ΠΡΟΣΚΕΚΛΗΜΕΝΕΣ ΞΕΝΟΓΛΩΣΣΕΣ ΑΝΑΚΟΙΝΩΣΕΙΣ ΕΛΛΗΝΩΝ ΕΡΕΥΝΗΤΩΝ

● RABEPRAZOLE 7-DAYS VS RABEPRAZOLE 10-DAYS TRIPLE THERAPY IN THE ERADICATION OF *H. PYLORI* INFECTION – A RANDOMIZED STUDY

S. Karatapanis, S. Georgopoulos, L. Papakonstantinou, D. Papamarkos, A. Mentis, V. Artikis

"Elpis" General Hospital, Athens, Greece

Objective: To evaluate the efficacy and safety of two triple therapies based on rabeprazole (RAB).

Methods: Ninety-seven *H. pylori* positive patients (CLO-test, histology) (median age 48, range 18-79) with peptic ulcer (n=59) or non-ulcer dyspepsia (n=38) were randomized to receive RAB 400 mg bid, Clarithromycin (CL) 500 mg bid, and Amoxycillin (AMO) 1 gr bid for 1 week (Group A, n=49), or RAB 400 mg bid, CL 500 mg bid and AMO 1 gr bid for 10 days (Group B, n=48). *H. pylori* eradication was assessed 4 weeks after completion of treatment (by CLO-test and histology). Clarithromycin sensitivity tests were carried out in the cultured pre-treatment (66/97, 68%) *H. pylori* strains.

Results: The regimen failed to eradicate three (4.5%) *H. pylori* strains (one in Group A and two in Group B) which exhibited primary CL resistance. The eradication rates according to intention to treat analysis (ITT) were: 40/49 (81.6%) in Group A and 40/48 (83.3%) in Group B, and according to pre-protocol (PP) analysis: 44/49 (89.8%) in Group A and 43/48 (89.6%) in Group B. Side effects in both groups were mild and no patient discontinued treatment due to adverse effects.

Discussion: We conclude that both (1-week vs 10-days) triple therapies based in rabeprazole proved equally effective and safe to eradicate *Helicobacter pylori* infection.

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● IS THERE A RELATIONSHIP BETWEEN *H. PYLORI* AND BLEEDING, IN NSAIDS USER PATIENTS, WITH PEPTIC ULCER?

M. Tzouvala, K. Patikos, M. Mylonaki, E. Tsironi, V. Xourgias, D. Karamanolis
"Tzaneion" General Hospital, Piraeus, Greece

The role of *H. pylori* (*Hp*) in bleeding ulcers in NSAIDs users remains controversial.

Aim: To investigate, prospectively, the role of *Hp* in bleeding and non-bleeding peptic ulcers in NSAIDs users.

Patients/Methods: Eighty-five patients who presented at the emergency room with upper GI bleeding and have been receiving NSAIDs during the last week (Group 1), as well as, 51 symptomatic, NSAIDs users (during the last week) [32 M/19 F, age (mean±SD) 49±16 (range 20-81) yrs], with endoscopically detected peptic ulcer (Group 2), were included in the study between March 1998 and September 1999. *Hp* status has been evaluated by serology, rapid urease and histology. The distribution of ulcers (gastric, duodenal), the type of the NSAIDs (aspirin, non-aspirin), smoking and alcohol consumption have been recorded.

Results: In group 1, duodenal ulcer was detected in 29 (34%) pts, gastric ulcer in 56 (66%) pts, 47 (55%) pts reported aspirin consumption and 34 (40%) pts presented with dyspeptic symptoms before bleeding. In group 2, duodenal ulcer was detected in 27 (53%) pts, gastric ulcer in 24 (47%) pts, 26 (51%) pts reported aspirin consumption. *Hp* was positive in 60 (71%) pts of group 1 versus 25 (49%) pts of group 2 (p=0.01). In duodenal ulcer patients *Hp* positivity was significantly related to bleeding (22/29 pts vs 13/27, p=0.03). In gastric ulcer pts *Hp* was frequently positive in bleeders though this observation did not reach statistical significance (38/56 pts vs 12/24 pts, p=ns). The type of the NSAIDs, smoking and alcohol consumption were neither related to bleeding nor *Hp* status.

