

KJ-19 Evaluation of a health food supplement containing anti-*H. pylori* urease IgY antibody on patients with chronic gastritis in Hanoi, Vietnam

Vu Van Khien¹, Nguyen Van Sa²

¹ Dept. of Diagnostic Endoscopy, 108 Military Central Hospital, Hanoi, Vietnam

² Immunology Research Institute in Gifu, EW Nutrition Japan, 839-7 Sano, Gifu, Japan

[Background]

Helicobacter pylori is considered the leading cause of gastritis, gastric ulcer and stomach cancer. Medication with a combination of 2-3 antibiotics is the common therapy of *H. pylori* infection. But antibiotic therapy fails in 10-20% of cases due to the development of antibiotic resistance. Studies conducted by IRIG (Gifu, Japan) in the past 10 years show that egg antibody (IgY) against urease of *H. pylori* is effective in reducing the bacterial load in stomach of *H. pylori* positive volunteers. This study was conducted to examine if combination of the antibody with current treatment regime could improve the eradication rate and clinical signs in *H. pylori* positive gastritis patients.

[Methods]

Volunteers were recruited among patients visiting 108 hospital. The volunteers that passed the selection criteria were divided into a test and a control group. Both groups were treated with a current treatment regime but only the test group received IgY-containing food supplement (GastimunHP, EW Nutrition Japan) as an adjunctive measure for 15 days. The subjects were examined before and 4 weeks after the treatment initiation by UBT and gastro-endoscopy.

[Results]

71 patients who were positive with *H. pylori* and had gastritis or gastro-duodenal ulcer were divided randomly into test (n = 36) and control (n = 41) groups. The average UBT levels in the test group at baseline and 4 weeks posttreatment were 161.64 ± 83.53 and 49.42 ± 44.21 , respectively. There was a significant decrease in UBT in this group after the treatment ($p < 0.0001$). 28 patients in this group became *H. pylori* negative by UBT test (77.78%). The UBT levels for the control group were 158.54 ± 43.73 at baseline and 73.37 ± 30.0 at 4 weeks, respectively, and the difference was statistically significant ($p < 0.0001$). 17 patients in this group became *H. pylori* negative by UBT test (41.46%). Mean changes of UBT in the test and control group were 112.22 ± 43.73 and 85.17 ± 37.9 , respectively, and the difference between the 2 groups was statistically significant ($P = 0.002$). Clinical symptoms including stomach pains, nausea, bloating, belching, and vomiting had a tendency to improve faster in the test group compared to the control group.

[Conclusions]

Food supplement fortified with IgY against urease of *H. pylori* enhances eradication of *H. pylori* when used in combination with medicines. This antibody could be useful especially in case of antibiotic-resistant *H. pylori* infections.

[Key words]

H. pylori, IgY, food supplement

Evaluation of a health food supplement containing anti-*H. pylori* urease IgY antibody on patients with chronic gastritis in Hanoi, Vietnam

Vu Van Khien¹, Nguyen Van Sa²

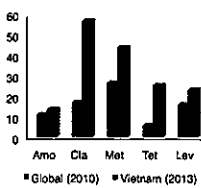
Dept. of Diagnostic Endoscopy, 108 Military Central Hospital, Hanoi, Vietnam¹
 Immunology Research Institute in Gifu, EW Nutrition Japan, Gifu, Japan²

Introduction and Aim

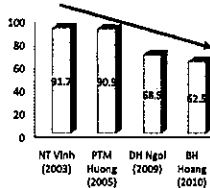
- *Helicobacter pylori* is considered the leading cause of gastritis, gastric ulcer and stomach cancer.
- Medication with a combination of 2-3 antibiotics is the common therapy of *H. pylori* infection. Antibiotic therapy fails in 10-40% of cases due to the development of antibiotic resistance.
- Studies conducted by IRIG (Gifu, Japan) revealed that egg antibody (IgY) against urease of *H. pylori* is effective in reducing the bacterial load in stomach of *H. pylori* positive volunteers and has synergetic effects when combined with probiotics.
- This study was conducted to examine if combination of the antibody with current treatment regime could improve the eradication rate and clinical signs in *H. pylori* positive gastritis patients.

