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Accepted Abstracts

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Contributions of up to EUR 10.000.--(or equivalent value in kind) per year per entity are considered “Modest”. Contributions above EUR 10.000.--per year are considered “Significant”.

Missing abstracts within the consecutive presentation numbers represent withdrawn papers.

ELECTRONIC POSTER ROUND 2: TREATMENT OF *H E L I C O B AC T E R* INFECTION

EP2.03 | European registry on *Helicobacter pylori* management (Hp--EuReg): First--line therapy in Israel

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Background: The antibiotic resistance profile of *H. pylori* is constantly changing. Up--to--date and reliable data for the effectiveness of first-line *H. pylori* treatments protocols for are necessary in order to provide evidence--based best--practice guidelines.

Objectives: We aimed to determine the effectiveness, compliance and safety of first--line treatment for *H. pylori* in Israel.

Methods: An observational, prospective, multicenter study was carried out in tertiary referral centers in Israel, as part of the European registry on *H. pylori* management (Hp--EuReg). *H. pylori*-infected patients were included from 2013 to March 2020. Data collected included demographics, clinical data, diagnostic tests, previous erad-ication attempts, current treatment, compliance, adverse events and treatment outcome.

Results: In total, 242 patients were registered including 121 (50%) who received first--line therapy, of whom 41% received clarithromycin based triple therapy and 58.9% received a four--drug regimen. The overall effectiveness of first--line therapy was 85% and 86% by modi-fied intention--to--treat and per protocol analyses, respectively. The effectiveness of both sequential and concomitant therapies were 100% while clarithromycin--based triple therapy achieved an eradica-tion rate of 79%. Treatment eradication was higher among patients who received high dose PPI compared to those treated with low dose PPI (100% vs 81.5% respectively, $P < 0.01$). No difference in treat-ment effectiveness was found between 7, 10 and 14--day treatment. **Conclusion**: The effectiveness of clarithromycin--based triple ther-apy is suboptimal. First--line treatment of *H. pylori* infection should consist of four drugs, including high doses PPI, in accordance with international guidelines.

D. Boltin: None. Z. Beniashvili: None. A. Lahat: None. J. Hirsch: None. O.P. Nyssen: None. F. Mégraud: None. C. O'Morain: None. J.P. Gisbert: None. Y. Niv: None.

EP2.05 | *Helicobacter pylori* eradication first--and second--line regimens prescriptions and effectiveness in Lithuania: Analysis from the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: It is important to administer effective *H. pylori* eradication and perform testing for the eradication success.

Aim: To evaluate the *H. pylori* treatment effectiveness in Lithuania with regards to Maastricht V guidelines.

Methods: The European Registry on H. pylori Management (Hp-EuReg) collecting the data of H. pylori diagnostics, prescribed treatment and outcomes. Data from 2013 to 2019 were analysed. The eradication success was calculated using the modified intention- to-treat (mITT) analysis.

Results: In total 1,408 patients from Lithuania were included in the Hp- EuReg. Overall, triple- therapy (proton pump inhibitor (PPI) + 2 antibiotics) was administered in 93.5% of the cases. For the first-line treatment, triple therapy with PPI, clarithromycin and amoxicillin (PPI+C+A) was prescribed in 93.6% of the cases. The most frequent second- line treatment was combination of PPI, amoxicillin and levofloxacin (PPI+A+L) – in 57.1% of the cases. The frequencies of other combinations is presented in Table 1. The confirmation of H. pylori eradication was assessed only in 298 (21.2%) cases. The effectiveness of first- line PPI+C+A regimen was 86.3% and of second- line PPI+A+L regimen was 86.2%. The overall effectiveness of H. pylori treatments was 86.9%.

Conclusions: The number of cases with confirmatory tests post treatment is extremely low. The effectiveness of most common eradication regimens remains suboptimal.

