

RESEARCH ARTICLE

MAHATIKTAKAM KWATHAM TABLET IN H PYLORI POSITIVE FUNCTIONAL DYSPEPSIA – AN UNCONTROLLED TRIAL

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Accepted 10th May, 2016; Published Online 30th June, 2016

ABSTRACT

Functional dyspepsia (FD) is the commonest condition approached by a gastroenterologist, with a prevalence of 12% among Indians, resulting reasonable socioeconomic burden. Patients with chronic dyspeptic symptoms for past 3 months prior to consultation, with the onset, at least 6 months preceding the diagnosis, is confirmed with FD, in the absence of any organic, systemic or metabolic basis, that could explain the ensuing pathology, as per the Rome III criteria.

The underlying pathophysiologic mechanism is so complex and varied, which includes the alteration in gastric motility, visceral hypersensitivity, altered gastric accommodation, genetic susceptibility, dietary factors, psychosocial factors, and also the infestation by *Helicobacter pylori*. For these ample ranges of mechanisms, a single drug or approach, seldom provides the results as expected, as per studies. *H pylori* has to be eradicated if traced out in a person with FD, as per the currently accepted protocol. In this study, Mahatiktakam Kwatham tablet was tried in those included with FD, who were also positive for *H pylori* with the Rapid Urease Test for a period of 30 days. Post test was done with Stool antigen test (HPSA) after 60 days of the therapy.

Aim: To evaluate the role of Mahatiktakam Kwatham tablet in *H Pylori* positive Functional Dyspepsia

Method: Open label uncontrolled study with sample size of 25

Result: There were significant changes in the symptoms of FD on assessment with the Gastrointestinal Symptom Rating Scale (GSRS). There was statistically significant result on *H pylori* as well, after the intervention as many of the subjects turned negative, for *H Pylori*. Many of the ingredients are having Raktaprasadana, Rasayana as well as Krimihara properties, which is ideal in managing organisms like *H pylori* in the gut.

KEY WORDS: Functional Dyspepsia, *H Pylori*, Krimi, Mahatiktakam Kwatham Tablet, Gsrs, Hpsa.

INTRODUCTION

Nearly everyone has experienced a disorder associated with the digestion and the social impact of gastrointestinal illness is probably being under appreciated. Digestion and its disorders are explained in detail in almost all the Ayurvedic classics, with pertinent management. The ancient medical science has described micro organisms in the perspective of Krimi while explaining the causative factor of many a disease like Athisara, Kushta, Hridroga etc (Agnivesha, 2009). Their respective role in the manifestation of such diseases has been appreciated and considerable magnitude has been imparted in the management. Functional dyspepsia (FD) is the commonest diagnosis in an Ayurvedic Gastroenterology clinic. Considering the high prevalence of FD in the current Indian population, socioeconomic burden of this disease in our community, is expected to be enormous and of serious in nature, as far as the nation's health status is concerned (Tally *et al.*, 1992).

The suspected underlying pathophysiologic mechanism is so complex and varied among the affected, which includes the alteration in the gastric motility, visceral hypersensitivity, altered gastric accommodation, genetic susceptibility, dietary factors, psychosocial factors, and also the infestation by the organism, *Helicobacter pylori* (Jones, 2003). The gold standard is that, if there is *H pylori* in the gut, stipulate the triple or quadruple therapy (Zullo *et al.*, 2014). Analogous is the precautionary measure to be done against the complications due to *H pylori*, including Gastric carcinoma. In these ample ranges of mechanisms, a single drug or approach is seldom providing the results as expected in FD, as per an assortment of the accessible studies (Toru Hiyama *et al.*, 2007). This study was objected to observe whether the study drug Mahatiktakam Kwatham tablet useful in the management of FD, is effective against *H pylori*, in those with *H pylori* positive FD.

AIM: To provide with a better management protocol for *H Pylori* Functional Dyspepsia

Objectives

- To evaluate the role of Mahatiktakam kwatham tablet in Functional Dyspepsia

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- To evaluate the role of Mahatiktakam kwatham tablet against H pylori in Functional Dyspepsia

Inclusion Criteria

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

Exclusion criteria

- Endoscopic findings of peptic ulcer/ gastritis
- Systemic disorders - CAD, HT, DM, thyroid disorder
- On NSAID's, antibiotics or other long-term medication
- Pregnant women and lactating mothers

Diagnostic criteria of Functional Dyspepsia (ROME III) (Magni *et al.*, 1987)

- Bothersome postprandial fullness
 - Early satiation
 - Epigastric pain
 - Epigastric burning
- No evidence of structural disease on upper endoscopy
 - Criteria fulfilled for the last 3 months with the symptom onset at least 6 months, prior to the diagnosis
 - RUT positive for H pylori

