

**Abstract no.: P09.15**  
***H. pylori* Eradication by Four Triple Therapies: Randomized Study in Double-Blind**

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**Aim:** To compare the eradication rates and tolerability of Four Triple Therapies administered in naive patients.

**Methods:** It was a controlled, double-blind study; 238 patients (women: 70%, average age: 33.4 years, duodenal ulcer: 57) infected by *Helicobacter pylori* were included. The infection was confirmed on the positivity of urea breath test (UBT) and/or two among the three following tests: histology, urease test, and culture. After randomization, patients received one of the four therapies: OAM7, OAM10, OAC, and RbcMT administered for 7 days with usual doses, with the exception of OAM10 prescribed for 10 days with a high dose of metronidazole (500 mg/3xj). Eight to 12 weeks after treatment, eradication has been affirmed on the negativity of UBT.

**Results:** The eradication rate of OAM7, OAM10, OAC, and RbcMT was in intention to treat (ITT) (and per protocol - PP) respectively 62.5% (67.3%), 74.2% (80.7%), 68.7% (79.3%), and 66% (68.6%), without a significant difference between the groups. The eradication rate of the resistant strains versus susceptible ones to metronidazole were respectively in ITT for OAM7, OAM10, and RbcMT: 62.5% vs 46.1%, 82.3% vs 66.7%, and 82.6% vs 50%. The difference was significant ( $p = .02$ ) only for RbcMT. The success rate in resistant cases versus susceptible to clarithromycin (OAC) was 76.9% vs 16.7% ( $p = .01$ ). Adverse events were minimal and more frequently with OAC. The compliance was complete in 98.4%.

**Conclusion:** The first-line tritherapies provide eradication rates of *H. pylori* not significantly different and are well tolerated. However, due to a slightly higher efficiency, low cost, and an increasing resistance rate to clarithromycin, the OAM10 regimen with a high dose of metronidazole seems more adapted in Algeria.

**Abstract no.: P09.16**  
**Original and Generic Pantoprazole-Based Standard Triple Therapies for the Eradication of *H. pylori* Infection in Duodenal Ulcer Patients**

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**Introduction:** Generic preparations are bioequivalent with original brands. However, it is not known whether their clinical efficiency is also similar.

**Aim:** To compare the original and two generic pantoprazole preparations' in eradication of *H. pylori* infection in duodenal ulcer patients.

**Methods:** Seventy-six endoscopically (Fujinon EC250WL Video system) confirmed active duodenal ulcer patients were enrolled in

<sup>1</sup>Original drug: Controloc® Nycomed, Germany; G1: Nolpaza®, Krka, Slovenia; G2: Pantoprazole Ratiopharm®, Ratiopharm, Germany.

an open, prospective, randomized study. *H. pylori* infection was confirmed from antrum and corpus samples by histology (modified Giemsa stain), immunohistology and, if needed, FISH. The patients were assigned to a 7-day standard regimen containing 2 × 40 mg pantoprazole, 2 × 1000 mg amoxicillin, and 2 × 500 mg clarithromycin; 24 cases received the original, while 26 and 26 patients, respectively, were given generic pantoprazoles (group G1 and G2). The eradication of the infection was controlled by <sup>13</sup>C-urea breath test performed 6 weeks after treatment.

**Results:** The eradication rate on an intention-to-treat basis was of 70% (95% confidence interval, CI: 51.2–90.4%) in patients receiving the original pantoprazole, 73.9% (54.5–93.3) in group 1 ( $p = .63$ ), and 77.8% (61.2–88.3) in group 2 ( $p = .57$ ). Per-protocol rates of eradication were 73.9% (54.5–93.3) in the original group, 86.9% (72.0–99.8) in the G1 group ( $p = .26$ ), and 84.0% (77.2–92.5) in G2 group ( $p = .39$ ).

**Conclusions:** The clinical efficiency of the original and generic pantoprazoles in the eradication of *H. pylori* infection in duodenal ulcer is similar.

**Abstract no.: P09.17**  
**Role of Rebamipide in the Therapy of Peptic Ulcer Associated with *H. pylori***

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Infection with *Helicobacter pylori* results in the lesions of mucous barrier of stomach (MBS) and enhances the aggressive properties of gastric juice.

The aim was to improve the effectiveness of peptic duodenal ulcer (PDU) therapy by introducing rebamipide into the therapy complexes.

Forty-two PDU HP-associated patients were under the observation. The size of ulcerative lesions was  $7.2 \pm 2.1$  mm. Mucus-producing function of MBS was evaluated by the content of N-acetylneuraminic acid (NANA) and fucose in the blood serum and by their excretion with urine.

The patients were divided into two groups: I (n = 22) – pantoprazole–clarithromycin–amoxicillin – anti-*H. pylori* therapy 10 days; II (n = 22) additionally took rebamipide 300 mg/day for 28 days.

Clinical and endoscopic PDU remission in 28 days was recorded in 21 (95.5%) patients in group I and 22 (100%) patients in group II, while *H. pylori* eradication in 19 (86.4%) patients in group I and 21 (95.5%) patients in group II.

After the therapy had been completed the NANA concentration in group I reduced 1.15 times; group II 1.3 times ( $p < .001$ ). NANA excretion with urine in group I decreased 1.1 times; group II 1.3 times ( $p < .05$ ). Due to the anti-*H. pylori* therapy and rebamipide, the NANA excretion with urine was 1.2 times ( $p < .05$ ) lower than that in group I. The blood serum concentration of fucose bound with proteins in group I patients increased 1.6 times ( $p < .001$ ). The similar changes were detected when studying fucose excretion with urine.

The administration of rebamipide in combination with anti-*H. pylori* therapy increases the therapeutic effectiveness by enhancing duodenal mucous barrier resistance.