Conslusions: A severe complication such as bleeding in NSAIDs users is significantly correlated with *Hp* status.

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● EFFICACY OF *HELICOBACTER PYLORI* ERADICATION REGIMENS IN FUNCTIONAL DYSPEPSIA – COMPARISON WITH PEPTIC ULCER DISEASE

D. Kamberoglou, I. Sanidas, V. Doulgeroglou, S. Savva, E. Patra, V. Tzias
Department of GI Endoscopy of 1st IKA Hospital and Pathology Department of "Amalia Fleming" Hospital, Athens, Greece

H. pylori (*HP*) *infection* is often diagnosed in patients with functional dyspepsia (FD) or non-ulcer dyspepsia. The aim of this retrospective study was to report any differences in *HP* eradication rate between patients with and without endoscopic findings using various treatment regimens.

Methods: Among 248 patients with *HP* infection (F: 92, M:156 with mean age 52.5 and range: 20-79 yrs) 106 (group A; F:56, M:50 with mean age 51.9) had FD with normal endoscopy or minimal endoscopic findings and 142 (group B; F:61, M:81 with mean age 52.2 yrs) had peptic ulcer or erosive gastroduodenitis. Regimens were based in either proton pump inhibitor (PPI) or ranitidine bismuth citrate (RBC) in combination with two antibiotics from: clarithromycin (250 or 500 mg), amoxicillin (1 g), tetracycline-HCl (500 mg), metronidazole (500 mg) and tinidazole (500 mg), all given bid for 1 week. Endoscopy was repeated 4 weeks after the end of the treatment and *HP* eradication was considered successful if both rapid urease test and histology from antrum and corpus were negative.

Results: There were no significant differences between the 2 groups with respect to age, gender, alcohol and NSAID's consumption; however, patients in group B were more likely to be smokers ($p<0.001$). *HP* was eradicated in 195/248 patients (78.6% with 95% CI's 73.5%-83.7%). Eradication rate was higher in group B compared to group A (81.7% vs 73.6%) but the difference was not significant (x^2 test; $p>0.05$). Moreover, there was no significant difference in *HP* eradication rate between patients in the 2 groups treated either with a PPI or a RBC based regimen.

Conclusion: Patients with functional dyspepsia appear to respond equally successfully to *HP* eradication therapies compared to patients with peptic ulcer disease.

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● P27KIP1 EXPRESSION IN *HELICOBACTER PYLORI* GASTRITIS AND INTESTINAL METAPLASIA

[1]P. Foukas, [1]S. Sougioultzis, [2]B. Gorgoulis, [2]M. Mousia, [1]M. Tzivras, [3]P. Davaris, [1]A. Archimandritis

[1]Gastroenterology Section, Dept of Pathophysiology, [2]Dept of Histology and Embryology, [3]Dept of Pathology, University of Athens, Medical School, Athens, Greece

Aim: The study of p27Kip1 expression by human gastric epithelial cells in *Helicobacter pylori* (*Hp*) gastritis before and after eradication of the microorganism. The expression of p27Kip1 in intestinal metaplasia (IM) was also studies.

Patients and methods: a. 25 patients, 21 *Hp*(+) without IM and 4 *Hp*(-). All patients were endoscoped for the evaluation of dyspeptic symptoms. 17/21 had duodenal ulcer (DU), 1/21 gastric ulcer (GU) and 3/21 mixed lesions (DU+GU). Patients were endoscoped again, after the administration of triple anti-*Hp* therapy, in 116±9d. b. 5 *Hp*(+) patients with IM. Biopsies were taken from antrum and corpus (anterior-posterior wall) for CLO test and histologic evaluation of gastritis (Sydney classification). The immunohistochemical studies were performed on paraffin-embedded tissue sections with a mouse anti-human p27 antibody (DAKO); quantitative evaluation (percentage of positive cells) according to three distinct zones was done (zone 1=surface+upper 1/3 of the pit, zone 2=the rest 2/3 of the pit, zone 3=glands).

