Chapter - 1

INTRODUCTION
The man and his evolution are being considered as the superlative creation in this universe. According to the Indian tradition, the ultimate goal of health is to accomplish the purushartha's, i.e., dharma, artha, kama, and moksha, which are the prime achievement in one's life\(^1\). Hence an affection of the health was being considered as a very serious obsession, as it affects the fulfillment of the ultimate aim of one's life i.e. the purushartha's during their entire life span. Many attempts are being explained to maintain as well as preserve the health and any variation or disruption in the same, is approached with serious apprehension, as per the Indian system of medicine.

The modern era and the associated changes with it has affected the human being in the several areas of his life, not only regarding the activities and habits, but also the manner of food, sleep, thoughts and expressions as well, in the due course. The engagement of humans in the excessive travelling so as to fulfill his several deeds and needs, have altered the food habits immensely, in a negative manner, as far as the health status is concerned\(^2\). Faulty life style along with the unbalanced food habits has affected the digestive system a lot, along
with its function and the disorders of the system are ever on the rise, as reported from studies all over the world. Food is an integral part of the daily life, but we spend fewer point of time for preferring, preparing, the intake as well as digestion of the food. Consequently many of us are not having food in an appropriate manner and form, as expected or as per the body’s demand, which may result in major as well as minor gastro intestinal dysfunction or complaints.

Practicing high-quality dietary habits require a little more instance and scheduling than we can usually afford, in this fast as well as altering world and the lifestyle. However, its benefits will pay off at the long run, because of the sufficient scientific evidence that links most G I disorders to diets\dietary habits, in general. Besides is the presence of a positive mind, that is considered necessary for the proper digestion, as well as assimilation of food.

Among the many a kind of the digestive disorders, the functional disorders are the dominating group, compared with the structural as well as the infectious disorders, affecting the tract. The Functional Gastrointestinal Disorders (FGIDs) can affect any part of the GI tract including the esophagus, stomach as well as the intestines. FGIDs account for about 40% of a gastroenterologist’s practice and is affecting the quality of life of such individuals in a noteworthy manner.

FGIDs are characterized by recurrent symptoms (ie. abdominal pain or discomfort, bloating, nausea, vomiting, early satiety, constipation, or diarrhea) that indicate a dysfunctional GI tract despite that an organic or biochemical rationale for the generation of the symptom, on investigation. Many of the disorders are diagnosed by exclusion of the related structural disorders, along with the diagnostic criterias.
STATEMENT OF THE PROBLEM

As per the available studies, more than 50% of the people with FGID’s symptom seldom consult a physician, although they may undertake over the counter medications, on the arousal of the symptoms for the relief, making the computing of the exact prevalence of the condition, as composite. Significant job absenteeism and disability are reported among these, than the people without these symptoms. The most reported or dominant FGID’s in the society are the Functional Dyspepsia (FD) and the Irritable Bowel Syndrome (IBS). The prevalence of FD has noted to vary between 11-29.2% as per available studies. The reported prevalence for dyspepsia varies widely among the different populations, possibly because, most of the studies have focused on the uninvestigated dyspepsia, rather than the FD. The definition and the diagnostic approach also have also been modified several times. One of the other affective variable being the difference in the food habits as well as the mode of life, within the various societies, where the studies have been conducted. Further more, some of these studies must have the inclusion of patients with the reflux disease, misclassified as FD; this makes the interpretation of the true prevalence, intricate and final. Variations in the definition of the dyspepsia and specifically the FD, is also affecting the prevalence, as per the experts in this field. The self limitation of the symptoms over a peculiar period of time and also over the counter treatment in some of the subjects is also considerably altering the statistics.

