THE SAFETY OF DUAL THERAPY WITH CLARITHROMYCIN AND OMEPRAZOLE IN THE TREATMENT OF PATIENTS WITH DUODENAL ULCER DISEASE ASSOCIATED WITH H. PYLORI INFECTION. C. Olson, M. Desart, R. Huppatz, J.C. Craft, Abbott Laboratories, Abbott Park, IL, USA.

 Clarithromycin (CL) was administered in combination with omeprazole (OM) in four large, well-controlled studies (two European and two U.S.) to assess the safety and efficacy of this combination in the eradiation of H. pylori from the gastric mucosa and prevention of duodenal ulcer recurrence. A total of 346 patients received CL 500 mg TID and OM 40 mg QD for the first 14 days, followed by OM 40 mg QD (in one study) or 20 mg QD (in three studies) for an additional 14 days.

**Most Frequently Reported Adverse Events** (Excluding Taste Perversion)

<table>
<thead>
<tr>
<th>Condition</th>
<th>发生人数</th>
<th>ADR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>16</td>
<td>5%</td>
</tr>
<tr>
<td>Headache</td>
<td>15</td>
<td>5%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>12</td>
<td>3%</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>11</td>
<td>3%</td>
</tr>
<tr>
<td>Infection</td>
<td>9</td>
<td>3%</td>
</tr>
<tr>
<td>Total</td>
<td>142</td>
<td>41%</td>
</tr>
</tbody>
</table>

*Number of patients reporting each adverse event.

Taste perversion, an adverse event common observed throughout the development of CL, was reported by 54 of the 346 patients (15%).

The percentage of CL-OM treated patients reporting adverse events in the U.S. studies (49%, 81/164) and European studies (41%, 75/182) were similar, (p=0.131).

Twelve (3%) of the 346 patients were prematurely terminated from study drug therapy due to adverse events. For each laboratory parameter, less than one percent (<1%) of the patients had laboratory values considered possibly clinically significant per criteria developed by Abbott Laboratories.

Overall, clarithromycin 500 mg TID in combination with omeprazole 40 mg QD is safe and well tolerated.


**Aim:** We tested the hypothesis that one-week effective eradication therapy is sufficient to heal H.pylori associated duodenal and gastric ulcers.

**Methods:** In 4 consecutive prospective studies, 112 patients with endoscopically proven H.pylori positive (culture and/or histology) duodenal ulcers (n=78), gastric ulcers (n=28), or gastroduodenal double ulcers (n=6) were treated with one-week triple therapy schedules consisting of omeprazole 20 mg od, clarithromycin 250 mg bid, and metronidazole 400 mg bd or tetracycline 500 mg bd (OAM, OCT), or with omeprazole 20 mg bd, amoxicillin 1 g bd, and clarithromycin 250 mg bd or metronidazole 400 mg bd (OAC, OAM). Ulcer healing and H.pylori eradication (urease test, culture, histology) were assessed 4 weeks after cessation of the eradication therapy.

**Results:** In all patients, symptoms referable to ulcer disease disappeared within one week of treatment. The overall 5-week ulcer healing rate was 96.6% (106/112 patients; 95%-CI: 99-98%). Out of the patients with healed ulcers, 96% have also cured their infection. Ulcer healing was more frequently observed in patients with cure of H.pylori infection as opposed to the group of patients with persisting H.pylori colonization (79%, p<0.02). Incomplete ulcer healing after 5 weeks was associated with either persistant H.pylori infection (n=2), intake of Aspirin/NSAIDs (n=3), or treatment with Aspirin (100 mg) and H.pylori persistence (n=1).

**Conclusion:** In the absence of concomitant treatment with ulcerogenic drugs, a one-week highly effective eradication therapy is sufficient to heal almost all duodenal and gastric ulcers. Thus, prescription of antulcer drugs beyond eradication therapy seems actually to be excessive.

COMPARISON OF TWO LOW DOSE ONE-WEEK TRIPLE THERAPY REGIMENS WITH AND WITHOUT METRONIDAZOLE FOR CURE OF H. PYLORI INFECTION. B.H. Jaus and A. Norby. Dept of Medicine, GLF Lundby Hospital, Göteborg, Sweden.

