

Poster presentations

Monday, October 21, 2019

Tuesday, October 22, 2019

Wednesday, October 23, 2019

H. Pylori II

09:00-17:00 / Poster Exhibition - Hall 7

P1340 Pan-European Registry on *H. pylori* management (Hp-EuReg): Analysis of 4,388 second-line treatments

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Introduction: After a failed eradication attempt, *H. pylori* treatment's efficacy is compromised due to the selection of resistant strains.

Aims & Methods: To evaluate the efficacy by intention-to-treat (ITT) and per-protocol (PP) of second-line treatments in Europe. A systematic prospective registry of the clinical practice of European gastroenterologists regarding *H. pylori* infection and treatment (27 countries

and 300 recruiting investigators). An e-CRF was created on AEG-REDCap to systematically register all adult patients infected with *H. pylori*. *Variables included:* Patient's demographics, previous eradication attempts, pre-scribed eradication treatment, adverse events (AEs), and outcomes (cure rates, compliance, follow up, etc.). *Data extraction:* All cases with treatment failure after just one eradication attempt. *Analysis:* Cases with an empiric treatment were evaluated separately from those with a tailored therapy.

Results: Overall, 4,388 second-line patients were included. Culture was performed in 9% of the total of cases. Resistance rates (when available) were: 63% to clarithromycin, 52% to metronidazole, and 40% to both. In total 4,019 were treated empirically: mean age was of 50 years, 64% were women and 5% had penicillin allergy. 58% of indications were dyspepsia and 17% gastroduodenal ulcer. ¹³C-UBT was used in 49% of the cases to diagnose the infection. Mean efficacy was 77% (by ITT) and 83.5% (by PP). 7 and 10-days regimens did not reach optimal efficacy except for single-capsule bismuth quadruple therapy (>90% PP). 14-days regimens with double doses esomeprazole reported better results (>90% PP) when qui-nolones were used in triple regimens and bismuth quadruple therapies. After non-bismuth quadruple failure, efficacy was reported higher when the triple therapy with moxifloxacin or the bismuth quadruple therapy with levofloxacin were used. Over 97% of patients were compliant. AEs were reported in 29% of the cases and tolerance was similar among therapies. Most frequent second-line use and efficacy per antibiotic combination is shown in the table.

Treatment	N	% Use	N (ITT)	ITT (%)	(95% CI)	N (PP)	PP (%)	(95% CI)
Triple-A+L	1,449	36.1	1,349	77	(75-79)	1,271	81	(79-83)
Pylera	510	12.7	466	87	(84-90)	442	91	(88-94)
Quadruple-A+L+B	459	11.4	446	88	(85-91)	421	90	(87-93)
Triple-C+A	414	10.3	358	51	(46-56)	221	79	(74-84)
Quadruple-M+Tc+B	179	4.5	167	81	(75-87)	158	84	(78-90)
Quadruple-C+A+M	145	3.6	133	83.5	(77-90)	131	84	(78-90)
Triple-A+Mx	140	3.5	138	88	(83-93)	134	91	(86-96)
Triple-A+M	85	2.1	79	56	(45-67)	73	59	(48-70)
Total	3,966	98.7	3,689	77	(76-78)	3,346	83	(82-8)

ITT - intention to treat, PP - per-protocol, 95%CI - 95% confidence interval, PPI - proton pump inhibitor, C - clarithromycin, M - metronidazole, T - tinidazole, A - amoxicillin, L - levofloxacin, B - bismuth salts, Tc - tetracycline, Mx - moxifloxacin, N - Total of patients receiving an empiric treatment

[Most frequent second-line use and efficacy per antibiotic combination]

Conclusion: Second-line triple therapies generally provide low eradication rates except when prescribing moxifloxacin for 14 days. Bismuth-containing quadruple therapies seem to provide higher efficacy, especially the combination of bismuth with a PPI, levofloxacin and amoxicillin or single capsule bismuth quadruple therapy.

Disclosure: Nothing to disclose

P2031 Efficacy in second-line regimens in Spain: results from the European Registry on *H. pylori* management (Hp-EuReg)

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Introduction: The use of an optimal second-line regimen to eradicate *Helicobacter pylori* (*H. pylori*) infection refractory to the previous treatment prescribed is crucial in order to save antibiotics for future infections, specially considering the relevance of antibiotic resistance growth worldwide.

