OP069

EMPIRICAL SECOND-LINE TREATMENTS IN EUROPE: RESULTS FROM THE EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG)

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Introduction: Even with the currently most effective treatment regimens, approximately 10–20% of patients will fail to achieve *H. pylori* eradication.

Aims & Methods: To evaluate the effectiveness and safety of second-line empirical treatments in Europe. A systematic prospective registry of the clinical practice of European gastroenterologists regarding *H. pylori* infection and treatment was established. All infected adult patients were systematically registered at AEG-REDCap e-CRF from 2013 to February 2021. *Variables included*: Patient's demographics, previous eradication attempts, prescribed treatment, adverse events, and outcomes. Modified intention-to-treat (mITT) and per-protocol (PP) analyses were performed and data were subject to quality review.

Results: Overall, 5,932 patients from 31 countries received a second-line therapy; from those, 5,228 (88%) were treated empirically and were therefore included for analysis. Mean age was of 51 (±15) years, 64% were women and 6% had penicillin allergy. Most frequent treatment indications were dyspepsia (55%) and gastroduodenal ulcer (17%). Endoscopy was performed in 47% of the cases and ^{13}C-urea breath test was used in 45% to diagnose the infection.

Overall effectiveness was 84% (both by mITT and PP). Over 97% of patients were compliant. Adverse events were reported in 28% of the cases and tolerance was quite similar among therapies. Most frequent second-line prescriptions and effectiveness per antibiotic combination is shown in table 1.

After failure of first-line clarithromycin-containing treatment, optimal eradication (>90%) was obtained with moxifloxacin-containing triple therapy, or quadruple therapy with levofloxacin and bismuth. In patients receiving triple regimens containing levofloxacin or moxifloxacin and levofloxacin-bismuth quadruple regimens, cure rates were optimized with 14-day regimens using high doses of proton pump inhibitors (PPIs). However, single capsule or quadruple therapy with levofloxacin and bismuth achieved consistent eradication rates regardless of the PPI dose, duration of therapy, or previous first-line treatment regimen.

Treatment	N	% Use	mITT, N (%)	(95% CI)	PP, N (%)	(95% CI)
Triple-A+L	1,624	32.1	1,434 (81)	(79-83)	1,413 (81)	(79-83)
Single capsule*	889	17.6	810 (89)	(87-92)	794 (90)	(88-92)
Quadruple-A+L+B	647	12.8	559 (88)	(86-91)	542 (89)	(86-91)
Triple-C+A	346	6.8	246 (78)	(73-84)	241 (78)	(73-84)
Quadruple-M+Tc+B	264	5.2	232 (84)	(79-89)	223 (85)	(80-90)
Quadruple C+A+B	257	5.1	154 (87)	(81-93)	148 (87)	(81-93)
Quadruple-C+A+M	221	4.4	207 (82)	(76-87)	202 (82)	(77-88)
Triple-A+Mx	143	2.8	135 (91)	(86-96)	135 (91)	(86-96)
Triple-A+M	103	2.0	48 (58)	(47-69)	86 (58)	(47-79)
Other	562	11.1	NA	NA	NA	NA
Total	5,056	100%	4,326 (84)	(82-85)	4,236 (84)	(80-83)

95%CI – 95% confidence interval, C – clarithromycin, M – metronidazole, T – tinidazole, A – amoxicillin, L – levofloxacin, B – bismuth salts, Tc – tetracycline, Mx – moxifloxacin, N – Total number of patients receiving an empirical treatment, Other – Other second-line empirical treatments with less than 100 patients treated in each category;*three-in-one single capsule containing metronidazole tetracycline and bismuth

Table 1. Frequency of second-line empirical treatment prescriptions and effectiveness by modified intention-to-treat (mITT) and per-protocol (PP) analyses

Conclusion: Empirical second-line regimens including either 14-day triple therapies with levofloxacin or moxifloxacin, or 14-day levofloxacin-bismuth quadruple or 10-day three-in-one single capsule bismuth quadruple therapies provided optimal effectiveness. However, many other second-line treatments evaluated reported low eradication rates.

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