Chapter - 7

DISCUSSION, SUMMARY & CONCLUSION
The observations during the study were recorded and analyzed with the suitable statistical tests and the possible inference was made by comparing with the available and published studies and also the supportive conceptual facts.

**Demographic Data**

In the clinical study, there was a slight male predominance in both the groups. Overall, several studies conclude that in Functional Dyspepsia, slight male predominance is observed. The reason may be due to the relative variations in diet, travelling and also the excessive stress compared to females. Most population studies have been able to obtain relatively equal ratios of male: female i.e. they have shown no differences in the prevalence of dyspepsia between genders, mostly where Ulcerative Dyspepsia is concerned\(^1\). Some other studies, in different populations, however, have also noted a consistent female preponderance with dyspepsia\(^2\). So noticeable variation cannot be observed in the case of gender in FD.
Half of the population was from the age group between 40 and 50 years. The remaining subjects were almost equally distributed in the other two groups which points to the increased occurrence of the disease, in the forties. All surveys that have been conducted have examined adults of 18 years or older. While most surveys have shown that dyspepsia does not emerge to be related to any particular age group, several studies have noted dissimilar trends. Peak prevalence of Ulcerative Dyspepsia have been noted between the ages 45-54 in a Canadian survey\textsuperscript{3} whilst FD appeared to peak in Chinese subjects of the age group 41-50 years\textsuperscript{4} and in Japanese adults of 50-59 years\textsuperscript{5}.

In contrast, a survey in urban part of Mumbai established that Ulcerative Dyspepsia was more prevalent in adults of age more than 40 years\textsuperscript{6}. Despite these trends, age extremities have not been identified as a predictor of dyspepsia, either functional or structural types. Majority of the population based studies do not show any gender difference in dyspepsia prevalence and few studies concluded that the prevalence is more in the old age population. It can be assumed that the dietary alterations in a negative manner is contributing to the condition gradually. Also the changes happening in the tract, by several years of insult by the food habits is causative. These leads to dyspepsia at a later stage, with the chronicity in the contributory factors.

The gradual decrease in the level of agni by age along with the continuous indulging in the nidanas lead to the condition, at a later age group. Vaghbata mentions this while explaining the management of Grahani that, even though one is indulging to the nidana of grahani, the disease is manifesting, when the status of agni declines, after a certain period only.

The Muslim community, which was the majority, nearby the institution
and the district, were also reflected in the study, as they contributed up to 60%. It is also reported that the gastrointestinal problems are on the rise in this community, due to their excessive and regular intake of the spicy and non-vegetarian diets. Likewise is the case of intake of processed and junk food as well. The role of the ethnicity is also being discussed worldwide. A reported study from Malaysia concludes with the increased prevalence of FD in the Chinese and the Indian population over there.⁷

The population was equally distributed among the married and unmarried groups. No studies pointing out to the relation between the marital status and dyspepsia could be traced out, at this stage.

Most of the people belong to the middle class in economy. This seems as expected as the hospital is approached chiefly by the low and the middle class community, from the center part of Kerala. In majority of the population based studies, prevalence of dyspepsia have not found to be linked with the social class. However studies examining the details of socio-economic status were able to elicit associations with dyspepsia. In a British study, it was found that people from lower socioeconomic classes, were more affected with Functional dyspepsia and other associated conditions⁸.

Majority of the subjects were having an education of secondary level and above. This is also the reflection of the low and middle class community approaching this hospital. Also majority of the people from this state is having an education of at least the secondary level. A survey study from Canada revealed that chronic GI symptoms were more prevalent in adults with lower household income, who were unemployed and with lower educational levels which cannot be a generalisation.⁹

While observing the occupation, the majority were in two groups ie. those with job having physical exertion and also the home managers. The condition of
dyspepsia is more reported in those with physical exertion. Home managers were also affected as their food timings were too irregular and they were having a much more stress level, than expected. Business men were also affected as their food habits were irregular, they were involved in excessive travelling and also associated with stress as well. In a study conducted at Nigeria, a larger sized family together with occupational scatter, was reported to have strongly associated with UD

**Observations regarding Dasavidha pareeksha**

Agni is one of the crucial factors to be studied in any disease peculiarly that affecting the GI tract. In this study, majority were having mandagni in both the groups. Vishamagni was also observed in more than a few. The relationship of agnimandya contributing to the manifestation of diseases such as Amlapitta is very much substantiated, by the number of patients reported with mandagni, in this peculiar study. Agnimandya leads to ama and the disturbed Pitta due to the above said nidana, incorporates with ama, leading to the Pitta becoming saama in nature. Hence the Kaphaja symptoms like hrillasa, gourava, avipaka etc. are manifested along with the Pitta symptoms such as hrit-kanta daha in Amlapitta. The initial management to be adopted is of Pitta Kapha samana, so as to subside the ama associated with Pitta. Later Pitta samana or Vatha Pitta samana protocol is advised as per the condition. Vishamagni is also contributing to the pathology by its alteration, but not as the usual level, as that of the mandagni.

Kroora koshta was observed in almost 60% of the subjects. It seems that kroora koshta is very much associated with the manifestation of symptoms of Amlapitta. The Vatha kopa in the GI tract in the case of kroora koshta is contributing to the symptoms of conditions like FD, resulting from the altered functioning of the other
doshas. Alteration in the Samana Vatha alters the status of both Kledaka Kapha and Pachaka Pitta, Vatha being the regulator. In this particular study, very few individuals were having mridu koshta, but the possible inverse relationship of the same, has to be studied in detail.

The nature of the pureesha is an indicator of the mechanism of digestion and its alteration is to be considered quite seriously, peculiarly in a GI tract disorder. That is the reason for pureesha pareeksha and its significance mentioned among the ashtavidha pareekshas. In this study, two parameters were assessed, whether the pureesha is sama or nirama and also whether the pravritti is badha or in the drava avastha, the details are mentioned in classics, while explaining the athisara.

In the study, majority were having malapravritti as nirama and a relation cannot be established between sama mala pravrithi and Amlapitta. 90% of them were having badha pureesha or were constipated. It seems that badha pureesha and dyspeptic symptoms are very much related, the associated Vatha kopa being the causative factor. The krichrapravritti of pureesha was also noticed in 10% of subjects.

The relationship between prakrithi and the increased occurrence of certain diseases according the prakrithi, has been studied. Almost 40% were having Vatha Pitta prakrithi. Also equal number was having Vatha Kapha prakrithi. All the other types of prakrithi, were fewer among the included subjects. An association of the same with the condition, is yet to be traced out.