Background: drug resistance and decreasing eradication rate

Resistance rate in Vietnam and the world



Successful eradication rate in Vietnam



1. Vincenzo DF et al. J. Gastro Liver Dis 2010
 2. DNQ Huø, DC Minh. Vietnamese J Gastro 2014

Background: anti-HP urease IgY

- Effective modes of action:
 - ✓ Urease activity inhibition resulting in growth inhibition
 - ✓ Adherence inhibition: prevents *H. pylori* from binding to gastric mucin
 - ✓ Cause damages to cell surface structure making *H. pylori* more susceptible to medicines

Materials and Methods

Volunteer clinical trial protocol

Place: Dept. of Diagn Endoscopy,
 108 Military Central Hospital, Hanoi

Subjects: Volunteers recruited from Hp positive patients with chronic gastritis or ulcer (n = 77)

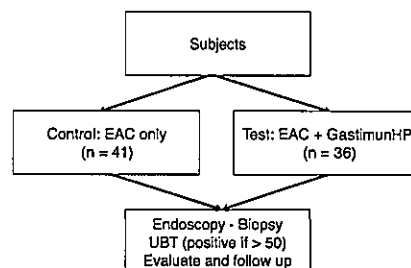
- Control group (n = 41):
 Treated with current regime of 3 drugs (EAC):-
 Esomeprazole 40 mg x 1 tablet/day x 28 days
 Amoxicillin 500 mg x 4 tablets/day x 14 days
 Clarithromycin 500 mg x 2 tablets/day x 14 days
- Test group (n = 36):
 Treated with EAC + IgY (GastimunHP):-
 EAC: same as above
 GastimunHP: 2 sachets/day x 15 days

Evaluation parameters:

- UBT value at 0 and 1 month post treatment
- Clinical symptoms (Stomach pain, Bloating, Belching) after 1w, 2w



Study design

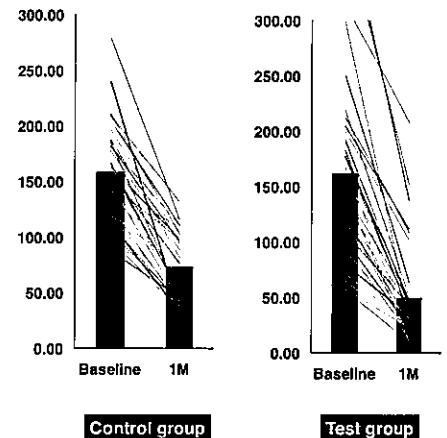


Demographic characteristics of participants

Characteristics	Test	Control
Number	36	41
Male/Female	16/20	22/19
Chronic gastritis	29	31
Gastroduodenal ulcer	7	10

Results

Change in UBT value of all subjects



UBT value before and after treatment

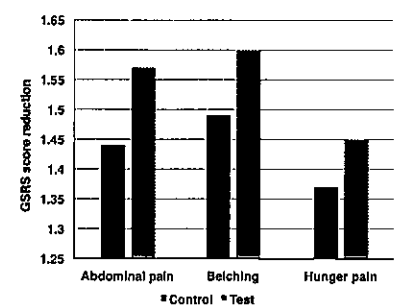
	Test (n = 36)	Control (n = 41)
Baseline (mean ± SD)	161.64 ± 83.53	158.54 ± 43.73
After treatment (mean ± SD)	49.42 ± 44.21 *	73.37 ± 30.0 *
Subject negative after treatment (%)	28 ^b (77.78%)	17 (41.46%)

*P < 0.0001 compared to baseline in each group, paired t-test
^bP = 0.002 compared to control group, Chi-square test

Clinical sign improvement

Sign	Test n (%)	Control n (%)	p
Reduced pain, 1w	19 (52.8)	16 (39.0)	< 0,05
Reduced pain, 2w	25 (69.4)	25 (60.9)	> 0,05
Reduced bloating, 1w	18 (50.0)	15 (36.6)	< 0,05
Reduced bloating, 2w	25 (69.4)	25 (60.9)	> 0,05

Reduction of other clinical signs 1 week after treatment



Note: one subject in the test group had diarrhea for 2 days

Conclusions and Discussions

- Health food supplement GastimunHP, used in combination with medicines, helps improve eradication of *H. pylori* and HP related clinical symptoms in patients with chronic gastritis or gastroduodenal ulcer.
- Anti-*H. pylori* IgY based food supplements could be valuable adjunct to current treatment regimes of Helicobacter infections, especially in case of drug resistance.
- Research needed to evaluate usefulness of combining IgY with PPI in eradication of *H. pylori*.