Results: a. Normal mucosa: p27 is expressed by few cells (0-2/pit), in zone 2 (proliferation zone). No expression was found on surface and glandular epithelium (zones 1,3). A lot of p27(+) lymphocytes in lamina propria and in the cortex of lymphoid follicles (when present) were detected; no expression by lymphocytes in the germinal center. b. *Hp* gastritis: Increase, not statistically significant, of the p27(+) epithelial cells in zone 2; no expression in zones 1,3. c. After eradication: p27 expression quantitatively and spatially almost like normal mucosa. d. Intestinal metaplasia: Significant (Mann Whitney, $p<0.05$) increase of p27(+) epithelial cells in zone 2 as compared with normal and *Hp*(+) without IM mucosa.

Conclusion: The terminal differentiated cells of the surface epithelium do not express p27Kip1. The relative increase of positive cells during inflammation and the significant increase of p27 expression in *Hp*(+) IM may represent a defensive mechanism of gastric mucosa against *Hp* infection.

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● MICs OF RABEPRAZOLE, A RECENTLY DEVELOPED PROTON PUMP INHIBITOR, AND OMEPRAZOLE, AGAINST *HELICOBACTER PYLORI*

A. Mentis, T. Rokkas
Hellenic Pasteur Institute, Athens, Greece

Several studies have shown that the proton pump inhibitors (PPIs) of the benzimidazole type (omeprazole, lansoprazole, pantoprazole) exert antibacterial in vitro activity against *Helicobacter pylori (H. pylori)*. However, few in vitro data exist on Rabeprazole, the newest PPI.

The **aim** of this study therefore, was firstly, to compare rabeprazole MICs against *H. pylori* with those of omeprazole and secondly, to examine whether these MICs were influenced by *H. pylori* susceptibility or resistance towards commonly used antibiotics for *H. pylori* eradication such as metronidazole, clarithromycin and amoxycillin.

Material and Methods: Fifty *H. pylori* strains were tested. All strains were recent clinical isolates from different patients with chronic gastritis and/or peptic ulcer. In addition, one reference strain, *H. pylori* CCUG38771, was also included in the study. For each component examined the MIC_{50} (the MIC at which 50% of strains were inhibited) and MIC_{90} (the MIC at which 90% of strains were inhibited) were determined by agar dilution.

Results: MICs (μg/mL) for omeprazole were within the range of 32-128 with MIC_{50} at 32 and MIC_{90} at 64. the respective values for rabeprazole were markedly lower (range 4-16, MIC_{50} 4 and MIC_{90} 16). *H. pylori* resistance percentages for metronidazole, clarithromycin and amoxycillin were 45%, 9.8%, and 0% respectively (E-test). Antibiotic resistance did not influence MICs of either PPI tested.

Conclusion: Rabeprazole? The newest PPI, is more effective than omeprazole in vitro against *H. pylori* clinical isolates and this effectiveness is not influenced by *H. pylori* resistance to commonly used antibiotics for *H. pylori* eradication.

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● EFFICACY AND SAFETY OF THREE 'TRIPLE' – DRUG REGIMENS IN *H. PYLORI* ERADICATION – FORERUNNING ANNOUNCEMENT

V. Balatsos, V. Delis, P. Kasapidis, A. Konstadinidis, I. Drikos, I. Karoubalis, A-M. Dielou, N. Skandalis

Dpt of Gastroenterology, General Hospital "G. Gennimatas", Athens, Greece

Background: There are many drug regimens of *H.p.* eradication. Several studies try to compare the efficacy and safety of these regimens.

Aim: To show the effectiveness and safety of the three ten-days 'triple' drug regimens in *H. pylori* eradication.