When the manasa prakrithi was assessed, 85% were of the rajasa prakrithi. These point to the increased occurrence of dyspepsia, in those with the rajasa prakrithi. These people are more with the custom of intake of katu- amla- lavana- ushna ahara and also excess psychological features like krodha and matsarya, resulting in the
aggravation of Pitta and associated conditions. The other two manasa prakrithi’s, the satwika and tamasa were not so dominant.

More than 60% of the subjects were of madhyama satwa. Actually it is found in studies that the Functional Dyspepsia and similar conditions are more found in the avara satwa persons. This study does not agree with the fact wholly but overall, one fourth of the patients were having avara satwa, as per the observation. This is expected to happen in functional conditions, with the psychological component as one of the main etiological factor.

The importance of satwa and its importance in the diagnosis as well as the management of diseases, have been explained by Charaka, in the Vimanasthana. Pravara satwa is also one of the contributors to the immune status of the individual. In a survey conducted in a selected population in Denmark, it was noted that UD was strongly associated with adults who had “experience of problems” and “psychological vulnerability”.

More than 80% of the subjects were having Vatha Pitta as the dosha status of the condition. In about 10%, the dosha status was Vatha Kaphaja. The dosha status can be concluded as Vatha Pittaja in nature and in some of the subjects, Kapha also seems significant, may be due to the association of the ama and its similitude with the Kapha. The relationship between the corresponding prakrithi and dosha has to be studied further.

While assessing the affected dhatus, from the observed lakshanas clinically, rasa dhatu was involved in 90% of the subjects as the symptoms of agnimandya, praseka, gourava, glani etc. were reported. Both rasa and rakta dhatu were affected in about 10% of the subjects. We can infer that the rasa dhatu is the primarily affected
one, as it is having direct relation with the digestion and metabolism of food. The defective agni is not able to transform the ahara rasa to proper rasadhatu. There was also slight involvement of the rakta dhatu even though not considerably significant, due to the ahara and vihara, causing the aggravation of Pitta and also the mutual association of Pitta and raktha. The other dhatus are having a chance of vitiation as the chronicity occurs in due course, as all the dhatus entail the nutrition, from the properly digested and absorbed ahara.

Factors regarding food intake and digestion

Most of the subjects were non vegetarians ie. 90%, this was also due to the area wise distribution. This is an indication of the increased occurrence of dyspepsia among the non vegetarians, as per studies. 14% of the subjects in the study group and 13% in the control were having processed food, frequently. 20% among the study group and 26% in the control group were of the habit of consuming non compatible food, in a frequent manner. These also are an indicator of the contribution of such factors, in the manifestation of FD. In an urban survey in India, it was proved that no differences in dyspeptic symptoms occurred between vegetarians and meat-eaters whilst spicy, fried or food prepared outside the home contributed insignificantly, to worsening of symptoms12.

Timing of meals is one of the most important aspects, regarding the digestion and absorption of the food. This is one of the areas which people are neglecting or not following now a days. In this study also, around 80% were having the habit of irregular timing of meals. Dyspepsia and irregular meal timings seem very much related, as per this study. Many were having the habit of skipping their meals, on a regular basis. Keeping a regular schedule is a necessity, for the timely digestion as well as absorption of the food.
The pace of intake of their food was slow in 2/3rd of the included and more than 1/3rd were having it, in a hurried manner. Alteration in the pace of food intake is really affecting the digestion as well as absorption of its contents, as per studies. The food habits have to be advised in such a manner so that, it may be chewed properly before swallowing, so as to support the digestion. Kharanada opines that one who is so paceful with food cannot evaluate the guna and dosha of it and those who are too slow cannot recognize the stage of tripthi ie. when to stop the food.

Almost 80% were having food, before they felt genuine appetite. This also seems affecting the mechanism of digestion. Around 10% were having processed food on a regular basis, which is also contributing to dyspepsia, as per studies. The overall rise in the intake of processed food has resulted, in the increased incidence of conditions like FD.

3/4th of the subjects were having their food in an atmosphere, which was not calm and was really tense as well. In the modern world, people are not allotting the time that is unique for the intake of food. They are having their food amidst of their stress situations with their profession and so. This is very much contributory to the conditions like Amlapitta. That is the reason behind the explanation of ahara vidhi and its details by Charaka so that, one must have food in a calm atmosphere with a relaxed mind, so as to enhance its digestion, as well as absorption. The altered psychological status, affects the intestinal movements and hence digestion.

In a retrospective study, it was observed that, alteration in the intake of meals such as changes in the usual timings, variation in the amount of food intaken and the regular practice of skipping meals, over a period of years is associated with the increased incidence of H Pylori infection and gastritis. The exact pathogenesis is yet
to be explained, but the resultant alteration in the secretions of the tract and also the bicarbonate layer, creates a positive situation for the organism to invade. Also the action by the organism results in a complex interaction between genetic, socio economic, environmental and bacterial factors, resulting in multiple outcomes\textsuperscript{14}.

**Quality of food**

The excessive use of any of the six rasas or its combination was assessed to review the etiological component of FD. Among which the excessive use of mainly three rasas amla, lavana and katu were reported. About 90% were using amla rasa more, 75% were using much of lavana and around 90% were having katu rasa in excess. The excessive use of these rasas are very much contributing to the Pitta kopa and the manifestation of the disease. This also shows the importance of avoiding such rasas in the diet resulting in the Pitta kopa, leading to Amlapitta and similar conditions.

The guna or characteristics of the food is having direct association in the manifestation of any disorder. In this study whether the subjects were using any peculiar type of ahara in excess, was traced. The four main gunas, snigdha, rooksha, ushna and seetha were recorded. It was observed that 1/3\textsuperscript{rd} were using snigdha guna in excess and ½ of them were using rooksha guna in excess. Seeta was used in excess in a few of the subjects overall. It seems that excessive use of both the snigdha as well as rooksha diet, leads to dyspeptic conditions, by affecting the act of digestion and altering the dosha status. As the agni is a sum of Samana Vatha, Pachaka Pitta and Kledaka Kapha, any alteration may cause distorted digestion. Similarly excessive use of ahara with the ushna guna contributes to Pitta kopa and hence dyspepsia. Ushna, rooksha and snigdha are the chief contributors here in this regard.
Factors of digestion

Abyavaharana is the capacity of food intake. It was affected considerably in most of the subjects. Abyavaharana sakthi was heena in almost 80% and it was pravara in minimum. From this it can be inferred that, abyavaharana sakthi is affected in almost all the subjects with dyspepsia. Aruchi is mentioned as one of the classical feature of Amlapitta as well.

Jarana sakthi is the ability to digest the intaken food in an appropriate manner. It was also affected as per the observation, but not to the extent of abyavaharana. In almost 60% of the subjects, jarana was madhyama in nature and it was heena in only 1/4th of them. The abyavaharana is affected much more than the jarana in this study, even though avipaka is also mentioned.