**Purpose:** We have recently shown that a one-week triple therapy consisting of omeprazole 20 mg bid, Clarythromycin 250 mg bid and tinidazole 500 mg bid is very effective with an eradication rate of 93%. We therefore investigated a similar regimen consisting of lansoprazole 30 mg bid, clarithromycin 250 mg bid and metronidazole 400 mg bid or tetracycline 300 mg bid in a prospective cohort study.

**Methods:** Two cohorts each of 60 patients, suffering from H.pylori infection associated with peptic ulcer disease or ulcer like dyspepsia were treated for one week with either lansoprazole 30 mg bid, clarithromycin 250 mg bid and metronidazole 400 mg bid (Cohort I, n=60) or tetracycline 300 mg bid (Cohort II, n=60). H.pylori infection and under-laying disease was diagnosed by endoscopy using rapid urease test and histology. 4 weeks after treatment withdrawal cure of H.pylori was evaluated by using the same criteria as mentioned above.

**Results:** Patients in the two cohorts had similar clinical and demographic characteristics. In cohort I, 55 patients out of 60 showed cure of H.pylori infection (92%). The treatment was well tolerated. Three patients reported sideeffects, two experienced limited diarrhea and one bad taste. In cohort II, which was free of metronidazole, the eradication of H.pylori was slightly less effective as only 50 out of 60 showed cure of H.pylori infection (83%). Two patients reported limited diarrhea. The difference between the cohorts of H.pylori eradication was statistically not significant.

**Conclusions:** Triple therapy for one week with lansoprazole as the antisecretory part, seems to be as effective as what is reported for omeprazole. Substitution of metronidazole by tetracycline is somewhat less effective but gives still a high eradication rate and could be an alternative to patients with metronidazole resistance.


**Aim:** The present study was conducted to evaluate the efficacy and tolerability of two simple one-week triple therapy schedules for eradication of H.pylon.

**Methods:** 120 consecutive patients suffering from histologically and/or culturally proven H.pylori infection and associated peptic ulcer disease (duodenal ulcer: n=69; gastric ulcer: n=21; duodenal and gastric ulcer: n=3) and functional dyspepsia (n=30) were recruited. Patients 1-60 were treated with omeprazole 20 mg bd, amoxicillin 1 g bd and clarithromycin 250 mg bd over one week (OAC). Patients 61-120 were treated with omeprazole 20 mg bd, amoxicillin 1 g bd and metronidazole 400 mg bd over one week (OAM). Patients were endoscopically re-investigated 4 weeks after cessation of eradication therapy including the assessment of the H.pylori status by means of an urease test, culture and histology.

**Results:** Three patients (OAC: n=1; OAM: n=2) were lost to follow-up. H.pylori infection was eradicated in 53 out of 60 patients of the OAC group (rate (intention-to-treat): 88%; 95%-CI: 77%-95%) and in 47 out of 60 patients of the OAM group (rate: 78%; 95%-CI: 66%-88%) [OAC vs OAM: p=0.022]. Nine patients of either group complained of side effects without necessity of discontinuation of the study medication (rates: 15% vs 15.5%; p>1.00).

**Conclusion:** One-week simple (bd regimen) triple therapies consisting of omeprazole, amoxicillin and either clarithromycin or metronidazole represent a sufficiently effective and well tolerated approach to the cure of H.pylori infection. In view of a 10% higher efficacy and a markedly lower rate of primary resistance of H.pylori to clarithromycin as to metronidazole, the OAC regimen should be preferred.
FACTORs AFFECTING THE ERADICATION SUCCESS IN GASTRic AND DUODEnAL ULCER PATIENTS
Dept. of Gastroenterology, Jichi Medical School, Tochigi, Japan.

Purpose: To investigate the factors affecting Helicobacter pylori (Hp) eradication success in gastric ulcer patients and duodenal ulcer patients.

Methods: 35 Hp positive gastric ulcer (GU: 13) and duodenal ulcer (DU: 22) patients were treated with Lansoprazole (LPZ) 30mg twice daily and Clarithromycin (CAM) 400mg twice daily for two weeks. All patients subsequently received 30mg LPZ for 2 to 6 weeks. At 4 weeks after cessation of the therapy, endoscopy was performed and two pairs of biopsies were taken from the middle antrum and upper body of the greater curvature.