Aims & Methods: The aim was to evaluate the efficacy of the second-line treatments more frequently prescribed in a Spanish cohort arising from routine clinical practice. We conducted an observational, prospective, multicenter study, carried out in 48 Spanish hospitals as part of the 'Pan-European Registry on *H. pylori* management'. The project was provided by AEG-REDCap. Patients were included from February 2013 to January 2018 by Spanish gastroenterologists. A multivariate analysis was performed considering the most efficacious therapies. The sex of the patient, type of PPI (first vs. second-generation), type of PPI dose (simple vs. double), treatment duration (10 vs. 14 days), compliance and penicillin allergy, were considered for evaluation.

Results: 1,868 patients received a second-line eradication therapy in our cohort: 67% of them were women, 6% had penicillin allergy and their median age was 50±14 years. 90% of the patients had previously received a therapy containing clarithromycin. The therapies most frequently pre-scribed were (all of them including a proton pump inhibitor, PPI): triple therapy comprising levofloxacin and amoxicillin (T-LA, 43%), quadruple therapy adding bismuth to the triple therapy mentioned (Q-BLA, 22%), three-in-one single capsule bismuth containing metronidazole, bismuth and tetracycline (Q-SINGLE, 15%), triple therapy combining moxifloxacin and amoxicillin (T-MXA, 5%), and the non-bismuth quadruple concomitant therapy (Q-NBCT, 5%). 10% of the remaining patients received other minority therapies. Efficacy of these therapies was analyzed on a modified ITT (mITT) and PP basis. Results are shown in Table 1, depending on treatment duration. Good compliance was associated with higher efficacy in Q-BLA and T-LA therapies ($p < 0.05$). The longer treatment duration (14 days) was also associated with higher efficacy in T-LA therapy ($p < 0.001$).

	Duration (days)	mITT efficacy		PP efficacy	
		N included	mITT (95% C.I.)	N included	PP (95% C.I.)
T-LA	10	593	70% (66-74%)	564	73% (69-76%)
	14	193	86% (80-90%)	180	92% (87-95%)
Q-BLA	14	408	86% (82-89%)	375	91% (87-93%)
Q-SINGLE	10	263	82% (77-87%)	232	92% (88-95%)
T-MXA	14	69	86% (75-93%)	66	89% (79-96%)
Q-NBCT	10	39	77% (61-89%)	37	78% (62-90%)
	14	46	80% (66-91%)	45	82% (68-92%)

[Table 1: Efficacy obtained in mITT and PP basis with the five more common treatments used as second-line regimens.]

Conclusion: The best efficacy results (closer to 90%) as second-line therapies were obtained using quadruple therapy combining levofloxacin and bismuth, and triple therapies with amoxicillin and a quinolone (levofloxa-cin/moxifloxacin), all of them prescribed for 14 days.

Disclosure: Dr. Gisbert has served as a speaker, a consultant and advisory member for or has received research funding from Casen Recordati, Mayo-ly, Allergan, Advia, Diasorin. Dr McNicholl has received retributions from Allergan and MSD for training activities, and he is an advisor for Mayo-ly. The rest of co-authors have no conflict of interests to declare.

P2032 Pan-European Registry on *H. pylori* Management (Hp-EuReg): first-line treatment use and efficacy trends in 2013-2018

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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 starting in 2013 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. *Variables in-cluded:* Patient's demographics, previous eradication attempts, prescribed treatment, adverse events, and outcomes. Intention-to-treat analyses were performed. Data monitoring was performed to ensure the quality of the data.

Results: So far 25,256 patients from 27 European countries have been in-cluded, 19,754 (77%) were naïve empirical prescriptions. Although, overall, the most common prescribed treatments in the 2013-18 period were triple therapies, a shift in antibiotic regimens was identified. Triple therapies decreased from over 50% of prescription in 2013/14 to less than 25% in 2017/18 while Pylera[®] has increased from 0-1% (2014/2015) to 25% (2018). Full description of most common treatments is shown in Table 1. Regarding the efficacy of each treatment no trend has been identified (data now shown), however there has been a 5% overall improve in first-line efficacy (Table 1).