Factors affecting the proper digestion of the food were also assessed accordingly. Of which, majority of the subjects were having physical exertion. Mental exertion was observed in 3/4th of them. 90% of them were having the habit of skipping the meals on a regular basis. Irregular sleep pattern was there in 1/4th of them. Both physical and mental exertions and the habit of skipping of meals are contributing to dyspepsia causing impaired digestion, as per the study.

In this study, 1/3rd of the subjects of the study group were having the regular habit of carbonated drinks. Even though this is more seen in the society, the decrease in the number may be due to the inclusion of more the lower and the middle class. This is one of the habits contributing towards the manifestation of condition like dyspepsia, as per studies. This is to be modified or altered. In this study alcohol, tobacco and smoking habits were reported in less than 10% of the subjects. A survey from Canada showed that the heavy intake of cola or carbonated drink was associated
with markedly increased prevalence of dyspepsia. Population studies in India and New Zealand have pointed to definite association between alcohol and UD.

Frequent use of NSAID’S are considered as a contributor to the manifestation of dyspepsia. In this peculiar study, 1/5 were using NSAID’s in excess. This was less when compared in accordance with the available studies. In a published study NSAID’s, Aspirin, hormone therapy, over the counter medications are significantly contributing to FD.

In the study group, half of the patients were having reduced or interrupted sleep. The alteration in the sleep pattern is very much, affecting the abdominal physiology and contributing to conditions like dyspepsia, as per studies. Similarly, day time sleep is also having a role in the functioning of the abdomen. This may lead to Vatha Pitta aggravation and hence to the condition. But in this peculiar study, very few of the patients were only having the habit of day time sleep, which is not so significant here. Prajagara or insufficient sleep is being mentioned as one of the causes of indigestion by Acharya Charaka, even though the agni is of normal in status.

Family History

Family history is very much being blamed for the manifestation of the conditions such as Functional Dyspepsia and there are studies supportive for it. In this study, 1/5th of the subjects were with the family history of dyspepsic symptoms, overall. This is not in accordance with the available studies as in the case of positive family history. Even though published studies are not available as such in FD, the family history is very much significant, when all the types of dyspepsias were studied.

Abdominal Examination

Regarding the shape of the abdomen, half of them were having distended
abdomen. Even though it doesn’t point to the abdominal dysfunction, it is a real indicator of the truncal obesity and abdominal fat deposition observed nowadays, in common. The lack of exercise or the zero exercise is the real contributor here. This is also affecting the normal peristaltic movements as well as the physiology of digestion. 1/3rd of the subjects were having the previous history of abdominal surgeries, prior to inclusion and were with the scar of previously performed surgeries. As far as tenderness is concerned, it was elicitable in the epigastrium in more than 95% of subjects and also in the umbilical region in more than 80% of them. In the other areas of the abdomen, the tenderness was distributed unevenly across the patients, on examination.

**Symptoms of Functional Dyspepsia**

The clinical presentation of those included in the study were observed, recorded and analyzed accordingly. The symptom of abdominal pain was noticed in almost all the patients from both the groups, with a mean duration of 18 months. Similar was the case of fullness of abdomen, with the mean duration of 20 months. These two are the most prominent presenting symptoms of those with FD, as per the observations.

Belching was also seen in most of the included subjects. Acid regurgitation was noticed in almost 90% of the subjects from both the groups. The burning sensation was complained in almost 98% of the subjects overall, but the duration was much less than abdominal pain or fullness (mean duration of almost 12 months). The symptoms of abdominal pain and fullness were reported at an earlier stage than the burning sensation, in this study.

The symptom of sucking sensation was not so common and seen in 1/3rd only. The symptom of nausea or vomiting was noticed in almost 70% of the subjects with a mean duration less than 9 months. Anorexia was recorded in ¾ of the subjects.
with a mean duration of almost 18 months. Borborygmi was observed in \(\frac{1}{4}\)th of the subjects with a mean duration of 12 months. The mean duration of increased flatus was around 18 months, but the symptom was there in only \(\frac{1}{4}\)th of the subjects.

Constipation was one of the most dominant symptom observed in almost 90% of the subjects with a mean duration of 22 months. Bothersome post prandial fullness was observed in all the subjects from both the groups with a mean duration of 20 months. The symptom of early satiation with food intake was also observed in all the subjects, but with duration slightly less than 18 months. Anorexia and constipation were the most prolonged symptom observed followed by fullness abdomen and the abdominal pain.

Among the included subjects, it was tried to categorize them into the types of Functional Dyspepsia ie. Post prandial distress syndrome and the Epigastric pain syndrome, as per the Rome III criteria. Most were having an overlapping nature of the two subtypes. It seems that in the post prandial distress syndrome, the symptoms are much more Kaphaja in nature, also seen much more in the earlier stage of the disease and the management with pachana drugs that do not aggravate Pitta, is the prime option. In the Epigastric pain syndrome, it is much more Vathika in presentation and Vatha samana chikitsa, including gritha preparations are ideal in this regard.

**Symptoms of Amlapitta**

Daha was observed in 99% of the subjects with a mean duration of 12 months. Amlodgara was noticed in 92% overall, with a mean duration of 10 months. Chardi was only there in 70% of the subjects, with a mean duration less than 8 months. Soola was observed in almost 98% of the patients, with a mean duration of 18 months. Avipaka was there in 70% of them, with a mean duration of 16 months. Soola and
daha were the most dominating and prevalent symptoms with the soola being reported, at an earlier stage of presentation.

**Efficacy of the therapy on the symptoms of Functional Dyspepsia**

The observations attained regarding the various symptoms in both the groups on the GSRS score both individually and in total, were analyzed and the inferences being made, as per the appropriate tests.

In the symptom of abdominal pain, there was significant efficacy in both the groups. The comparison in between the groups was done and was also significant. The comparison between the two groups was highly significant on the first assessment, significant on second and not significant on the follow-up. The study drug seems to be of more swift in action compared with the control and as the intervention goes on, the efficacy seems similar in nature. There was also better percentage of relief in the study group. Mahatiktaka yoga by its action at the level of pachana, agnideepana and anulomana seems to have an efficacy on the symptom of abdominal pain, in the subjects. The drug is also able to subside the associated ama, which is contributing to soola.

In heart burn, the efficacy was there in both the groups after the intervention. There was slight less relief in the control, during the follow up period. This shows that the attained improvement in the heart burn was not maintained by the control group, during the follow-up period, as the study drug. On comparing the efficacy between the groups, it was highly significant on first assessment, not significant on second and it was minimal on follow-up. It can be inferred that the study drug works early and by the end of the medication, both are having similar efficacy. The percentage of relief was better in study group. The symptom daha is very much associated with
the Pitta dosha and many a drugs in the combination of Mahatiktaka seems Pittasamana, explaining the action of the drug in this context.