Methods: 134 outpatients, 63 men and 71 women, aged 18-75 years, were subjected to endoscopy for upper gastrointestinal symptoms. The presence of *H.p.* infection was estimated by CLO test and histological examination (modified Giemsa stain, H-E). All patients were assigned to three different triple-drug regimens of *H.p.* eradication by simple blind 'haphazard' randomization; amoxycillin 1 gr bid, clarithromycin 500 mg bid and omeprazole 20 mg bid (group A: 40 patients) or lansoprazole 30 mg bid (group B: 34 patients) or salt ranitidine-bismouth 400 mg bid (group C: 29 patients) were given for ten days. The 1st follow up was done after 60-70 days.

Results: 103 patients were checked again up to now matched to age, sex, alcohol reception and smoking. *H.p.* eradication was achieved in group A in 31 pts (77,5%), in group B in 23 pts (67,6%) and in group C in 22 pts (75,8%). Side effects (epigastric pain, diarrhea, vomiting etc) were observed in 3 pts of group A, in 2 pts of group B and in 6 pts of group C.

In group A, 1 of the pt stopped therapy on the 9th day but *H.p.* was eradicated while the other 2 pts continued therapy. In group B, 1 of the pt stopped therapy on the 7th day but *H.p.* was eradicated while the other pt continued therapy. In group C, 2 of them continued therapy, 2 were given another regimen of *H.p.* eradication, 1 stopped therapy on the 7th day but *H.p.* was eradicated and 1 pt withdrew due to side effects.

Conclusions: From the forerunning results of our study, the giving of the three 'triple' regimens of *H. pylori* eradication is satisfactory in confronting the infection of *H.p.* Perhaps, the side effects of group C in comparison with the other two groups constitute a cautions factor in providing the drug regimen.

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● NSAIDS USE DOES NOT AFFECT *H. PYLORI* (*HP*) ERADICATION RATE IN PATIENTS WITH DUODENAL ULCER (DU) OR EROSIVE DUODENITIS (ED) WHEN TRIPLE THERAPY IS USED

S. Michopoulos, P. Tsibouris, A. Balta, I. Vougadiotis, M. Zissis, N. Kralios
Gastroenterology Dept, Alexandra Hosp, Athens, Greece

NSAIDs use could reduce the efficacy of eradication regimens in curing *HP* infection. The aim of our study was to evaluate if *HP* eradication rate is affected by NSAIDs use in patients with DU or ED, when a triple eradication regimens is used.

Patients and methods: 315 patients (220 DU-95 ED, mean age 51.7±14.3 years, 175 men, 105 smokers, 125 on NSAIDs treatment at least 3 times a week), all *HP* positive, received a 10 days eradication regimen with omeprazole 20 mg bid, clarithromycin 500 mg bid, amoxyxillin 1 g bid. Of those initially receiving NSAIDs: 57 continued NSAIDs during eradication treatment (Group I), while 68 discontinued them (Group II), All patients initially not receiving NSAIDs did not receive NSAIDs during eradication treatment (Group III, n=190). Endoscopy was performed 4-6 weeks after treatment completion. *HP* eradication was verified by histology, CLO-test and ^{13}C-urea breath test. Stat: X^2 test, t-test.

Results: 295 patients had a follow up endoscopy. 20 lost during follow-up, 6 discontinued treatment prematurely. Patients of Group III were younger. More smokers were included in group II. Intention to treat eradication rates were: Group I: 80,7% (CI 70.1-91.3), Group II: 79.4% (CI 69.6-89.3), Group III: 83.7% (CI 78.4-89)- p>0.1. Per protocol eradication rates were: Group I: 85.2% (CI 75.4-95), Group II: 84.4% (CI 75,2-93,5), Group III: 89.8% (CI 85.3-94.3)- p>0.1. There was no difference in eradication rates among the 3 groups when patients with DU and ED or smokers and non-smokers were examined separately.

Conclusions: NSAIDs use seems no to affect *HP* eradication rates, when a triple regimen comprising omeprazole, amoxycillin and clarithromycin is received.

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