Conclusion: European gastroenterological practice is constantly adapting to the newest published evidence and recommendations, and although this shift is delayed and slow, it improves clinical practice outcomes.

Treatment	2013	2014	2015	2016	2017	2018
Triple C+M	116	271	317	262	41	8
Triple C+A	1,541	2,192	1,478	1,127	1,002	196
Triple A+M	164	181	75	31	19	1
Triple A+L	76	104	117	75	11	1
Sequential C+A+T	231	263	236	61	302	69
Sequential C+A+M	354	156	54	21	6	1
Quadruple M+Tc+B	70	83	12	2	6	1
Quadruple C+A+T	6	31	91	34	8	7
Quadruple C+A+M	753	910	943	786	663	65
Quadruple C+A+B	42	83	195	766	408	148
Pylera	1	1	21	502	788	183
Other	136	189	239	200	174	47
mITT	85.8%	86.3%	86.2%	88.3%	89.7%	90.4%

[Treatment prescription and overall eradication trends 2013-2018 (Hp-EuReg)]

Disclosure: Dr McNicholl has received retributions from Allergan and MSD for training activities, and he is an advisor for Mayoly. Dr. Gisbert has served as a speaker, a consultant and advisory member for or has received research funding from Casen Recordati, Mayoly, Allergan, Advia, Diasorin.

P2033 First-line *H. pylori* eradication therapy in Europe: Results from 21,487 cases of the European Registry on *H. pylori* Management (Hp-EuReg)

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Introduction: The best approach for *Helicobacter pylori* management re-mains unclear. Audit processes are essential to ensure that clinical practice is aligned with best standards of care.

Aims & Methods: International multicenter prospective non-interventional registry starting in 2013 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. *Variables included:* Patient's demographics, previous eradication attempts, pre-scribed treatment, adverse events, and outcomes. Intention-to-treat and per-protocol analyses were performed. Data monitoring was performed to ensure the quality of the data.

Results: So far, 21,487 first-line prescriptions from 27 European countries have been evaluated. Average age was 49 years, 60% women, and 18% had peptic ulcer. Pre-treatment resistance rates were: 24% to clarithromycin, 34% metronidazole, and 14% both. Drug prescription and efficacy is shown in the table. Triple therapy with amoxicillin and clarithromycin was the most commonly prescribed(45%), achieving, overall, < 80% eradication rate. Over 90% eradication was obtained only with 10-day bismuth quadruple therapies or 14-day concomitant treatment. Longer treatment duration, higher acid inhibition and compliance were associated with higher eradication rates in the multivariate analysis.

Conclusion: Triple therapies account for the majority of prescriptions, how-ever, only quadruple therapies lasting at least ten days are able to achieve over 90% eradication rates.

Treatment	N	% Use	ITT	mITT	PP
PPI + C+A	8,374	39%	68.4%	84.2%	84.7%
PPI + C+A+M	4,156	19%	86.1%	90.0%	90.5%
PPI + C+A+B	1,525	7.1%	78.6%	92.8%	93.1%
PPI + M+Tc+B s.c.	1,520	7.1%	82.9%	94.7%	95.3%
PPI + C+A+T seq	1,166	5.5%	76.9%	91.3%	91.9%
PPI + C+M	1,043	4.9%	70.0%	81.1%	81.5%
PPI + C+A+M seq	608	2.8%	74.8%	81.0%	83.2%
PPI + A+M	560	2.6%	65.8%	85.4%	85.5%
PPI + A+L	404	1.9%	76.6%	81.4%	81.8%
PPI + M+Tc+B	188	1.3%	77.6%	93.1%	93.7%
PPI + C+A+T	172	0.9%	83.6%	94.9%	96.1%

ITT - intention to treat, PP - per-protocol, 95%CI - 95% confidence interval, PPI - proton pump inhibitor, Seq - sequential, C - clarithromycin, M - metronidazole, T - tinidazole, A - amoxicillin, L - levofloxacin, B - bismuth, Tc - tetracycline, s.c. - single capsule

[Overall first-line eradication rate per by treatment]

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