Eradication was assessed by smear, culture and tissue section. Pretreatment histological findings (Hp density, atrophic change, inflammatory cell infiltration) were assessed by using the Sydney system and the data of eradication success and failure patients were compared.

Results: At the end of the therapy all ulcers had healed. The Hp eradication rate was 53.6% (7/13) in GU and 77.3% (17/22) in DU. Minor side effects were observed in only one case in the GU group (2.9%). Between eradication success and failure patients in each disease, there were no significant differences in severity of inflammation and atrophic change. But the bacteria score of upper body was significantly higher in treatment failure group than success group in GU patients (p<0.05).

Conclusion: Eradication success is affected by the bacteria density of upper body in GU patients. Lower eradication of Hp in GU seems to be related to the spreading of Hp infeciton to the upper body.

A 2-HOUR TOPICAL THERAPY FOR THE TREATMENT OF HELICOBACTER PYLORI INFECTION
Dept. of Gastroenterology, Jichi Medical School, Tochigi, Japan.

Objective: A novel topical therapeutic methodology for the treatment of Helicobacter pylori infection was developed and studied in 18 patients with Hp pylori to evaluate safety and efficacy.

Methods: The patients had been given lansoprazole (30mg) orally and promazin(18,000 tyrosine units b.i.d) for 2 days before topical therapy. One hundred milliliters of solution with 7% sodium bicarbonate containing bismuth subnitrate (4g), amoxicillin (4g), metronidazole (1g), and promazin (36,000 tyrosine units) were instilled into the stomach undergoing endoscopy. A double lumen tube with a balloon at the tip was inserted into the duodenum along with the endoscope. The balloon was inflated with 25ml of air and lodged postbulbarly. The solution was kept in the stomach for 2h and patient's position was changed every 30min from the sitting to the prone and right lateral position to expose the entire gastric mucosa. The solution was suctioned at the end of the procedure.

Results: Hp pylori infection was successfully cured in 15 (83.3%) patients, confirmed 4wk after the therapeutic procedure by negative smear, culture, and histology of the antral and corpus biopsy specimens. Side effect was observed only in one case (loose stool).

Conclusion: The endoscopic topical therapy is safe, effective and well tolerated procedure for the treatment of Hp pylori infection. With further modification of the drug regimens as well as the method itself, this method may become the optimum anti-H. pylori therapy.
HAEMOPHILIC PATIENTS

While H. pylori eradication therapy for asymptomatic patients or those with non-ulcer dyspepsia remains controversial, such a measure may be more justified for haemophilic patients for whom an upper gastrointestinal bleeding can be fatal. Methods: Phase one: stored plasma samples from 219 haemophilic patients were tested for H. pylori antibodies with a quantitative ELISA assay (HELICO-G kit; Porton, Cambridge, UK). A plasma antibody level above 7.3 u/ml was considered positive. Phase two: All patients older than age 10 years with an antibody level above 6 u/ml were invited to the hospital for a 13C urea breath test. Patients with a positive urea breath test were treated with amoxicillin (750mg tds), metronidazole (400mg tds) and ranitidine (300mg nocte) for twelve days. A second urea breath test was performed four weeks after the eradication therapy.

Results: Phase one: 78 haemophilic patients (36%) were found to have a positive ELISA test. Phase two: 36 ELISA test-positive patients and 4 test-negative patients (Ab titre 6 - 7.3 unit/ml) returned for the urea breath test. Only 15 patients were confirmed to have active H. pylori infection (one was ELISA test negative). 12 patients (80%) became breath test negative after the eradication therapy. Five patients reported nausea, two patients noticed a bitter taste and one patient had transient vomiting during the treatment period.

The ELISA test on stored plasma samples can be used as a screening test, but it over-diagnosed active H. pylori infection. In these patients, eradication of H. pylori infection was 80% successful in the well-motivated haemophilic patients.

THE CLINICAL CONSEQUENCES OF HELICOBACTER PYLORI ERADICATION IN PATIENTS PREVIOUSLY TAKING LONG-TERM HISTAMINE ANTAGONISTS: A GENERAL PRACTICE STUDY.

