

PHYTOCID™

CHAPTER 17 PRELIMINARY EVALUATION OF PHYTOCID™-GT IN BENIGN DYSPEPSIA

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Dyspepsia is considered a pain-related sensation or discomfort in the upper abdomen; it is often recurrent.

It is described by most patients as indigestion, gassiness, early satiety, postprandial fullness or burning. Several common causes are or may be involved.

Patients may have positive findings on tests (eg, duodenitis, pyloric dysfunction, motility disturbance, *Helicobacter Pylori* gastritis, lactose deficiency, cholelithiasis); these problem correlate poorly with symptoms and often, the correction of the main condition does not alleviate symptoms.

Non-ulcerative functional dyspepsia is defined as the presence of symptoms without abnormalities at physical examination and upper GI endoscopy.

The following symptoms (Table 17.1) may be associated to a severe clinical problem (the Merck Manual, 12th edition) and should be always excluded.

Table 17.1.

Acute episode with dispnea, diaphoresis, tachycardia
Anorexia
Nausea, vomiting
Weight loss
Blood in stools
Dysphagia, odynophagia
Failure to respond to treatment with H2 blockers or proton pump inhibitors (PPIs)

Standard management (also according to the Merck manual, 12th Edition) include non well defined treatment steps.

When coronary ischemia (as angina) can be excluded, blood tests are normal (excluding anemia or GI blood loss), endoscopy is negative, particularly for otherwise healthy subjects younger than 45, without risks or indications of cancer, an empiric therapy with anti-secretory agents may be used for 2-4 weeks.

This period may be followed by an endoscopy in case of symptoms persistence.

Screening for H. Pylori is usually considered but caution should be used in using H Pylori or non-specific findings to explain symptoms. Esophageal manometry and pH studies are indicated if reflux persists (after endoscopy) and a 2-week trial with PPI.

Patients without identifiable conditions should be observed and reassured.

Specific food causing or aggravating dyspepsia should be identified and eliminated.

Small, repeated meals are suggested.

PPI are used, or in alternative subjects may use H₂ blockers or cytoprotective agents according to individual needs and individual results.

Prokinetic drugs (mainly metoclopramide, rarely erythromycin) as liquid suspensions, may be tried for dysmotility-like dyspepsia.

Table 17.2 shows the key points to always consider for these patients.

Table 17.2.

Coronary ischemia is possible in patients with 'gas' or distension
Endoscopy is needed in any unclear case (age >45)
Empiric treatment with acid blockers (subjects <45, no alarming conditions).
If there is no response further evaluation is needed

Our Registry

Subjects, younger than 45 years were included into the present registry.

Characteristics: subjects were characterized by dyspepsia, no other condition, negative endoscopy.

Phytocid™-GT was used at the dose of 3 capsules/day.

Phytocid-GT (Alchem) is a natural product specifically developed – using natural elements – to treat dyspepsia; it includes Ginger and Turmeric and can be used as an anti-emetic; it also has a significant anti-inflammatory action. Turmeric can modulate excessive peristaltic activity and it has been used for abdominal cramps and irritable bowel syndrome.

Both Ginger (50 mg) and Turmeric (100 mg) are strong antioxidants and have a mild antimicrobial activity. Phytocid™-GT has been used against indigestion, motion sickness, oral infections, irritable bowel syndrome, in ulcerative colitis, pregnancy-related nausea and vomiting, nausea and in vomiting due to gastroenteritis (as a supportive agent) and in chemotherapy-induced nausea and vomiting.

Three groups were created by the choice of the single subjects (after briefing).

DYSPEPSIA SYMPTOMS SCORE: the score was designed as follows:

0: no symptoms; 1: minor occasional; 2: daily, mild; 3: daily, important; 4: daily, non-severe, continuous; 5: severe, requiring medical assistance.

RESULTS

The 3 groups (including 38 subjects) resulted comparable. Results of the specific score are shown in Table 17.3.

Figure 17.1 shows variations in dyspepsia score in the 3 groups, with projected trends at 4 weeks (the registry is in

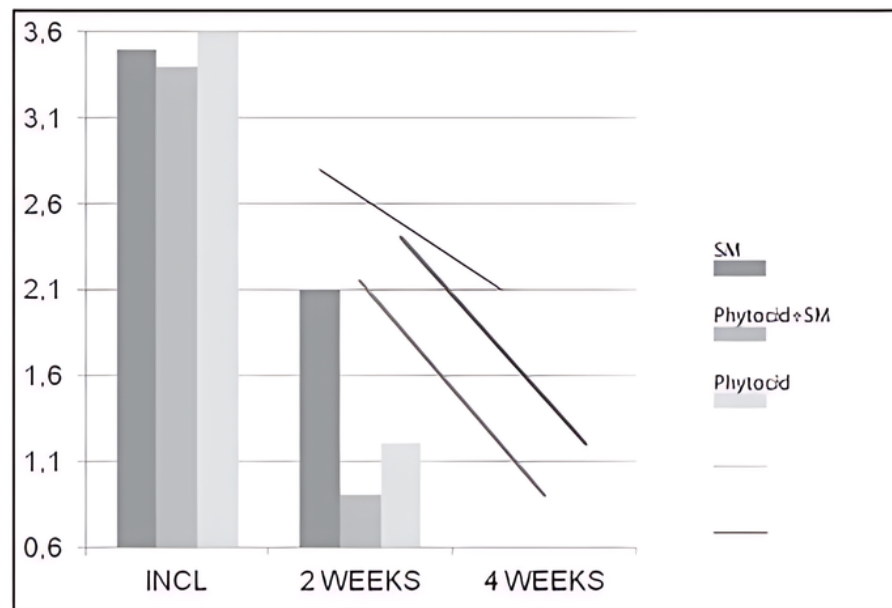


Figure 17.1. Variations in dyspepsia score (at inclusion and 2 weeks) with projected trends at 4 weeks. Mobile medias (trends) are shown.

progress).

Table 17.3.

Management groups	Number	Age	0-5 score	Weeks	
	Fem		Inclusion	2	4
a. Standard management, diet	14(6)	43.1;1	3.5;1	2.1;1	-
b. Standard management + Phytocid™-GT	11(5)	42.2;2.2	3.4;1.1	0.9;1.1	-
c. Only Phytocid™-GT	13(6)	43;1.3	3.6;1.4	1.2;1	-

No side effects were observed.

A good tolerability was reported. Improvements occurred in an average period of 3-5 days.

The score decreased both in association with SM and when the product is used as a single controlling agent.

Conclusion, Phytocid™-GT can be used to control dyspepsia symptoms in otherwise healthy subjects both as an oc-

casional supplementation and for more structured management for 2-4 weeks. It can be used as a single control supplement or in association with PPI if required by the clinical picture.

Longer and more inclusive studies (including more complex subjects and more complex situations) are in progress.