

Oral Presentations

Sunday, October 11, 2020

H. pylori: What is the best treatment in 2020?

16:30-17:30 / Hall 5

OP046

EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG): EMPIRICAL FIRST-LINE TREATMENT USE AND EFFECTIVENESS TRENDS IN EUROPE IN THE PERIOD 2013-2020

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Introduction: The impact of consensus, prescription choices and efficacy trends on clinical practice over time has not been studied in depth.

Aims & Methods: International multicenter prospective non-interventional registry aimed to evaluate the decisions and outcomes of *H. pylori* management by European gastroenterologists. All infected adult patients were systematically registered at AEG-REDCap e-CRF from June 2013 to April 2020. *Variables included:* Patient's demographics, previous eradication attempts, prescribed treatment, adverse events, and outcomes. Modified intention-to-treat (mITT) and time trend analyses were performed. Data were subject to quality review.

Results: So far 28,194 patients from 29 European countries have been included, and 24,882 (88%) were first-line empirical prescriptions. Although, overall, the most common prescribed treatments in the 2013-20 period were triple therapies; however, a shift in antibiotic regimens was identified. Triple therapies decreased from over 50% of prescription in 2013/15 to less than 20% in 2018/20; concomitant therapy likewise decreased from 21% in 2013/14 to 13% in 2019/20, while Pylera® increased from 0-1% in 2014/2015 to 18% in 2018/20. An increase in the average duration of treatments from 10.9 days in 2013 to 12.0 in 2020, and of the daily dose of PPI was identified (full description of most common treatments is shown in Table 1).

Regarding the effectiveness of each specific treatment, no trend was identified (data now shown); however, there was a 5% overall improvement in first-line mITT overall effectiveness (Table 1).

Conclusion: European gastroenterological practice is constantly adapting to the newest published evidence and recommendations (reducing the use of triple therapies and increasing the duration of treatment and the dose of PPIs), with a subsequent improvement in overall effectiveness.

Year	2013	2014	2015	2016	2017	2018	2019	2020
Quadruple-C+A+B	0.5%	0.9%	5.2%	17.2%	10.2%	15.3%	5.2%	5.7%
Pylera®	0.0%	0.0%	0.5%	12%	24.5%	22.3%	17.6%	17.8%
Quadruple-C+A+M/T	20.0%	21.4%	26.9%	22.3%	21.2%	10.6%	11.8%	14.4%
Sequential-C+A+M/T	8.1%	3.4%	1.8%	0.9%	0.3%	0.5%	0.2%	0.3%
Triple-C+M	3.9%	6.4%	9.0%	6.6%	1.4%	1.0%	1.0%	4.0%
Triple-C+A	53.6%	54.3%	42.7%	28.2%	30.5%	34.0%	40.6%	34.3%
7 days /	31.3%	28.1%	24.7%	16.7%	7.8%	1.8%	2.3%	10.1%
10 days /	48.3%	52.7%	55.9%	46.4%	46.9%	43.9%	30.8%	31.7%
14 days length	20.5%	19.2%	19.4%	36.8%	45.3%	54.2%	66.8%	58.3%
low / standard / high dose*	62.0% / 18.7%	56.7% / 25.5%	47.1% / 26.5%	36.2% / 24.5%	39.2% / 23.7%	28.5% / 28.8%	24.0% / 34.6%	33.4% / 24.4%
PPI	19.3%	17.8%	26.4%	39.4%	37.1%	42.8%	41.4%	42.2%
Eradication rate (mITT)	85.3%	85.1%	85.9%	87.4%	88.2%	90.9%	92.2%	91.3%

[Table 1. Prescriptions and effectiveness trends of first-line empirical treatments in Europe in 2013-2020]

PPI: proton pump inhibitor; mITT: modified intention-to-treat ; A - amoxicillin, C - clarithromycin; M - metronidazole; T - tinidazole; L - levofloxacin B; - bismuth salts; Tc - tetracycline. *Low PPI dose - 4.5 to 27 mg omeprazole equivalents, b.i.d., Standard dose PPI - 32 to 40 mg omeprazole equivalents, b.i.d., High dose PPI - 54 to 128 mg omeprazole equivalents, b.i.d.

