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Increased Prevalence of Helicobacter pylori 23s rRNA Gene Mutations in

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therapy, 2) to evaluate the effect of antibiotic resistance on the treatment outcome and 3) to elucidate other causes of eradication failure for this triple therapy. Methods: *Helicobacter pylori*-positive 155 patients by culture were assigned to 7-days eradication therapy with lansoprazole 30 mg b.i.d., amoxicillin 750 mg b.i.d., and metronidazole 250 mg b.i.d. The outcome of eradication was assessed by 13C urea breath test. Minimum inhibitory concentration (MIC) of clarithromycin, amoxicillin or metronidazole were retrospectively investigated for *H. pylori* isolates from all patients by agar dilution method. The relationship between eradication failure and the patients' background (age, gender, drinking, smoking, number of previous eradication attempt, and antimicrobial resistance of the isolated strain) were analyzed. Results: After eradication treatment, 150 patients returned to the physician and were evaluated for the outcome from therapy by 13C urea breath test. Fifteen patients were posistive for *H. pylori*, including one patient who failed to complete the medication because of diarrhea. No other severe adverse event was reported. The eradication rate was 90.3% (140/155) by intention-to-treat analysis and 94.0% (140/149) by per-protocol analysis. Antimicrobial resistant strains were isolated from one patient for amoxicillin, from 58 for clarithromycin and from eight for metronidazole. Six patients with metronidazole-resistant strains were successfully eradicated and no significant effect on eradication rate by antibiotic resistance was observed. The risk of eradication failure was significantly related only to the number of previous treatment failure with odds ratio of 2.62 (1.09-6.25, 95% confidence interval) by one previous failure. Conclusions: The triple therapy with lansoprazole, amoxicillin, and metronidazole is safe and effective regardless of MIC of the isolated strains in Japan. However, eradication therapies after two or more failed attempts are at risk of another failure, which is unrelated to the resistance of the strains.

M1090

Rifabutin Resistance of *H. pylori* Isolated from Japanese Patients

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Background and Aim. Recently, the number of *Helicobacter pylori* (*H. pylori*) isolates showing antibiotic resistance has been increasing. Rifabutin, although not currently available in Japan, is reported to be one of the candidate components of a new regimen for *H. pylori* eradication (*Antimicrob Agents Chemother* 43:1497-1499, 1999). Rifabutin is an antituberculosis agent derived from rifamycin-S. In the present study, the MICs of rifabutin and the resistance-determining genes to rifabutin were examined using strains isolated from patients in two different types of hospitals in Japan, in order to clarify the relationship between the MICs of the drug and the presence of mutations of the resistance-determining gene in the isolates. Methods. The MICs of rifabutin were examined for 48 strains of *H. pylori* isolated from the patients of a general hospital (Keio University Hospital) and 46 strains isolated from the patients at a specialized hospital for chronic respiratory diseases (National Minami-Yokohama Hospital), and the isolates were examined for the presence of point mutations of *rpoB*. Results. Although 3 of the 48 strains (6.3%) isolated from patients in Keio University Hospital showed point mutations (V538I) of the *rpoB* gene, the MICs of rifabutin were low for all of the 48 strains (MIC<0.015). On the other hand, seven of the 46 strains (15.2%) isolated from the patients at National Minami-Yokohama Hospital showed point mutations in the resistance-determining regions of the *rpoB* gene of rifabutin, and the MICs of rifabutin were high (MIC > 0.5) for five of these seven strains (71.4%) with point mutations in the *rpoB* gene (PPV: 71.4%, NPV: 97.7%, sensitivity: 71.4%, speciality: 97.7%, p<0.001). In particular, the MICs were high for strains isolated from patients with a past history for treatment with rifampicin (PPV: 85.7%, NPV: 98.9%, sensitivity: 85.7%, speciality: 98.9%, p<0.001). And, the relationship between the MICs of RBU (more than 0.015μg/ml) and RFP for the strains is a significant linear correlation. Conclusion. Although rifabutin might be a potential candidate component of a new regimen for *H. pylori* eradication therapy following failure of the first-line and/or second-line regimens, it should be used only after the patient is checked for a past history of treatment with rifampicin.