On comparison in acid regurgitation, it was inferred that both the groups were highly significant. The post hoc was significant at all levels with slightly less in control, during follow up. On comparing between groups, it was highly significant on first, not significant on second and minimal on final assessment. It can be inferred that the study drug performs more on the first and final assessments i.e. the initial stage and the follow-up with better relief percentage. The study drug is maintaining the attained efficacy in a better manner. The symptom of amlodgara has to be managed by the Pittahara as well as the Vathanulomana combination, which is accomplished by the study drug here.

On fixing the efficacy of the two groups on sucking sensation, it was found that the study group showed minimal significance than the control group, but was not effective statistically. Both the groups showed significance at all levels, except follow up. The benefit was not able to maintain by both the drugs. On comparison, the study drug showed highly significant difference than the control, in all assessments with a better percentage of relief. The study drug is definitely having superior efficacy than the control drug in this symptom. The sucking sensation is resulting from the agnimandya and the resultant vridhi of Kapha in the amasaya. The pachana and the anulomana effect of the drugs in the Mahatiktaka combination seems to overcome the condition.

In the symptom of nausea/ vomiting, there was highly significant efficacy in both the groups and also during the multi level comparison. The control drug is not performing upto the level as the study drug, on the follow up period. On comparison, the minimal significance on the first assessment was not able to maintain further even
though, better relief was reported in the trial. The symptom of nausea/vomiting seems to result from amadosha and also the pratiloma gati of Vatha, which seems to have worked upon by the study drug, on its use. The pachana as well as anulomana drugs of the study drug are useful here.

There was high significance in borborygmi in the study group, while the control group showed only minimal significance, after the intervention. This point to the difference in the efficacy and both were not significant at the follow up. On comparison between groups, after the intervention, it was significant, but not on follow up. The study drug was not able to maintain the initial benefit in the later stages. The symptom of borborygmi seems due to the aggravation of the Vatha dosha and there is slight limitation on the action regarding the same as far as the Mahatiktaka tablet is concerned, due to the rookshata of the formulation.

Highly significant efficacy was observed in both the groups after the intervention, on abdominal distension. The study drug has a significant action better than control on the first 15 days of therapy and later, the two drugs are similar in efficacy. In the symptom of abdominal distension also, the Mahatiktaka tablet is not showing a promising effect due to its limitation on the action on the Vatha dosha due to the rooksha nature. The kashaya as a whole seems sthambana to an extent, like wise is the tablet. The attained effect may be due to resultant Vathanulomana, due to drug.

The pre and post therapy scores show high significance on eructation in both the groups pointing to their efficacy. The multiple comparisons were also significant in both, except the follow up period in control. It can be inferred that the control drug is not maintaining the efficacy as the study drug, during the follow-up period. The significance attained by the study drug after the intervention was not there, on follow
up. Here also the study drug was not having the expected efficacy on eructation as the attained vathanuloma was not up to the mark.

The intervention was highly significant in both the groups except during the follow-up period, in increased flatus. It shows that both the drugs are not maintaining the same results, in the follow-up period. On comparison between the two groups, it was found as significant on all the assessments. This shows that the study drug is having supremacy over the control, in increased flatus. Many of the drugs in the Mahatiktaka is renowned for pachana as well as anulomana activity, which is being presented here.

Both the groups were not statistically significant before and after the intervention and not effective, in managing the decreased stool. On comparing the efficacy between the two groups, it was found that it was highly significant on all the three assessments in favour of the study drug. The efficacy was not uniform throughout the therapy. Even though the efficacy was not statistically significant overall, the study drug works better than its control. The study drug is being used with success in many a conditions of the lower GI tract such as Irritable Bowel Syndrome, Inflammatory Bowel disease etc. in the clinical level. Here also, the pachana, deepana and anulomana factors are on the role.

The difference in the efficacy of the treatment was not statistically significant in both the groups, on loose stool. On the efficacy at various stages of assessment, the significance was between the first and last assessments only. The other levels were not significant. The improvement attained was not uniform. On comparing the significance between groups, it was highly significant on all the three assessments. Here also the study drug is having supremacy, even though there was not much difference on the pre
and post scores. Many of the drugs are having the function of pachana and grahi, which is very much relevant in this regard.

On assessing the efficacy on hard stool after the intervention, it was observed high significance in both the groups. On comparing the efficacy at the various stages, it was found as highly significant in both, but the study drug was not performing as the control on follow up. There was highly significant difference in the efficacy between the groups, at all levels of assessment. This shows that the study group is better on the symptom of hard stool but efficacy not maintained on follow up. Here also the anulomana property of drugs in the Mahatiktaka is performing the job.

There was no significant efficacy in both the groups with the intervention in the urgency of defecation. The control group performed a bit better when compared within the stages of assessment. On comparison between groups, the trial drug was highly significant in all the three levels of assessment. There was uneven distribution of efficacy between groups. The urgency of defecation is one of the symptoms mentioned in condition like Kaphaja athisara or Grahani. Here also a drug which is Kaphahara, pachana as well as grahi in action like Mahatiktaka, is having its own efficacy.

In the feeling of incomplete evacuation, both the groups were not significant. The multi level assessment was varied which shows that the initial response attained is not maintained at the other levels of the assessment, in both the groups. While comparing the efficacy between groups, it was found that the difference was highly significant between the groups, at all the assessments. The symptom resembling the feeling of incomplete evacuation has been explained by Acharya Vaghbata while explaining Kaphatisara lakshana and it is Vatha kaphaja in nature. The Kapha samana, pachana and the grahi nature of selected drugs of the Mahatiktaka is working here.
Efficacy on the GSRS total score

There was reduction in the total score of GSRS in both the groups, after the intervention. When it was assessed for efficacy before and after the treatment, it was observed that, both the groups were highly significant. When the efficacy was compared at all the stages of the assessment, high significance was observed at all levels, in both the groups, by post hoc test. The efficacy between the groups when compared showed varied results. It was not significant on 1st assessment, significant at 1% level on second and highly significant on the final assessment. There was better percentage of relief in the trial group.

The results indicate that, in the initial stages, the two drugs are having a similar efficacy. But as the intervention progresses, the study drug acts further and the results are maintained well, during the follow up period also, on comparison with control. This explains the improving significance throughout the intervention. Mahatiktakam kwatham tablet exhibits better results on its continuous administration. Even though it starts working at a slower pace, it makes up and performs better than the control, in due course of the therapy. The better percentage of relief is also an indicator of the same.