A recent study from Mumbai had shown that almost a third of the population suffered from dyspepsia among which, 12% of them experiencing the symptoms of the disease, considerably. There is a balance in the actual number of people reporting the new symptoms and the number of people reporting the
disappearance of the same. Bearing in mind, the high prevalence of FD reported in the Indian population, socio-economic burden of this disease in the Indian community, is predicted to be considerable and enormous. No Indian study is available to show the health related quality of life in relation with this condition, as less number of studies are aiming such a direction. Studies from the other Asian countries indicate that the FD is associated with the substantial impairment in the quality of life, work absenteeism, decreased productivity and use of health care resources, with the resultant consequent economic burden\textsuperscript{10}.

**FUNCTIONAL DYSPEPSIA – CURRENT SCENARIO**

Patients having the chronic dyspeptic symptoms for the past 3 months with the onset at least 6 months prior to the diagnosis, in the absence of any structural abnormality on upper GI endoscopy and possible metabolic or systemic causes, so as to explain the existing symptoms, are classified as the Functional Dyspepsia. ROME III criteria is the most used worldwide, for its specific as well as constant diagnosis\textsuperscript{11}. The 2006 Rome III criteria defined the FD and its two subgroups, Postprandial distress syndrome (PDS) and Epigastric pain syndrome (EPS), based on the clinical presentation\textsuperscript{12}.

Multiple mechanisms such as abnormal gastric emptying, visceral hypersensitivity, impaired gastric accommodation and central nervous system factors are likely involved in the pathogenesis of the disease entity. The other area of interest to be discussed is that of the H pylori and its eradication, in the role, as well as the management of FD. According to several authors, the combination of physiological, environmental, genetic and psychological factors definitely occupy their role in the disease\textsuperscript{13}.  

**Introduction**
Currently, the possibilities of available pharmacological agents in the management of the FD are still having its own limits; however, the experience of administering prokinetics, tricyclic antidepressants, Selective Serotonin Reuptake Inhibitors (SSRIs), Proton Pump Inhibitors (PPIs), and several alternative techniques has been accumulated and tried as well\textsuperscript{14}. The diverse combination of the alterations in the physiologic functions of the gastrointestinal and central nervous system, result in the very heterogeneous nature of FD so that, the present available protocols, have their own limited areas in the studied efficacy. World is looking ahead to the alternative systems for their contribution to these patients, so as to provide them with a superior prospective.

Due to geographical, social, cultural, educational, and the psychological aspects, the universally pertinent guidelines on the diagnostic and therapeutical measures, are not in a perfect condition so as to implement\textsuperscript{15}. The wide range of the available therapies reflect the uncertainty about the currently explained pathogenesis and the lack of satisfactory management of the condition. Many of the studies have concluded that, Omeprazole is observed to be more effective than placebo, in controlling the symptoms of Functional Dyspepsia\textsuperscript{16}. The real comparison was with the placebo only, as far as such studies are concerned. The placebo studies are undergoing worldwide in almost all the functional conditions, without an expected yield or outcome. The world is in search of identifying new as well as efficient drugs in this regard.

**THE AYURVEDIC APPROACH AND THEIR ROLE**

Several Ayurvedic practitioners are dealing with conditions like FD in a satisfactory manner and the system of medicine has definitely a key role to play
in the FGID’s, especially. The tridosha theory in Ayurveda, approaches any clinical condition in a functional manner, rather than the structural abnormalities or alterations. It is stressing a good deal on the functional attributes of the body. It is of the view that the functional alterations have to be improved initially, before approaching the limitations in the structure. Once the functional status is normalized, the rest of the problems can be approached with ease. Encouraging perspectives have been recently performed by methodologically well designed interventional studies, with the herbal drug preparations. Herbal drugs, yielded their proven efficacy in clinical trials, offer a safe therapeutic alternative in the management of FD, which is often favored both by the patients and the physician.

Amlapitta is the commonest diagnosis in an Ayurvedic gastroenterology clinic. Many a clinical conditions like FD are managed on the luminosity of the protocol, mentioned for Amlapitta. The symptoms of the condition FD, resemble very much that of the Amlapitta. The drugs mentioned in the management of Amlapitta need special significance here, in the management of the condition. Mahatiktaka yoga is one such widely used combination, mentioned by Acharya Charaka, with proven clinical efficacy in such a condition. This drug was selected for the clinical study due to the confidence attained from the efficacy of the drug, from the reported clinical practice. Several studies are available and contributory in this regard.