M1091

Ten-Day Sequential Therapy Is Superior to Triple Therapy for the Eradication of *Helicobacter pylori*: Systematic Review and Meta-Analysis

Luigi Gatta, Dino Vaira, Nimish Vakil

Background: The success of the current recommended therapy for H pylori infection (PPI-triple therapy) has declined to unacceptable levels. Sequential therapy is a novel treatment strategy that has shown promise in several controlled. Aim: To perform a systematic review and meta-analysis to determine the therapeutic efficacy of sequential therapy compared to the PPI-triple therapy in adults and children. Data Sources: Studies were identified by searching the Cochrane Trial Register (Issue 3, 2007), MEDLINE (1966 - September 2007), EMBASE (1980-September 2007), two register trials, and abstracts from the major US and European gastroenterology conferences. Study Selection: Randomized controlled trials comparing sequential therapy to PPI- triple therapy in adults and children H pylori infected. Data Extraction: Two investigators separately performed the search, selected the studies, and jointly performed data extraction. Quality assessment was performed using a scale described by Jadad. A third investigator arbitrated in the event of a lack of agreement. Subgroup analyses were performed evaluating: age of patients, duration of triple therapy, Jadad score, presence of NUD or PUD, number of tests performed to confirm the eradication. Results: 7 randomized controlled trials enrolled adult patients and the pooled relative risk for eradication of H pylori with sequential therapy compared to triple therapy was 1.22 (95% CI 1.18 to 1.26; I2= 0%) with a number needed to treat of 6 (95% CI: 5 to 7). 2 studies enrolled children and adolescents, and the pooled relative risk for eradication of H pylori with sequential therapy compared to triple therapy was 1.21 (95% CI 1.04 to 1.40; I2= 0%) with a number needed to treat of 6 (95% CI: 4 to 26). Conclusion: Sequential therapy is superior to triple therapy in the eradication of H pylori. It should be evaluated further as a potential new first-line therapy in infected patients

M1092

A Randomized Double Blinded Clinical Trial with Omeprazole, Levofloxacin and Escalated Dose of Rifaximin for *Helicobacter pylori* in Treatment-NaïVe Population

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Purpose: *Helicobacter pylori*(H pylori) is an insidious infection with a significant progression to gastric carcinoma, lymphoma,peptic ulcer disease and is a WHO class 1 carcinogen.Prevalence was estimated at about 70% in developing countries and 30-40% in the United States. Resistance to currently used drugs{eg.,Metronidazole (28.9%),Clarithromycin(10.9%) and Amoxicillin (12%)}is a limiting factor in treatment.Tripe therapy with Clarithromycin,Amoxicillin and a Proton Pump Inhibitor (PPI)has been the gold standard.Rifaximin and Levofloxacin were used individually with success in various clinical trials as salvage therapy for recurrent H pylori.Our prior experience with this novel regime of Rifaximin 400mg,Omeprazole 20mg and Levofloxacin 250mg twice daily as first line therapy for eradication of H pylori in the treatment-naïve population had 50% efficacy.So we proposed a similar double blinded randomized trial with increased dose of Rifaximin(for better efficacy) and same dose of Levofloxacin and Omeprazole, all for ten days. Methods: Patients with dyspepsia were evaluated with upper endoscopy,biopsy and stool antigen testing for H pylori(Quest Diagnostics Inc,Teterboro,NJ).Thirty patients of diverse ethnic background with stool antigens positive for H pylori and confirmed histologically were randomized in a double blinded fashion in two arms.Patients with use of PPI,Non-Steroidal Anti-Inflammatory Drugs,Aspirin or antibiotics in 4 weeks preceding detection of H pylori were excluded.One arm(n=15)was treated with Rifaximin 600mg, Omeprazole 20mg and Levofloxacin 250mg all twice daily for 10 days and the other arm(n=15) with Rifaximin 800 mg,Omeprazole 20 mg, and Levofloxacin 250mg all twice daily for same duration.Follow up stool testing for H pylori antigen was performed after cessation of Omeprazole for atleast 2 weeks. Results: 6 patients(40%) and 8 patients(53%) cleared H pylori in the 600mg Rifaximin and 800mg Rifaximin arms respectively.10 patients(33%) experienced mild to moderate side events but completed the full course. Conclusion: There is no statistically significant benefit with escalated doses of Rifaximin for eradication of H pylori. These regimes' eradication rate compared with 50% in our earlier study using 400mg of Rifaximin twice daily.Cost benefit analysis of higher doses do not justify this strategy for initial treatment.We foresee no added therapeutic or economic benefit with this combination in naive or salvage therapy in future.