In a group general practice, patients were computer identified as having taken HP-antagonist treatment for more than 1 year. H. pylori infection was confirmed by 13C-Urea Breath Test (European Standard) in 55 patients having radiologically proven peptic ulcer disease, gastritis or duodenitis. Cure of H. pylori infection was successful (13C-UBT confirmed) in 45/55 (81%) patients using either Omeprazole / Amoxicillin / Ranitidine. Dual therapy or Standard Bismuth Triple Therapy (8 patients having two treatment courses).

Two years following therapy, 31 patients were retested using the 13C-UBT and questioned about the use of acid lowering therapy and their general well-being. 29/31 (94%) were H. pylori negative. 16/31 (52%) of patients had not taken any acid lowering therapy in the intervening period and an additional 10/31 (32%) of patients had taken antacid only. Of the 29/31 (94%) of patients reverting to HP-antagonist therapy, two had endoscopically proven reflux (both were HP-ve) and 21 patients (71%) had patient breath tested positive. More than 90% of patients had felt well since treatment and over 50% noticed they were able to eat more than usual. The study demonstrated that in General Practice, H. pylori eradication treatment in ulcer patients is an effective management strategy.

IMPACT OF H. PYLORI INFECTION ON SYMPTOMS AND EFFECT OF RANITIDINE IN PATIENTS WITH FUNCTIONAL DYSPEPSIA (FD).

The impact of HP in patients with FD is controversial. This double-blind, placebo (Pla) controlled, multicentre trial compares symptoms and effect of ranitidine (Ran) in HP +ve patients with those in HP -ve Patients and methods: 226 patients with FD were included. At inclusion, the patients’ dyspeptic symptoms were recorded in detail, their dyspepsia was classified as reflux-like, ulcer-like, dysmotility-like or idiopathic, and two biopsies were taken from the antrum for HP assessment (rapid urease test). Overall symptoms were evaluated on a 100 mm VAS. The patients were randomised to 6 weeks’ alternating treatment with Ran 150 mg b.i.d. and Pla, 1 week of each alternative, and at the end classified as “Responders” or “Non-Responders”. They were then re-randomised to 4 weeks’ continuous treatment with Ran 150 mg b.i.d. or Pla. 212 and 206 patients were available for analysis after 6 and 10 weeks respectively. Treatment effect was change in VAS score (in mm). The results are given as median values. Results: The number of HP +ve and -ve patients were 58 and 154 respectively. Median age of the HP +ve and HP -ve were 49 and 41 years respectively (p=0.001) and median duration of symptoms were 120 and 72 months respectively (p=0.05). 18 (31%) of HP +ve and 62 (40%) of HP -ve patients, were responders (ns). The numbers of patients with reflux-like, ulcer-like, dysmotility-like and idiopathic dyspepsia were 34 (16%), 82 (39%), 49 (23%) and 47 (22%) respectively, without any statistically significant differences between HP +ve and HP -ve patients. The tolerability in overall effect between Ran and Pla in HP +ve and HP -ve were 5.5 (ns) and 7 (p=0.017). In HP +ve and HP -ve patients with reflux symptoms the differences between Ran and Pla were 5.5 (ns) and 15.5 (p=0.009) respectively.

Discussion and conclusion: HP +ve patients with FD were older and had a longer duration of symptoms than HP -ve, but no other differences in demographics or symptoms were seen between the two groups. Ran was highly superior to Pla in HP +ve patients with reflux symptoms, but not in HP -ve patients with the same symptoms. Thus, it looks as if HP infection and symptoms might affect the outcome of treatment in patients with FD.
Helicobacter pylori Eradication as a Surrogate for Reduced Peptic Ulcer Recurrence: A Literature-Based Meta-analysis
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Purpose: A literature-based meta-analysis was performed to determine whether Helicobacter pylori (HP) eradication should be used as a surrogate for reduced peptic ulcer recurrence for clinical trial purposes.

Methods: A MEDLINE search strategy, years 1982-1994, identified 62 manuscripts (36 original articles and 26 review articles) which evaluated both HP eradication and duodenal ulcer (DU) and gastric ulcer (GU) recurrence. An additional 12 abstracts were found using different search terms. The studies were considered evaluable for meta-analysis, if they satisfied the following criteria: (1) HP eradication assessment must have been done at two or more different times; (2) at least two of three endoscopic tests (histology, culture, and a urease test) must have been used; (3) only active ulcer patients must have been included; (4) long term ulcer recurrence (≥6 months after completion of therapy) must have been assessed, and (5) ulcer recurrence data must have been available for all healed patients regardless of their HP status after treatment. All manuscripts and abstracts were reviewed independently by each of the three authors.