**SELECTED PREVIOUS STUDIES**

1. Effects of Proton Pump Inhibitors on Functional Dyspepsia, A meta-analysis of Randomized Placebo Controlled Trials, Wei Hong Wang et.al., Clinical Gastroenterology and Hepatology 2007;5:178–185.


7. Anti Helicobacter activity of certain food plants extracts and juices and their composition invitro, Anna babarikina etal. Food and nutrition sciences 2011, 2, 868-877

8. Comparative clinical study of Indukanta gritha and Mahatiktaka gritha in Parinama soola, PK Warrier etal. JRAS vol I no- 2, pp 15-29

10. CH Srikrishna etal, Etiopathological study of Amlapitta and its management with Chinnodbhavadi Yoga Ghana Vati and Medhya Rasayana compound, AYU, Vol 29, ISS 2, pp 93-99


12. Effect of Gut Gard in the Management of Helicobacter pylori: A randomized double blind placebo controlled study, Sreenivasulu puram etal, Evidence-Based Complementary and Alternative Medicine, Volume 2013 (2013), Article ID 263805, 8 pages

13. Role of stress in hyperglycemia – A cross sectional study and a pharmaco- clinical trial with Mahatiktakam Kashayam, Snigdha Roy, Prakash M, VPSV AVC, Kottakkal, 2014

**SIGNIFICANCE OF THE CLINICAL STUDY**

Eventhough many studies have been conducted with the Ayurvedic drugs since several years, still there are quite a few areas to be explored. Drugs like PPI’s are studied extensively and shows positive response in the condition of the FD. The subsequent level of exploration is the comparative study in this direction, with the allopathic counterparts. Such was the thinking behind such an initiation and the commonest PPI, Omeprazole was fixed as the control drug.

Mahatiktaka gritha is attaining efficacy in Non ulcer dyspepsia, as per the study conducted by CCRAS. But there are difficulties in the administration of the drug in the gritha form in many a patient, with associated life style disorders and if there is further restriction, in the administration of sneha preparations. The
alternate option is the kwatha form of the combination. But nowadays the prepared kwatha is on the use, which are having added preservatives. The use of such kwathas is adding on to the dyspepsia, if used in a persistent and repeated manner. That led to the thinking of administering the combination in the kwatham tablet format. This form also helps us to administer the drug in a more accurate dose and is expedient, without the affront of the preservatives. Hence the Mahatiktaka yoga was used in the form of the kwatham tablet, as the study drug.

In the contest of the FD, H pylorus is the most predisposed organism without much substantial evidence regarding the same. This combination of Mahatiktaka was also tried for the action on H Pylori in selected subjects in those which, the Rapid Urease Test, was positive on inclusion. It was a Randomized Controlled Clinical Trial with 100 subjects in each group of those attending the OPD of VPSV Ayurveda College, Kottakkal within the proposed inclusion criteria during the study period and submitted due written consent.

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 Mahatiktakam Kwatham Tablet with Omeprazole in Amlapitta with special reference to Functional Dyspepsia.

Null Hypothesis

There is no significant difference in the role of Mahatiktakam Kwatham Tablet when compared with Omeprazole in Amlapitta w.s.r. to Functional Dyspepsia.
Alternate Hypothesis

There is significant difference in the role of Mahatiktakam Kwatham tablet when compared with Omeprazole in Amlapitta w.s.r. to Functional Dyspepsia.

The recorded observations were analyzed and the drawn conclusions were compiled and prepared in the format of the proposed thesis, which consists of the following sections arranged accordingly.

The conceptual part consists of three sections

1. Review – Functional Dyspepsia
2. Review – Amlapitta
3. Drug review – Mahatiktaka yoga

Clinical study part consists of three sections

1. Methodology of clinical study
2. Observations, Analysis and Interpretation
3. Discussion, Summary and Conclusion.