M1093

Levofloxacin- and Amoxcillin-Based Quadruple Therapy for the Third-Line Treatment of *Helicobacter pylori* Infection

Ping-I Hsu, Deng-Chyang Wu

Background: A standard third-line therapy for *Helicobacter pylori* (H pylori) infection is lacking, and antimicrobial sensitivity data for patients failing eradication are often unavailable in clinical practice. We therefore designed the prospective study to assess the efficacy of a novel third-line levofloxacin- and amoxcillin-based quadruple therapy. Patients and methods: From September 2005 to August 2007, 42 consecutive H pylori-infected patients who had failed standard first-line and second-line treatments underwent a 10-day quadruple therapy comprising rabeprazole 20 mg b.d., bismuth subcitrate 300 mg q.d.s., amoxicillin 500 mg q.d.s., and levofloxacin 500 mg o.d. Follow-up endoscopy with rapid urease test, histological examination and culture was performed at six weeks after the end of treatment to evaluate the response to therapy. Results: H pylori was successfully eradicated in 37 out of 42 patients (88% by both intention-to-treat analysis and per-protocol analysis). All patients (100%) complied with the eradication therapies, and only nine (21%) patients complained of mild-to-moderate adverse events. Amoxicillin- and levofloxacin-resistant strains were observed in 17% and 22% clinical isolates, respectively. There were no significant differences between H pylori eradication rates and antibiotic resistances. Conclusions: The 10-day levofoxacin- and amoxicillin-based quadruple therapy is well tolerated and achieves a high eradication rate in third-line empirical treatment for H pylori infection.

M1094

Increased Prevalence of *Helicobacter pylori* 23s rRNA Gene Mutations in Patients with Gastritis in Pakistan

Javed Yakoob, Wasim Jafri, Zaigham Abbas, Shahab Abid, Rustam Khan, Nida Jafri, Zubair Ahmad

Background The major cause of *Helicobacter pylori* treatment failure is clarithromycin resistance which is attributed to point mutations within the peptidyltransferase-encoding region in domain V of the 23SrRNA gene. Several distinct point mutations including A2142G, A2143G, A2142C, A2115G and G2141A have been described. Aims: The aim of this study was to determine the prevalence of clarithromycin point mutations A2142G, A2143G and A2142C in patient presenting with *H. pylori* associated nonulcer dyspepsia, gastric and duodenal ulcer and gastric carcinoma and lymphoma. Methods PCR-restriction fragment length polymorphism (PCR-RFLP) was used to allow the identification of mutations A2142G and A2143G using the BbsI and BsaI restriction enzymes, respectively and for detection of mutation A2142C using the enzyme BceAI A 267-bp fragment was amplified by PCR using primers 5_-AGGTTAAGAGGATGCGT CAGTC-3 (HPY-S) and 5- CGCATGATATTCCCAT-TAGC AGT-3 (HPY-A), corresponding to nucleotides 1931 to 1952 and 2197 to 2175, respectively, of the 23S rRNA gene of *H. pylori*. Differences in proportion were assessed by using Pearson Chi square, Fisher exact or likelihood ratio test where appropriated. P value less than 0.05 was considered as statistical significant, all p value were two sided. Result: There were 55 (59%) males. Abdominal pain was present in 79(85%). CLR mutation was present in 34 (37%) patients. Mutations were common in patients with symptoms p=0.008. Endoscopically, antral gastritis was present in 32(34%), pangastritis 34(37%), gastric ulcer 7(8%), gastric carcinoma 15(16%) and duodenal ulcer in 5(5%). Histology showed acute on chronic inflammation in 57(62%), chronic inflammation 18(19%), gastric adenocarcinoma 15(16%) and lymphoma 3 (3%), respectively. *Helicobacter pylori* was positive on histology in 74(80%) and *H. pylori* glmM PCR in 93(100%) patients. CLR mutations were significantly