Results: 19 studies (DU=16, GU=5) with a total of 888 patients (DU=684, GU=204) met the above criteria. Only one study stated that some patients were taking nonsteroidal anti-inflammatory drugs (NSAIDs). HP eradication was associated with a 6% (DU) and 4% (GU) recurrence rate whereas persistent HP infection was associated with a 67% (DU) and 59% (GU) recurrence rate. No significant difference in DU recurrence was found among eradicated patients when HP eradication was defined at four weeks after the completion of therapy versus ≥12 weeks. Conclusion: HP eradication (4 weeks after the completion of therapy) should be considered a surrogate for reduced DU and GU recurrence for the purpose of clinical trial design and patients not taking chronic NSAIDs.

Patient Factors that Predict Failure of Omeprazole, Clarithromycin and Tindazole (OCT) to Eradicate Helicobacter pylori (H pylori)

Purpose: Omeprazole 20mg bd, clarithromycin 250mg bd and tindazole 500mg bd for one week has proved to be the most effective H pylori eradication regimen used in our centre. A number of patients still fail to eradicate the infection with this treatment. Some treatment failures may occur because of differences in patient characteristics and we have investigated this further.

Methods: Patients infected with H. pylori who received OCT were retrospectively evaluated for characteristics which might predict treatment failure.

Results: Successful eradication (SE) of H. pylori was achieved in 238/273 patients (eradication rate=87%) with 35 treatment failures (FE). Factors that were not associated with treatment failure were patient’s age (SE 50.0 ± 13.5 years vs FE 48.4 ± 13.1 years; p=0.51), sex (SE 114 males vs FE 14 males; p=0.31), endoscopic diagnosis (e.g. SE 20 duodenal ulcers vs FE 1 duodenal ulcer; p=0.32) or alcohol history (SE 9.8 ± 13.0 units vs FE 8.8 ± 19.0 units; p=0.70). Peptic symptoms strongly associated with treatment failure were smoking history (SE 7.2 ± 10.0 cigs/week vs FE 12.1 ± 13.5 cigs/week; p=0.008) and H. pylori pre-treatment (SE 50 patients (21%) vs FE 18 patients (51%); p=0.001). These factors remained significant when stratified for other variables (HRA pre-treatment p=0.002 smoking history p=0.05, Mantel-Haenszel summary Chi squared).

Conclusion: Smoking and HRA pre-treatment are significantly associated with failure of OCT to eradicate H. pylori suggesting these agents should be discontinued before commencing therapy.

Antimicrobial Activity of Lansoprazole Against Helicobacter pylori in Vitro and Relation with Cytotoxic Production of Strains
N. Figura, *J.E. Crabtree, †**M. Dattilo. School of Gastroenterology, University of Siena, Italy; †Dept. Clinical Medicine, St. James’s University Hospital, Leeds, U.K.; †Cyarnndi Italia. S.p.A., Medical Research Division, Pomezia, Italy.

Purpose: Lansoprazole is an inhibitor of the gastric parietal cell proton pump which also exerts an antimicrobial activity against Helicobacter pylori. The aims of this study were to investigate: a) whether lansoprazole had a bacteriostatic or bactericidal activity by determining its minimal inhibitory and minimal bactericidal concentrations to clinical isolates and standard strains; b) whether susceptibility of cytotoxic strains to the drug was different from that of non-cytotoxic organisms; c) whether the activity of lansoprazole was pH dependent; and d) whether the drug inhibited the vacuolating activity on cells in vitro of a cytotoxic H. pylori broth culture filtrate.

Results: MICs of lansoprazole activated at pH values 3, 5, and 7 were 2.5 µg/ml, 5µg/ml and 2.5µg/ml respectively. The susceptibility of cytotoxic strains of H. pylori did not differ from that of non-cytotoxic strains. MICs were two to four times higher than MICs. At pH concentrations (<5µg/ml), lansoprazole did not inhibit toxin induced vacuolization of epithelial cells.