Efficacy of the therapy on symptoms of Amlapitta

The efficacy of both the groups on the selected symptoms of Amlapitta according to the Amlapitta rating scale was also evaluated, as per the recorded observations. The five selected as well as the common symptoms of Amlapitta, as well as the total score were recorded.

Pre and post intervention scores was highly significant in both the groups, in daha. It was found on multiple comparison that at all the levels, the efficacy is highly
significant in both the groups. On comparison between the groups, it was not significant on the first assessment, highly significant on second and not significant on the final one. The action of the drug varies throughout the course. The initial effectiveness was similar, but on finishing the therapy, the study drug has a better action but on the follow-up period, it was not maintained. There was positive difference in the case of study drug, in the percentage of relief. Mahatiktaka yoga is much Pitta samana in nature and is working on daha. But the improvement attained was not maintained during the follow up. This is an indication of the need for further continuation of the drug for attaining better results in daha.

The efficacy of the intervention was highly significant in both the groups in chardi. On the changes in each stage of assessment, the control was significant at all levels, but the study drug was not significant, during the follow up. On comparing between, it was only significant on first assessment only. The earlier supremacy of the study drug on the symptom of chardi was not maintained through the rest of the intervention, as there was no difference in efficacy. The maintainence during follow up was also poor for the study drug. It can be concluded that there is no difference in the efficacy on chardi between the groups after the intervention, as well as the follow-up. But there was significant difference between, after 15 days of the therapy. Mahatiktaka acts at a better pace on the symptom of chardi, but it was not maintained through out.

On computing the efficacy of the treatment in soola, it was observed that there was highly significant change, in both the groups. The post hoc test seems highly significant at all levels of assessment, in both the groups. On comparison between the groups, there was significant difference between the two groups at all the assessments. This shows the supremacy of the study drug in the condition of soola. There was no
significant difference between the two groups in the percentage of relief. Mahatiktakam kwatham tablet is more effective in soola, when compared with the control.

In avipaka also, it was found that the difference in efficacy was highly significant in both the groups, after the therapy. There was highly significant improvement at all the levels in control, but it was not significant on the follow up, in trial. The initial significance obtained on comparison was not maintained later and became insignificant. The difference of the percentage of relief was more during the 2nd assessment between the groups, indicating that the study drug was better after the intervention, but not maintained as such during the follow up.

Regarding the symptom amlodgara also, the efficacy in both the groups were highly significant. The comparison in between groups were also significant, but at a lower level on follow up. There was highly significant difference at all levels on comparison between. This indicates that the study drug is better than the control in relieving amlodgara and is working better on the follow up period.

**Efficacy on the total score of Amlapitta**

In the total score of Amlapitta, there was significant reduction in the total score in both the groups. On assessing the efficacy of the therapy, it was highly significant in both the groups. It seems that both the groups are effective in Amlapitta. On detailing the attained improvement in both the groups, it was found that in the study group as well as the control, it was highly significant at all the levels of the assessment showing the improvement at all the levels of the therapy. On comparing the groups for efficacy, it was significant at 1% level on the 1st assessment, not significant at 2nd assessment and minimally significant at the final assessment. This indicates that the efficacy varies between the two groups throughout, with a slight better response in the study group.
The initial response seems better in the study group but at the end of the intervention, both were similar in efficacy. But on the follow-up period, there was significance, as the study drug maintained the improvement in a better manner. On the percentage of relief, there was slight better improvement in the study group as well.

**Level of significance on the GSRS score with the therapy**

Highly significant difference was observed in the symptoms of sucking sensation, increased flatus, decreased stool, loose stool, hard stool, urgency of defecation and the feeling of incomplete evacuation. Of the above symptoms, except the sucking sensation, all are related with the lower GI tract, where the study drug shows superiority in action over the control. The drugs present in the Mahatiktaka yoga seems to be contributing to the efficacy. From the outcome, it seems that there is better efficacy for the study drug, in the symptoms of the GSRS score, in relation with the intestinal symptoms, when compared with the control drug.

The symptoms without significance after the completion of the intervention were heart burn, acid regurgitation, nausea/vomiting and abdominal distension. The symptom heartburn and acid regurgitation showed minimal significance on the follow-up, which indicates that the study drug is maintaining the result, in a better manner, throughout the follow-up period, when compared with the control. There was no significant change in the symptom of the nausea and the abdominal distension on the follow-up assessment as well. But there was significant difference between the groups on the first assessment, in all the four symptoms mentioned above indicating to the better performance of the study drug in the earlier stages of the therapy.

On the symptom of abdominal pain, borborygmi and eructation, the high significance attained in the first assessment, was not maintained later. The significance
lessened at the end of the medication i.e. at the second assessment and it was not significant after the follow up.

Nausea and abdominal distension were the symptoms without significance after the medication and also at the follow-up. There was significant difference in these two symptoms on the first assessment.

In the total score of the GSRS, it was observed that it was not significant on the first assessment. The significance was at 1% level on the 2nd assessment. During the 3rd assessment, it was observed that there was a highly significant difference between the groups. These point to the fact that, in the initial stages, both of the drugs have no noticeable difference, in the action. The control have better performance in the second half, but is not maintained as such in follow up. As the therapy goes on, the study drug performs better and is maintaining it well also in follow up period. This is the reason for the increase in significance throughout.

**Level of significance of efficacy on the Amlapitta rating scale**

The level of significance was high at all the assessments in the symptom of soola, as per the Amlapitta rating scale. It is the only symptom among these, which shows high significance at all the levels. Amlodgara was also significant on all the three assessments, but the significance level reduced on the follow-up (1% level) when compared with the other two assessments.

The symptoms of daha and avipaka were significant at the end of the medication, but not after the follow-up. The symptom daha had a highly significant difference at the end of the therapy, which was not maintained afterwards. The relief attained on chardi was neither significant after the treatment nor the follow-up period,
but there was significance in this symptom on the first assessment indicating the faster action of the study drug, on the Chardi.

On the total score of the Amlapitta rating scale, there was significance at 1% level on the first assessment, but the significance came to minimum after the follow-up period. There was no significant difference between the two groups after the completion of the intervention, on efficacy. The study drug is performing faster in the earlier phase and also maintaining the attained efficacy, through follow up. On the completion of the treatment, both were equal in efficacy.

There was slight difference between the results in the two scales due to the following reasons. There were only five symptoms and their total in the Amlapitta rating scale, instead of fifteen in the GSRS, along with the total score. The grading was from 0 to 4 in the Amlapitta rating scale, but it was from 1 to 7 in the GSRS.

**Test for association between various factors on GSRS**

The various factors that affect the condition of Amlapitta were assessed through the test of association with the chi square test. The observations recorded according to the GSRS score was used for testing the association. The median score of both the groups were computed as 32 and it was taken for comparison.

