for performing the statistical tests.