Assessment

- Gastrointestinal Symptom Rating Scale (GSRS) (Christopher Harmon *et al.*, 2010)
- Amlapitta Rating Scale (Ghosh Kuntal *et al.*, 2011)
- RUT and HPSA tests for H Pylori (Howden and Hunt, 1998)
- On the 1st day and the 60th day of the intervention

Clinical observations during the study

About 60% of the subjects were having mandagni and also the koshta was kroora on assessment. Almost 90% were non vegetarians and 70% among were violating the Ahara vidhi mentioned in the classics. Amla, lavana and katu rasa were used in excess and also rooksha and ushna guna dominated, in the diet of the major. Reduced or interrupted sleep was observed in half of them. 80% of them were observed to have rajasa prakrithi. Many were using carbonated drinks in excess and 60% of the subjects were having more than a tolerable level of stress.

Tests for H pylori

At the time of inclusion, along with the Upper GI scopy, Rapid Urease Test was done for the confirmation of H pylori. The trial drug was administered continuously for 30 days. Post test was done on the 60th day of inclusion using ImmunoCard STAT![®] HpSA from Meridian Bioscience Inc with a sensitivity 90.6% and specificity of 91.5%.

BLUE band at Control Line plus PINK-RED band at Test Line was considered as positive (Camilleri, 1996). Statistical analysis was done with Instagram pad 1.0 version with appropriate tests (Kothari, 2008).

Efficacy on the GSRS score

Table 1.

| BT (mean + SD) | AT (mean + SD) | MD | t value | P value |
|-----------------|-----------------|-------|---------|---------|
| 34.2 ± 5.96 | 13.96 ± 3.86 | 20.24 | 23.21 | < 0.001 |

The overall efficacy of the therapy was significant at 1% level after the intervention on the total score of GSRS scale, as the mean score reduced from 34.2 to 13.96. Among the individual symptoms in the GSRS, that of abdominal pain, borborygmi, sucking sensation, increased flatus, decreased stool, loose stool, hard stool, urgency of defecation and the feeling of incomplete evacuation, there was statistically significant difference between the groups. There was no significant difference in the attained improvement in the symptoms of heart burn, abdominal distension, nausea and acid regurgitation, after the intervention. While considering the percentage of relief, after the therapy, 3 were unchanged, 59 slightly improved, 37 moderately improved and 1 got marked improvement.

Efficacy on the Amlapitta rating scale

Table 2.

| BT (mean + SD) | AT (mean + SD) | MD | t value | P value |
|-----------------|-----------------|------|---------|---------|
| 14.04 ± 2.03 | 5.6 ± 1.29 | 8.44 | 21.51 | < 0.001 |

On the Amlapitta rating scale there was significant difference between the groups after the intervention on the total score, at 1% level. In the Amlapitta rating scale, the individual symptoms of daha, amlodgara and soola were having high significance, avipaka was having minimal significance, and the symptom of chardi was having no significant difference between the groups, after the intervention.

Association between negative H pylori and GSRS score

Table 3.

| Observed | Expected | Chi square | p value |
|----------|----------|------------|----------|
| 3 | 1.94 | 1.106363 | |
| 4 | 5.02 | | |
| 4 | 5.02 | | 0.298584 |
| 14 | 12.94 | | |

To assess whether there is any association between those with the negative H pylori test and FD, Chi square test was done, which was not significant in this study.

DISCUSSION

While considering the drugs in the Mahatiktaka yoga, it was observed that they dominate in Tikta rasa, Seetha veerya, Rooksha and laghu guna, Katu vipaka and Pitha Kaphahara in action, as the kwatha format (Vaghbata, 2010).

Drugs like *Acorus calamus*, *Curcuma longa*, *Terminalia chebula*, *Phyllanthus emblica* etc. deactivates the H pylori infection as per the reported studies, at the experimental level (Gaddekar, 2010). The krimihara action of the selected drugs in the combination is contributing to the same as well (Adesina and Filoterapia, 1991). The drug seems effective in conditions like FD or Amlapitta where sama Pitta is the contributor and we have to opt for the Pitta Kapha samana chikitsa (Tiwari *et al.*, 2002). This combination seems to unravel the multifactorial pathology of conditions like FD and hence effective in this regard.

Conclusion

Ayurvedic management has an immense role to play in the forthcoming days, in the management of functional gastrointestinal disorders, including FD. Mahatiktakam kwatham tablet is statistically significant compared with the control drug, on its efficacy, in the management. There was no reported incidence of adverse effects throughout the study. The efficacy of this drug in the management of H pylori has to be studied in detail even though it was statistically significant, in the selected subjects. Several other drugs useful in this condition is to be tried, with appropriate methodology so that, it may be a real boon for the affected community.

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