Among the six rasas, those having significant association with the GSRS score were computed. It was observed that, the madhura, amla, lavana and katu rasa in excess were having significant association with the GSRS score, in the subjects of this study. The high Odds ratio calculated of these rasas (>2), ie. katu, amla and lavana is an indicative that those who are indulging more on these rasas in diet, is further prone to FD. Tikta rasa and kashaya rasa seems to have no significant association in this regard.
The amla, lavana and katu rasas are having contribution to the manifestation of Amlapitta, as per several studies, as they result in the aggravation of Pitta. In this study, it was also observed that madhura rasa is also contributory. Eventhough the madhura rasa is not considered as a prime etiological factor, it leads to agnimandya and hence vitiation of Kapha or ama, which leads to dyspepsia like conditions of Kaphaja in nature. The symptoms like hrillasa, gourava, avipaka and klama of Amlapitta are very much related with Kapha. Madhura rasa also is to be restricted in the early stages of Amlapitta, where there is association of ama along with Pitta.

It was observed that there was no significant association between the excessive use of snigdha ahara as well as the use of ushna guna in ahara with the GSRS score.

The main alterations in the status of agni was assessed among the subjects in the study. How the alteration of the agni is affecting those with the dyspepsia was assessed, by the test for association. In those with mandagni and their GSRS score, the association with the two factors was not significant. In those with vishamagni, it was found that, there was no significant association as well. The computed Odds ratio was also supportive of the same.

Most of the included subjects were having the koshta as kroora. It seems very much along with those with the FD, in the clinical presentation. The association between the kroora koshta and the score was studied and found that there was no significant association between the two, in the study, even though Odds ratio was 1.5.

Among all the subjects assessed, the majority were of Vatha Pitta prakrithi and the Vatha Kapha prakrithi. In Vatha Pitta prakrithi, it was observed that, there was minimal significant association between it and the GSRS . It can be concluded that there is more chance of presenting FD in a Vatha Pitta prakrithi person. In the
Vatha Kapha prakrithi, it was noticed that there was no significant association with the GSRS score pattern. The Odds ratio was also supportive in this regard. In the manasa prakrithi, most were of rajasa prakrithi in nature, on assessment. So the association was also studied with the GSRS score. It was observed that, there was no significant association between rajasa prakrithi and the dyspeptic score, to formulate a conclusion.

It was assessed whether in those with the intake of refrigerated food frequently were having ascent in GSRS score by test of association, it was found as negative. Many of the subjects were skipping meals frequently, but on assessment, it was found that there was no significant association, with the GSRS score.

Many of the subjects were having their food in an unsound atmosphere. In the classics of Ayurveda, it is mentioned that the presence of mind is very much essential for the proper digestion of food. Along with that, the psychological factors are having utmost ability to affect the digestion, says Acharya Charaka. On studying, it was found that there was no significant association between the food taken in an unsound atmosphere and GSRS score, in this study population.

Food intake after feeling appetite is one of the qualities of ideal food as mentioned and not followed as such today, by the society. In this study also, the association between the food intake after having appetite and the GSRS score was observed and found to be not significant.

Irregular timing of meals is one of the commonest habits nowadays. It is one of the contributory causes for the dyspeptic symptoms. In this study the association between irregular meals and GSRS score was studied and found to be highly significant. This indicates the role of irregular timings in FD and its importance in management.

Many of the subjects were having processed food frequently and the
calculated Odds ratio was 1.9. It was found that the association was significant at 5% level, pointing to the role of the same, in the manifestation. Similarly due to the hectic schedule of their work, many were having the food, which was prepared so earlier. Those working abroad were having the habit of preparing food items for a week, making it warm and having it, when required due to their inconvenience. The association between the same and the GSRS score was also studied. It was found that there was highly significant association between stale food and the GSRS score. The ahara of paryooshita in nature is causing aggravation of all the three doshas, opines Acharya Vaghbata.

Many of the subjects included were having the habit of regular intake of carbonated drinks and the association was not significant between the same and GSRS score. It was also assessed that the quantity of food intake is having any sort of relation with the symptoms of dyspepsia. It was observed that there is no significant association between these two.

The dietary habits have been changed enormously within the last few years. People are using much non-vegetarian food than the previous period. In this study also many of the subjects were having mixed food. The computed Odds ratio in this regard was more than 4, indicating to the increased manifestation with the mixed diet. On testing the association, it was found that it was significant, pointing out to its magnitude. The compatibility of food is also having a key role in the dietary habits. On studying the association between the habit of regular intake of non compatible food and the GSRS score, it was not significant.

Physical exertion after food intake was noticed in several subjects in the study and hence its association was computed, with the GSRS score. There was also
a high Odds ratio as well. It was found that the association between the two is highly significant as expected. Similarly, mental exertion and its association were also worked out. The Odds ratio was about 4 and it was observed as highly significant and have to be considered, as a very prominent role. Now a days, all are having the habit of travelling excessively. This is definitely affecting the food habits and timings and hence also creating the digestive problems. In this study, such an association was being tried to trace out and concluded that, there was real significance.

Similar is the case of the habits of sleep as well. People are going to sleep very late and the early rising habits also have been reversed. The technological advancements and also the life style are contributory here. Likewise is the timing of food habits. It was studied whether there is any association between the alterations in the habits of sleeping and FD and observed that, it was not significant in this population.

Family history is one of the contributory factors in almost all the diseases including the Functional Dyspepsia. In this study, the association between those with a positive family history and the nature of the symptoms, were studied. It was found that there was no significant association between the two factors.

In those with the routine use of drugs like NSAID’s, dyspepsia is being reported more, according to published studies. The Odds ratio was more than 2. It was observed that there was significant association between the frequent NSAID use and the GSRS. It is really pointing to the role of such drugs, in the manifestation of FD. Even the continuous use of kwatham for a certain period, with the preservative, is leading to the condition in many. Similarly the fast way of life has lead to the people using most of the food items with preservatives, as they are purchasing in a prepared manner, resulting in gastric disturbances.
Many female subjects included in the study were had attained menopause. For a matter of curiosity, it was observed whether there is any peculiarity in the dyspeptic scores in those, after menopause. Even though the calculated Odds ratio was 2, it was observed that there was no significant association in between.

Of all the categorized occupations, the most dominant were those performing a job with physical exertion, like casual laborers. Their level of GSRS was compared for the association. It was observed that there was no significant association between this type of job and the GSRS.

Similarly many of the subjects included were the home managers. They were also studied for the association as the Odds was more than 2. It was noticed that there was significant association between these group and the GSRS score. It was observed that the stress level in home managers are more than employed women. It can be concluded that the untimely food and the stressful life situations faced by them, is contributing to dyspepsia.