Conclusions: Lansoprazole has a bacteriostatic activity against H. pylori and there is no difference in susceptibility between cytotoxic positive and negative strains. The drug does not influence the vacuolating induction by H. pylori toxin. Lansoprazole is active in acidic as well as in neutral environments and therefore its antimicrobial activity does not depend on the acidic conversion.

Helicobacter pylori Infection and Metronidazole Resistance in Gloucester
P. Nair, CAM McNulty, J Dent, Frenchay Hospital and Gloucester Public Health Laboratory Services.

Introduction: Successful eradication of H. pylori with a combination of antimicrobials including metronidazole is widely used in eradication regimens. The problem of primary resistance has been associated with treatment failure with levels of metronidazole resistance in the UK varying from 20-37%. The aim of this study was to find the prevalence of H. pylori infection and metronidazole susceptibility in the Gloucester population.

Methods: We studied 2232 patients attending with dyspepsia for endoscopy at Gloucester Royal Hospital between July 1992 and June 1994. At endoscopy both antral and body biopsies were obtained for urease testing, histology and culture. Details of ethnic background, previous exposure to metronidazole and abdominal surgery were obtained. Isolates found to be resistant to metronidazole were defined as those having MICs > 8µg/ml, corresponding to a zone < 6mm in diffusion tests using 5ug metronidazole disc.

Results: 682 H. pylori isolates were identified. 390 (57%) were males (mean age 51yr) compared to 292 (43%) females (mean age 55yr). Metronidazole resistance was found in 243 (36%) patients. A significantly higher prevalence of metronidazole resistance was found in females (41%) compared to males (32%); p< 0.02. 659(97%) were Caucasians compared to 23(3%) Non-caucasians. Non-caucasians were found to have a higher prevalence of metronidazole resistance (48%), compared to Caucasians (36%).

Conclusions: A higher prevalence of metronidazole resistance was found in females, especially in the 31-40yr group and in Non-caucasians. It is therefore advisable that higher risk groups be identified and antimicrobial sensitivity obtained prior to...
European H pylori Study Group

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IMPORTANCE OF OBTAINING BIOPSIES FROM GaSTRIC BODY IN THE FOLLOW-UP AFTER H. PYLORI ERADICATION THERAPY.


PURPOSE: To study the utility of obtaining biopsies from gastric body in addition to samples usually taken from the gastric antrum, to check H.pylori eradication after therapy.

METHODS: Sixty four H.pylori duodenal ulcer patients were prospectively studied. Two therapy regimens were used: Amoxycillin/clavulanate plus Omeprazole (n=32) and standard triple therapy with bismuth, tetracyclin and metronidazole (n=32). At initial endoscopy and one month after completing therapy biopsies were taken from gastric antrum and body for microbiology (Gram stain and culture); and histology (H&E stain). A patient was considered to be H.pylori-positive when microbiology or/and histology demonstrated colonization in any location.

RESULTS: Overall H.pylori eradication was achieved in 64% (n=41) of patients. A non-eradicated patients (n=23). H.pylori was detected in the antrum in 70% of cases (30% false negative diagnoses), while it was observed in the body in 96% of such patients (P=0.05).

CONCLUSION: Only sampling the gastric antrum after H.pylori eradication therapy is associated with a high percentage of false negative results. Therefore additional biopsy samples should be obtained from gastric body.

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A DECISION ANALYSIS OF HEALTHCARE COSTS FOLLOWING ERADICATION OF H. PYLORI WITH OMEPRAZOLE IN COMBINATION WITH EITHER AMOXICILLIN OR CLARITHROMYCIN.

P G Davey, A M Craig, F Murray, M Malek. PERC, Department of Clinical Pharmacology, University of Dundee and Department of Management, University of St Andrews.