TABLE 1

	No. of patients	% of all cases	No. of patients tested post--treatment	mITT
H. pylori eradication regimen (first--line treatment)				
PPI+C+A	1,137	93.6%	234	86.3%
PPI+C+A+B	27	2.2%	2	100%
PPI+C+M	23	1.9%	7	100%
PPI+A+M+B	7	0.6%	1	100%
PPI+A+L+B	7	0.6%	–	–
PPI+A+L	6	0.5%	–	–
PPI+A+M	4	0.28%	2	100%
PPI+A+C+T Sequential	1	0.08%	1	100%
PPI+C+M+B	1	0.08%	–	–
PPI+C+L	1	0.08%	–	–
PPI+C+A+M	1	0.08%	1	100%
H. pylori eradication regimen (second--line treatment)				
PPI+A+L	84	57.1%	29	86.2%
PPI+C+A	18	12.2%	8	62.5%
PPI+A+L+B	16	10.9%	–	–
PPI+A+M	9	6.1%	3	100%
PPI+A+M+B	7	4.8%	–	–
PPI+C+M	4	2.7%	2	100%
PPI+C+A+B	4	2.7%	1	100%
PPI+A+C+T sequential	3	2%	–	–
PPI+C+M+B	1	0.7%	–	–
PPI+C+L+B	1	0.7%	–	–

PPI, proton pump inhibitor; C, clarithromycin; A, amoxicillin; L, levofloxacin; M, metronidazole; T, tinidazole; B, bismuth; mITT, modified Intention-To-Treat.

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P2.06 | ***Helicobacter pylori*** **eradication treatment in Lithuania during 2013--2019: Trend analysis of the European Registry on** ***H. pylori*** **management (Hp--EuReg)**

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Background: In recent years eradication of Helicobacter pylor is shifting from triple to quadruple therapy and a treatment duration from 7 to 10-14 days.

Aim: To evaluate the trends of H. pylori eradication regimens and duration in Lithuania. Methods: We analysed the data from the European Registry on H. pylori Management (Hp-EuReg) collected from 2013 to 2019. H. pylori eradication regimens were defined as triple or quadruple regimens and by length (7, 10 or 14 days). Results: 1.408 patients were included. Between 2013 and 2019, triple therapies were mostly prescribed. Most of the quadruple therapies were introduced from 2018. (The bismuth introduced in the Lithuanian market only in 2018). The most common duration of treatment between the years 2013-2017 was 7 days however, since 2018 the most common duration was 10-14 days. This could be influenced by the Maastricht V guidelines in 2016 (7 days therapies not recommended). The most commonly prescribed eradication regimen in Lithuania (PPI, clarithromycin and amoxicillin) for 7 days was the preferred choice between 2013 and 2017; however, since 2015 the number of 10-14 days duration treatments increased and was most frequent in 2018. The detailed data are in Table 1. Conclusions: Although triple therapy remains the most common treatment regimen in Lithuania, quadruple therapies have increased since 2018. During the 2013-2019, a clear shift from 7 to 10 or 14 days duration was observed.

TA B L E 1

	Year of visit and treatment duration by days																				
	2013			**2014**			**2015**			**2016**			**2017**			**2018**			**2019**		
Treatment regimen	**7**	**10**	**14**	**7**	**10**	**14**	**7**	**10**	**14**	**7**	**10**	**14**	**7**	**10**	**14**	**7**	**10**	**14**	**7**	**10**	**14**
Triple C+M	1	1	–	2	1	–	4	–	–	3	3	–	2	1	–	1	2	2	3	–	–
Triple C+A	63	5	–	136	2	–	136	2	–	74	25	–	123	84	15	14	159	137	27	105	26
Triple A+L	–	7	–	1	12	–	3	8	–	2	14	–	1	23	1	–	5	6	–	19	2
Triple A+M				2	–	–	1	–	–				1	–	–	1	2	3	1	2	–
Triple C+L													1	–	–						
Seq A+C+T	–	4	–				–	1	–												
Quadruple C+A+M										1	–	–									
Quadruple C+M+B																–	1	–	–	1	–
Quadruple C+A+B																–	2	18	–	7	6
Quadruple A+M+B																–	4	2	–	7	3
Quadruple A+L+B																–	1	12	–	4	18
Quadruple C+L+B																			–	1	–
Triple Total	64	13	–	141	15	–	144	10	–	79	42	–	128	108	16	16	168	148	31	126	28
Quadruple Total										1	–	–				–	8	32	–	20	27

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EP2.10 | First--line *H. pylori* eradication therapy in Europe: Results from 24,882 cases of the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: The best approach for *Helicobacter pylori* management remains unclear. An audit process is essential to ensure clinical prac-tice is aligned with best standards of care.