These factors are pointing to the contributing factors of the disease, and are very helpful for the aspect of the management. Among these the highly significant ones need special mentioning as, the physical exertion after intake of the food, mental exertion and the habit of intake the previously prepared food. Next in significance is the habit of excessive travelling which has influence on the dietary habits and the quality of food. All the other factors are also to be considered accordingly.

**H Pylori**

H pylorus is considered to have a key role in many of the reported dyspepsia. The role played by the organism in this condition is well studied worldwide

It was studied, whether there is any association between the subjects positive with H
pylori and the severity of GSRS score, in this population. Here the calculated Odds ratio was 1.3 in this regard. On testing the statistical association between those with RUT positive for H pylori and the severity of FD as GSRS score, it was observed that the chi square value obtained was 0.456 and it was not significant. It was recorded that there was no significant association between the two factors in the case of FD, in this peculiar study.

**Comparison of the efficacy of groups on H Pylori**

In this study also, even though it was not listed among the objectives, those positive with H pylori on endoscopy, with the Rapid Urease Test (RUT), was also assessed for efficacy, after the intervention on IgG H pylori. Among the 100 subjects included in the trial group, 25 were positive for H pylori with RUT. 2 months after the intervention, on testing with the Immunocomb II Helicobacter pylori IgG kit, 19 were only positive and the rest 6 became negative. In the control group, 18 were positive with RUT and after 2 months of the therapy, 16 were positive with IgG H pylori test, so the rest 2 became negative.

Even though it was seen in less number of patients in both groups, the results were assessed statistically using the unpaired t test with unequal sample. It was observed that, there was significant efficacy for the trial group against the control on the H pylori at 1% level. The action of the study drug in the condition of Functional Dyspepsia may be also due to the effectiveness of the drug against H pylori. Many drugs in the Mahatiktaka combination like yashti, darvi, vacha etc. are proven to have anti- H pylori action, as per reported trials. Even though it cannot be generalized or concluded with this, we can plan for further studies with the same drug in an entirely positive population.
Correlation Analysis

In the correlation study conducted regarding the various factors of Functional Dyspepsia, it was observed that katu, amla and lavana rasa showed a positive correlation with the GSRS. These are the main rasas involved in the pathogenesis of the diseases, resembling Amlapitta.

A positive correlation was also noticed in the female gender, home makers, kroora koshta, job with physical exertion, job with mental exertion and irregular timing of food. These support the test for association, which had been explained earlier.

Female are more prone to stress and much anxious and are very much irregular in their food habits, which contributes to the observation. The irregularities in the bowel habits are always seem to aggravate the presentation. Similarly exertion at both the physical and the mental level is really contributive to diseases like FD. Similarly is the case of intake of meals not on proper time.

Regression Analysis

On the regression analysis done with the various factors contributing to the GSRS score, it was observed that the R square value was 0.25, which suggests that the GSRS score is contributed by 25% due to the studied variables. The succeeding ANOVA was highly significant, which points to the contribution of the variables in the manifestation.

On studying the individual variables, the physical exertion showed significance at 0.1% level, mental exertion showed a significance at 1% level and the irregular timing of meals showed significance at 5% level. These three can be considered as the most contributory among all the variables in this study, in the pathogenesis.
On studying the role of rasas, there was a positive regression coefficient pointing to the contribution of the amla, lavana and katu and it was highly significant on F test. While considering individually, lavana and katu was highly significant at 1% level, but amla at a minimal level.

**Percentage of relief on GSRS**

The percentage of relief observed after the intervention was analyzed between the groups. The whole subjects was graded into 4 groups, according to the relief observed. It was compared at two levels, after the therapy and after the follow-up period.

In the study group, after the therapy, 60% were slightly improved while more than 30% moderately improved. In the control group, almost 90% slightly improved and less than 6% moderately improved. After the follow up, in the study group 88% of the subjects were moderately improved while in control, 60% were having mild improvement and more than 40% moderately improved. This shows that the study drug is having efficacy which is not only maintaining, but also improving, throughout the follow-up period as well. The control drug responded well early but the rate of response was not up to the level of the study drug later. The control drug also maintained and improved the efficacy over the follow-up period but not to the extent of study drug. Every subject got a minimal response in the control group as there was no one unchanged one, unlike the study drug.

**Percentage of relief on Amlapitta rating scale**

In the study group, after the therapy, almost 60% were improved moderately while in control, 66% improved slightly only. On the follow up, 87% improved moderately in trial while upto 60% improved moderately in control. The study drug is having efficacy which is not only maintaining, but also improving throughout...
the follow-up period. Initially the response was a bit more in the control group, but at the end of the intervention, the study drug shows better percentage after follow-up.

**Mode of action of the drug**

The characteristics of the Mahatiktaka yoga by its pharmacological properties individually were studied. The individual drugs of the Mahatiktaka yoga are having mainly tikta in rasa. The next rasas in dominance are kashaya, katu and madhura rasas. The combination is having the slight dominance of seeta veerya. The yoga is rooksha in guna as well as laghu, peculiarly when it is in the form of kwatha. The vipaka is mainly katu and to an extent, madhura.

The combination as a whole seems Pitta kaphahara in action as 56% of the drugs seems resemblance in action, accordingly. According to Kashyapa, the drugs most useful in the management of Amlapitta must be Kapha Pittahara in action. Also the apt as well as sodhana karma mentioned is also Vamana as the amasaya is the sthana of Kapha. This point to the significance of the Kaphahara drugs in the management. Eventhough the disease seems Paittika in nature as well as the presentation, the better management seems Kapha Pittahara, as the Pitta is mostly associated with ama ie. sama Pitta. For sama pitta, the treatment should be samana in nature, both to Kapha and Pitta and the Mahatiktaka yoga contributes in this regard. Amlapitta is one of the indications mentioned of the Mahatiktaka yoga, by Charaka.

A clinical study conducted by Snigdha etal. concluded that the Mahatiktaka Kwatha when administered in hyperglycemia associated stress, was effective in controlling the stress as per the Stress Assessment Questionnaire and also the blood sugar level. The anxiolytic activity of the drug was comparable with the benzodiazipine as per the study. This is very much contributory to the role of Mahatiktakam kwatham
in the management of FD, as the psychological factors are a great deal in contributory to the condition.

This is proved by the Mahatiktaka yoga by its efficacy, in this particular study. When administered as kwatha or kwatham tablet form, the combination as a whole works as Kaphapittahara as mentioned above. The drug when processed in the form of gritha ie. Mahatiktaka gritha becomes much more Vathahara in action as reported by the study on parinama soola, conducted by the CCRAS. It is good for chronic conditions and in cases with the considerable involvement of the Vatha. But the patient must be fit and ideal for snehana. If otherwise, we have to go for the kwatha or the tablet form.