present in patients with gastritis 30(88%) as compared to gastric carcinoma 1(3%) and peptic ulcers 3(9%) (p=0.02). On histology, 24 (71%) patients with chronic active gastritis had CLR mutations compared to 10 (29%) with chronic inflammation and gastric carcinoma and lymphoma 1(3%) (p= 0.004). Conclusion: Clarithromycin mutations were present in clinical isolates of *H. pylori*. They were significantly associated with endoscopic gastritis with chronic active gastritis compared to peptic ulcer and gastric carcinoma.

M1095

Empirical Rescue Therapy After *H. pylori* Treatment Failure: A 10-Year Single Center Study of 500 Patients

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BACKGROUND: The most commonly used first-line eradication therapies may fail in up to 20-30% of patients. Several "rescue" therapies have been recommended, but they still fail to eradicate *H. pylori* in more than 20% of the cases. Currently, a standard third-line therapy is lacking, and international guidelines recommended culture in these patients to select a third-line treatment according to microbial sensitivity to antibiotics. However, cultures are often carried out only in research centers, and the use of this procedure as "routine practice" in patients who failed several treatments is not feasible. AIM: To evaluate the efficacy of different "rescue" therapies empirically prescribed (antibiotic susceptibility was unknown) during 10 years to 500 patients in whom at least one eradication regimen had failed to cure *H. pylori* infection. METHODS: Design: Prospective single-center study. Patients: Consecutive patients in whom at least one eradication regimen had failed. Intervention: Rescue regimens included: 1) Quadruple therapy with omeprazole-bismuth-tetracycline-metronidazole; 2) ranitidine bismuth citrate-tetracycline-metronidazole; 3) omeprazole-amoxicillin-levofloxacin; and 4) omeprazole-amoxicillin-rifabutin. Antibiotic susceptibility was unknown (rescue regimens were chosen empirically). Outcome: Eradication was defined as a negative 13C-urea breath test 4-8 weeks after completing therapy. RESULTS: Five-hundred patients were included (76% functional dyspepsia, 24% peptic ulcer). Compliance with 2nd, 3rd, and 4th-line regimens was 92%, 92%, and 95%. Adverse effects were reported by 30%, 37%, and 55% of the patients receiving 2nd, 3rd, and 4th-line regimens. Overall, *H. pylori* cure rates with the 2nd, 3rd, and 4th-line rescue regimens were 70%, 74%, and 76%. Cumulative *H. pylori* eradication rate with 4 successive treatments was 99.5%. CONCLUSION: It is possible to construct an overall treatment strategy to maximize *H. pylori* eradication, based on the administration of four consecutive empirical regimens; thus, performing bacterial culture even after a second or third eradication failure may not be necessary.

M1096

High Dose vs. Standard Dose Proton Pump Inhibitor Triple Therapy for *Helicobacter pylori* Eradication: A Meta-Analysis

Albert Villoria, Xavier Calvet, Pilar Garcia, Javier P. Gisbert, Valentí Puig Diví