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OP047

EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG): ANALYSIS OF 1,782 EMPIRICAL RESCUE THERAPIES ON THIRD AND SUBSEQUENT LINES

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Introduction: *H. pylori* treatment's effectiveness decreases as treatment eradication attempts fail.

Aims & Methods: The aim was to evaluate the use and effectiveness of empirical rescue therapies on third and subsequent lines in Europe. This was a sub-study of the the European Registry on *H. pylori* Management (Hp-EuReg), an international multicenter prospective non-interventional registry starting in 2013 aimed to evaluate the decisions and outcomes of *H. pylori* management by European gastroenterologists (27 countries, 300 researchers). All infected adult patients were systematically registered at AEG-REDCap e-CRF. All cases with three or more eradication attempts were extracted until June 2019. Only the empirically prescribed therapies (without a result of antibiotic resistance testing) were analyzed. Data were subject to quality review.

Results: In total, 1,782 rescue treatments were included: 1,264, 359, 125 and 34 third-, fourth-, fifth- and sixth-line treatments, respectively. Mean age was 51 years, 69% of patients were women and 5% were allergic to penicillin. Sixty-three different therapy regimens were used, being Pylera® the most commonly prescribed. The most frequent regimens are shown in the table. Overall effectiveness was 73% by modified intention-to-treat (mITT) and 74% by per-protocol (PP) analyses. Three regimens approached an optimal eradication rate ($\geq 90\%$, by mITT): Pylera® prescribed in third line (86%), quadruple PPI-bismuth-tetracycline-metronidazole (95%) and triple PPI-amoxicillin-levofloxacin (90%), these two latter irrespective of line, but only when high PPI doses and 14 days' treatment duration were used. The use of doxycycline instead of tetracycline was associated with lower eradication rates in classical bismuth quadruple therapies ($p < 0.05$). Quadruple PPI-amoxicillin-levofloxacin-bismuth therapy was not superior to triple PPI-amoxicillin-levofloxacin as third or subsequent rescue therapy.

Conclusion: Empirical rescue treatments in third and subsequent lines obtain, in general, suboptimal eradication rates in Europe. Only Pylera® and the optimised versions of triple PPI-amoxicillin-levofloxacin and quadruple PPI-bismuth-tetracycline-metronidazole achieve acceptable outcomes.

Rescue therapy	Use, N (%)	mITT n	mITT effectiveness (95% CI)	PP n	PP effectiveness (95% CI)
Pylera®	416 (23%)	363	84 (80-87)	350	85 (81-88)
Triple PPI-A-L	277 (15%)	213	78 (72-83)	206	78 (72-84)
Triple PPI-A-R	231 (13%)	205	66 (59-72)	198	67 (60-74)
Quadruple PPI-B-Tc-M	171 (9.6%)	162	73 (65-80)	157	73 (66-80)
Quadruple PPI-B-D-M	115 (6.5%)	109	63 (54-72)	105	64 (54-73)
Quadruple PPI-A-L-B	95 (5.3%)	81	78 (67-86)	79	80 (69-88)
Quadruple PPI-C-A-M	62 (3.5%)	57	58 (44-71)	54	59 (45-72)
Triple PPI-A-M	54 (3.0%)	47	68 (53-81)	45	69 (53-82)
Triple PPI-C-A	43 (2.4%)	33	67 (48-82)	30	67 (47-83)

[Overall eradication rates of the most prescribed empirical therapies on third and subsequent lines]

A, amoxicillin; B, bismuth; C, clarithromycin; D, doxycyclin; L, levofloxacin; M, metronidazole; Mx, moxifloxacin; Tc, tetracycline; R, rifabutin; 95% CI, 95% confidence interval.

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