While analyzing the individual symptoms on the basis of the three doshas, it was found that strict generalization is not possible. Among the Vathika symptoms, there was significant improvement in increased flatus, decreased stool, hard stool and the urgency of defecation. There was no significant difference in the efficacy in abdominal pain, abdominal distension and eructation. These symptoms are seemed to have much more response in the clinical level, the combination being administered in the gritha form and on attaining better anulomana.

There was significant response in both the symptoms, which are Paittika in nature, the heart burn as well as the loose stools. In the symptoms resulting from the Kapha dosha, it was observed that there was significant response in the sucking sensation and also the feeling of incomplete evacuation. But the symptom of nausea/vomiting didn’t respond significantly. The study drug seems to have better action as far as the lower GI symptoms are concerned, in comparison with the upper tract.

The mode of administration of the Mahatiktakam kwatham tablet seems
very comfortable for the subjects. The lack of preservatives in the combination is very much positive, as far as the dyspeptic features are concerned. On the subjects who are taking the prepared kwatha continuously, the preservatives are creating disturbances, peculiarly on the continuous use. Here they feel so much comfortable and an adequate dose can be administered as there is no matter of dilution. The palatability also is highly appreciable as compared to the kwatha. Many of the subjects were having regular travelling as a part of their profession and the medicine in the tablet form added to their comfort and also the regular dosage of the same as preferred by them. The shelf life of the kwatham tablet is more, when considered with the same kwatha. We can also propose studies with blinding method with the kwatham tablets.

**Dropouts**

There were 10 dropouts throughout the study, 5 each in the control group and the study group. Of these 5 subjects migrated to other countries as a part of their job, without completion of the intervention. Two people affected with episodes of fever during the treatment and stopped the drug in between. One got an attack of diarrhea and was discontinued. One discontinued person complained of the difficulty in swallowing of the study drug and stopped the same. One person had an attack of bronchial asthma in between, was admitted and discontinued the medicine. It seems that none had discontinued the medicine due to any relative adverse reactions of the drug. This indicates to the safe administration of Mahatiktakam kwatham tablet in the subjects.
Functional Dyspepsia is one of the commonest clinical conditions in a gastroenterology OPD, affecting up to one fourth of the population in India. A variety of pathophysiologic mechanisms like dietary misconduct, motility disturbances, alteration in visceral sensitivity, psychological factors, H pylori etc. have been proposed to elucidate the symptoms of Functional Dyspepsia. Due to the varied pathogenic factors, in the management also several drugs are being tried out with varied efficacy.

In Ayurveda, the disease is being approached with the management protocol mentioned for the disease, Amlapitta. The disease had been dealt in detail in the treatises like Kasyapa samhitha and Madhava nidana. Here even though the core dosha seems Pitta, the protocol is to be adopted considering the associative dosha, which is Kapha in the initial stages and Vatha in the later stages of the disease. Hence a drug like Mahatiktaka which is a Pitta Kapha samana combination, is one of the options for the samana chikitsa, for the condition. The scope of sodhana chikitsa and satvavachaya chikitsa is also being discussed here in this regard.
Clinical study

Of the various drugs used successfully by the Ayurvedic fraternity, the Mahatiktaka yoga mentioned by Acharya Charaka was selected for the study due to two reasons, Amlapitta is one of the indications mentioned and also it seems effective, in the clinical scenario. It is also a drug with proven psychological efficiency and also is krimihara in action. Mahatiktaka was prepared in the form of kwatham tablet and used for the study.

The Allopathic counterpart, the PPI group of drug Omeprazole was used as control drug for the study. It was a Randomized Controlled Trial with the setting as the OPD and IPD of Vaidyaratnam P S Varier Ayurveda College, Kottakkal with the inclusion of 200 subjects, those fit with the proposed criteria and also furnishing written consent. The period of administration was 30 days continuously. The observations were analyzed according to GSRS score and the Amlapitta rating scale.

The overall efficacy of the therapy was significant at 1% level after the intervention and 0.1% level at the follow-up, on the GSRS score. As per the Amlapitta rating scale, there was no significant difference between the groups after the intervention, but on the follow-up, there was statistical significance at the 5% level.

The individual symptoms of abdominal pain, borborygmi, sucking sensation, increased flatus, decreased stool, loose stool, hard stool, urgency of defecation and the feeling of incomplete evacuation showed statistical significance between the groups, after the intervention. There was no significant difference in improvement between the groups in the heart burn, abdominal distension, nausea and acid regurgitation.

In the Amlapitta rating scale, there was significant difference between the
groups on daha, soola, avipaka and amlodgara while there was no significant difference in the symptom of chardi between the groups, after the intervention. After the follow-up period, the symptom of daha and amlodgara showed significant difference between the groups. The observation after the follow-up period shows that, the study drug is able to maintain the attained efficacy later.

Significant association was observed between the GSRS score and the contributory factors of Functional Dyspepsia like mental exertion, irregular food timings, excessive use of katu, amla, lavana rasas, processed food, physical exertion after food intake etc. Those having regular mixed dietary habits, excessive travelling, frequent use of NSAID’s, Vatha Pitta prakrithi etc. were prone to the manifestation, as per the observations. In the selected subjects, the study drug showed statistically significant efficacy on H pylori, when compared with the control.

The drug administration can be considered as safe as there was no observable adverse effects recorded throughout the study.
The study entitled “A Randomized Controlled Clinical Trial to assess the role of Mahatiktakam Kwatham Tablet in Amlapitta w.s.r to Functional Dyspepsia” has two objectives.

The study drug Mahatiktaka gritha was studied to assess the role in Functional Dyspepsia. The study shows that there is significant efficacy of the drug on Functional Dyspepsia according to the GSRS score, at all the levels of the assessment. (P<0.001)

The efficacy of the study drug Mahatiktaka Kwatham tablet was compared with the control drug, Omeprazole in Functional Dyspepsia regarding its efficacy. It was observed that the overall efficacy of the therapy was significant at 1% level after the intervention and 0.1% level after the follow-up on the GSRS scale, when compared between the groups.

It was also observed that with the Amlapitta rating scale, there was no
significant difference between the groups after the intervention, but on the follow-up there was significance at 5% level.

The study drug was also having significant efficacy on H Pylori when compared with the control in selected subjects.

It can be concluded that the alternate hypothesis is accepted after the study. ie.

There is significant difference in the role of Mahatiktakam kwatham Tablet when compared with Omeprazole in Amlapitta w.s.r to Functional dyspepsia.

Mahatiktaka kwatham tablet is effective in the management of Functional Dyspepsia and also safe and improves the quality of life of those affected with the disease.