Introduction: The usefulness of using high-dose proton pump inhibitor (PPI) in triple therapy for *H. pylori* eradication is controversial. Objective: To review the evidence on the possible usefulness of high dose PPI in standard triple therapy for *Helicobacter pylori* eradication. Methods: A systematic search was performed in multiple databases (MEDLINE, ISI Web of Knowledge, Embase, Cochrane Database of Randomized trials and CINAH), and in the abstracts submitted to the Digestive Diseases Week and the European Helicobacter Study Group congresses between 2000-2007. The references of the relevant articles or reviews were also assessed. Randomized trials comparing a standard dose PPI (omeprazole, rabeprazole or esomeprazole 20 mg, lansoprazole 30 mg or pantoprazole 40 mg) twice a day with high dose PPI (esomeprazole, rabeprazole or omeprazole 40 mg, lansoprazole 60 mg or pantoprazol 80 mg) twice a day in triple therapy, strategies combining a PPI plus clarithromicyn and either amoxicillin or metronidazole were selected. Results: Six studies including 1703 patients fulfilled the inclusion criteria. All of them used triple therapy for 7 days. High dose PPI achieved a mean intention to treat cure rate of 82.5% vs. 73.9% with standard dose PPI (RR 1.10, IC95%:1.02-1.19). Per protocol cure rate analysis was performed in 5 studies; respective cure rates were 89.5% and 82.9%, (RR 1.08, IC95%:1.03-1.13). No statistically significant difference was found between both groups in terms of side effects. Conclusion: High dose PPI increase *H. pylori* eradication cure rates in triple therapy when compared with currently used standard dose.

M1097

Reflux Symptoms Worsen After Eradication of *Helicobacter pylori* in Japanese Patients with Atrophic Gastritis

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[Background]Eradication of *Helicobacter pylori*(HP) does not affect, or improve gastro-esophageal reflux symptoms in Western people in whom HP causes antrum-predominant gastritis. However, it may not be true in Japanese people whose gastritis is pangastritis or corpus-predominant gastritis. [Objective]To evaluate whether the reflux symptoms worsen or not after eradication of HP in Japanese patients. [Methods]A total of 175 patients with HP received the eradication therapy. Reflux symptoms were assessed by using Gastrointestinal Symptom Rating Scale (GSRS) before and three months after eradication. The sum of the scores of heartburn and acid regurgitation was determined as reflux score graded from point 2 (none) to 14 (the most severe). Patients were classified into three groups according to the change of reflux score after the eradication therapy; "Worsen", "No change", or "Improve" groups when the reflux score increased, did not change, or decreased, respectively. The successful eradication was judged by the urea breath test three months after eradication. The change of reflux score was compared according to the success or failure of eradication. Sex, age, pretreatment findings (ulcer, hiatal hernia, and the reflux score before eradication) were evaluated as risk factors. [Results]The eradication was successful in 123 patients (70.3%) and 52 patients failed. In patients with successful eradication, the reflux scores worsened in 29 patients (24%), did not change in 49 patients (40%), and improved in 45 patients (36%). On the other hand, in patients with eradication failure, 4 patients were classified as "Worsen" (8%), 22 "No change" (42%), and 26 "Improve" (50%). The rate of worsening of the reflux scores was significantly higher in patients with successful eradication (p=0.02). In a multivariate analysis including sex, age, and pretreatment findings, the eradication success was judged as the only risk factor for the worsening of reflux scores (OR=4.1, 95%CI=1.3-12). In 29 patients with worsening of reflux scores after eradication, the increased points of reflux score were evaluated. In 5 patients with hiatal hernia, the mean increased reflux score was 2.2 points, which was higher than 1.4 points in 24 patients without hiatal hernia (p=0.02). In 11 patients with some reflux symptoms (>2 points) before the eradication, the change of score showed a higher tendency than those without pretreatment reflux symptoms (1.7 points vs 1.3 points, p=0.17). [Conclusions]The reflux symptoms worsened after HP eradication in Japanese patients. Hiatal hernia and pretreatment reflux symptoms may be risk factors for more severe worsening of the reflux symptoms.