Omeprazole plus clarithromycin (OC) has achieved eradication rates of about 80% versus 50% for omeprazole plus amoxicillin (OA) (sources UK manufacturers’ data sheets). The drug costs for OC are £102.92 compared with £38.96 for OA using generic amoxicillin and £51.63 using branded Amoxil. The aim of this analysis was to estimate the total healthcare costs to the general practitioner of eradication therapy. Data about current practice in the UK were obtained from a survey of 502 hospital specialists and general practitioners. It was assumed that patients would derive no benefit from eradication therapy unless they had a duodenal ulcer and that all OA patients received generic amoxicillin. The survey confirmed that OA was the commonest eradication therapy prescribed by UK general practitioners. Three distinct patient groups were identified: Patient group Expected total cost per patient

Proven DU already on medication

Omepr + Amox £173

New dyspeptic patient £335

New dyspeptic patient £239

<45 years old

≤45 years old

Omepr + Claris £157 £349 £246

The results are sensitive to the costs of hospital referral or endoscopy, the use of branded Amoxil instead of generic amoxicillin and the accuracy of diagnosis of new dyspeptic patients. Nonetheless, the model clearly shows that the higher drug cost of OC is likely to be substantially offset by savings on other healthcare costs.

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EFFICACY OF LOW DOSES OF CLARITHROMYCIN FOR ONE WEEK IN ERADICATING H. PYLORI.


Triplicate therapy schedules for 14 days with Clarithromycin (from 4 to 2 g daily) could eradicate H.pylori infection in up to 90% of cases. Two studies showed that low doses of Clarithromycin can obtain the same results.

AIM: To verify whether such results could be obtained even with a triple therapy 7 day treatment and low dosages of Clarithromycin.

PATIENTS & METHODS: 101 consecutive outpatients (64 males, 37 females, mean age 55.5, range 27-84) entered the study, subdivided as follows: 10 GU, 43 DU, 8 association of GU & DU, 40 gastritis. In all patients a gastroscopy was performed in conjunction with multiple biopsies (at least 6) of gastric mucosa and a blood sample for determination of serum Gastrin, PQA, PGC and anti-Hp antibodies (IgG) at the entry of the study and two months after stopping treatment. Hp infection was confirmed by histology (Giemsa modified stain) and rapid urease test (CLO test). Patients were randomly allocated in two therapeutic schedules: A: Clarithromycin 250mg bid + Omeprazole 20mg bid + Metronidazole 500mg bid x 7 days and B: Clarithromycin 250mg bid + Omeprazole 20mg bid + Metronidazole 250mg bid x 7 days. Statistical analysis was performed by means of Students ‘t’ test for paired data.

RESULTS: The Hp cure rates were 81.5% (44/54) for schedule A and 84.28% (32/38) for schedule B. Eradicated patients showed a statistically significant decrease of PQA (p<0.001) and 1gG anti-Hp (p<0.005) but not of Gastrin.

CONCLUSIONS: Clarithromycin at the dosages of 250mg bid for 7 days, in association with Omeprazole & Tindazole or Metronidazole is a very effective regimen for eradicating Hp infection.

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The eradication of Helicobacter pylori (Hp) infection has been claimed to improve gastritis symptoms and reduce ulcer relapse rates; however the success rate is widely spread in the literature. The aim of this study was to identify different factors that have to be taken into account while suggesting antibiotic therapies for Hp eradication. Methods: 378 consecutive patients underwent different triple therapies for Hp infection eradication. Using a questionnaire we investigated smoking habits (n = 203), alcohol intake (n = 186) and age, while the activity of gastritis was histologically evaluated in the antrum and corpus according to the Sydney system. For each therapeutic schedule no statistically significant difference was found for the investigated parameters. Results: Among 203 patients 88 were smokers (S) and 115 were not smokers (NS). The overall eradication rate in the NS was 69% while in the S was 46% (p<0.005). In the smokers group the nicotine intake was 10.7 in Hp-ve patients and 10.8 in the Hp+ve patients (p=n.s.). Among 186 patients 84 had an alcoholic intake lower than 40 g/day (NA) and 102 greater than 40 g/day (A). There were no differences in the eradication rates between the two groups (NA = 65%, A = 63%). All the 378 patients were divided according to the age limit (296 pts. <65 yr: 82 pts. ≥65 yr). No differences were found in the overall eradication rates between the two groups (87.9% vs. 70.2%). In the antrum, before treatment, moderate-severe gastritis activity was found in 24% of cured patients and in 6% when therapy was not successful (p<0.05). Conclusions: 1) Cigarette smoking, but not nicotine intake, is related with a significant reduction in Hp eradication rate. 2) High grade of gastritis activity, before the treatment, is a predictive factor of successful eradication therapy.

3) No influence on the success of therapy has been found as regards alcohol intake and age.