M1098

Increased Rates of Peptic Ulcer Disease (PUD) and *Helicobacter pylori* (HP) Related Hospitalizations in U.S. Children: A 15 Year Analysis

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Background: Approximately 70-80% of primary PUD in adults is caused by Hp; an infection primarily acquired during childhood. Population-based studies of PUD in adults show a significant impact in hospitalized persons. PUD prevalence and epidemiology in US children is poorly characterized. Methods: We analyzed the Pediatric Health Information System (PHIS) database from 43 US pediatric hospitals to determine the prevalence of PUD, gastritis, bleeding ulcers, and Hp infection in hospitalized children between the years 2002-2007. Results were compared to our previous analyses from the PHIS database over the years 1992-2000. Results: There were 2,361,578 hospital discharges from 2002-2007 compared to 2,052,743 from 1992-2000 (32 US pediatric hospitals included). The proportion of discharged patients with diagnoses of PUD, gastritis, and Hp are shown in Table 1; overall PUD prevalence increased significantly for this period. 1121 (0.047%) patients had a discharge diagnosis of bleeding ulcers from 2002-2007. From 2002-2007, Hp infection was associated with a greater number of children hospitalized with duodenal ulcer (DU; 16.5%) than with gastric ulcer (GU; 6%). Of 1578 children with a diagnosis of Hp, 1191 (75.5%) had a concurrent diagnosis of gastritis or duodenitis, 314 (19.9%) had a diagnosis of gastrointestinal bleeding, 94 (6%) had a diagnosis of GU, and 178 (11.3%) had a diagnosis of DU. Yearly percentages of total discharges significantly decline in PUD, and gastritis/duodenitis plus Hp between 2004 and 2005 (p=0.005 and p=0.002 respectively), which mirrors a decline in Hp (p=0.001) these same years. These discharge diagnoses increased subsequently. Gender, race/ethnicity, and age all affected rates of discharges due to PUD, gastritis or Hp. Discussion: Rates of discharge diagnoses of PUD, Hp, and gastritis have increased significantly in hospitalized children over the past 15 years. The decline in Hp seen in pediatric hospitals from 2004 to 2005 is similar to adult studies over the same years. The cause for this temporary decrease in Hp-related discharge diagnoses is unclear. Prospective studies are needed to ascertain the epidemiology of PUD and the impact of Hp infection among children in outpatient populations. Future PHIS analyses will include extensive demographic information and financial impact that PUD and associated complications have on the pediatric health system.

Table 1: Percentages of total discharges, PHIS

Years	PUD(%)	Gastritis(%)	Hp(%)
1992-2000	0.12	0.6	0.03[a]
2002-2007	0.13*	0.72*	0.07*

[a]Only data from 1995-2000 is available; *p< 0.0001

M1099

Symptom Association During Impedance Testing (pH-MII) Is Not Useful in Predicting Outcome After Fundoplication

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Background: Causal relationships between symptoms and gastroesophageal reflux are difficult to prove. Previous pilot data has suggested that the number of reflux events detected by pH-MII may not predict outcome after fundoplication. The role of symptom association in predicting outcome is unknown. The aim of the study was to assess if symptom indices are useful to predict which patients will improve symptomatically after fundoplication. **Methods:** Records for patients who underwent fundoplication with preceding pH-MII testing between January 2002 and October 2007 were reviewed. 34 children were included in the analysis. pH-MII tracings were blindly reviewed and the symptom index (SI) and the symptom sensitivity index (SSI) were determined for each patient. Patients were categorized as improved or not improved after surgery. Patients who improved were further classified as improved from a gastrointestinal (GI) and/or respiratory (RESP) perspective. ROC curves were generated to determine the utility of SI and SSI testing in predicting surgical outcome. Logistic regression was performed to determine predictors of overall outcome. **Results:** 22 patients (65%) experienced overall symptomatic improvement after fundoplication; 20/27 patients with GI symptoms improved and 15/31 patients with respiratory symptoms improved. Mean symptom indices (±std) are shown in Table 1. Area under the curve and p values for the ROC curves are shown in Table 2; the SI and the SSI could not adequately determine who did and did not improve after fundoplication. Furthermore, logistic regression revealed that neurologic status, age at fundoplication, number of reflux events by impedance, pH probe results and symptom indices were not predictive of fundoplication outcome (p>0.2). **Conclusions:** The SI and SSI may not be useful tests for predicting symptomatic improvement after fundoplication.