Design: International multicentre prospective non--interventional registry starting in 2013 aimed to evaluate the decisions and outcomes in *H. pylori* management by European gastroenterologists. Patients were registered in an e--CRF by AEG--REDCap up to April 2020. *Variables included*: 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 to ensure information reliability.

Results: In total 36,319 patients from 29 European countries were evaluated and 24,882 (70%) first--line empirical *H. pylori* treatments were included for analysis. Triple therapy with amoxicillin and clarithromycin was most commonly prescribed (40%), followed by concomitant treatment (19%) and bismuth quadruple (Pylera®) (10%) achieving 83%, 91% and 95% mITT eradication rate, respectively. Over 90% effectiveness was obtained only with 10 and 14--day bis-muth quadruple or 14--day concomitant treatment (Table). Longer treatment duration, higher acid inhibition and compliance were as-sociated with higher eradication rates.

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Conclusions: Management of *H. pylori* infection by European gastroenterologists is heterogeneous. Only quadruple therapies lasting at least 10 days are able to achieve over 90% eradication rates.

TABLE 1. Effectiveness (by modified intention--to--treat and per--protocol analyses) of first--line empirical treatments in Europe

First--line treatment	Length (days)	mITT, N (%)	95% CI	PP, N (%)	95% CI
Triple-C+A	7	1,903 (83)	81-84	1,886 (83)	81-85
	10	3,057 (83)	82-85	3,015 (84)	82-85
	14	2,264 (89)	88-90	2,238 (89)	88-91
Triple-A+M	7	118 (81)	74-89	117 (81)	74-89
	10	163 (85)	79-90	161 (85)	79-91
Triple-C+M	7	724 (84)	82-87	721 (85)	82-87
	10	114 (65)	56-74	112 (66)	57-75
	14	80 (70)	59-81	80 (70)	59-81
Triple-A+L	7	178 (79)	72-85	176 (78)	72-85
	10	142 (85)	79-91	136 (86)	80-92
Sequential-C+A+M/T	10	596 (83)	80-86	556 (85)	82-88
Quadruple-C+A+M/T	10	2,378 (88)	87-90	2,316 (89)	88-90
	14	2,228 (93)	92-94	2,180 (93)	92-94
Quadruple-C+A+B	10	394 (86)	82-89	390 (86)	83-90
	14	1,194 (91)	89-93	1,178 (91)	90-93
Quadruple-M+Tc+B	10	130 (94)	89-98	130 (94)	89-98
Pylera® (M+Tc+B)	10	2,267 (95)	94-96	2,223 (95.5)	95-96

A, amoxicillin; B, bismuth salts; C, clarithromycin; L, levofloxacin; M, metronidazole; mITT, modified intention--to--treat; PP, per--protocol; T, tinidazole; Tc, tetracycline.

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EP2.11 | Room for improvement in the treatment of *Helicobacter pylori* infection: Lessons from the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: Managing *Helicobacter pylori* infection requires constant decision--making, and each decision is open to possible errors.

Aim: To evaluate common mistakes in the eradication of *H. pylori*, based on the European Registry on *Helicobacter pylori* management (Hp-EuReg).

Methods: International multicentre prospective non--interventional registry evaluating the decisions and outcomes of *H. pylori* management by European gastroenterologists in routine clinical practice.

Results: Countries recruiting over 1,000 patients were included (26,340 patients). The most common mistakes (percentages) were: 1) To use the standard triple therapy where it is ineffective (46%). 2) To prescribe eradication therapy for only 7--10 days (69%) (Table 1). 3) To use a low dose of proton pump inhibitors (48%) (Table 2). 4) In patients allergic to penicillin, to prescribe always a triple therapy with clarithromycin and metronidazole (38%). 5) To repeat certain antibiotics after eradication failure (>15%). 6) To ignore the importance of compliance with treatment (2%). 7) Not to check the eradication success (6%). Time--trend analyses showed progressive greater compliance with current clinical guidelines.

Conclusion: The management of *H. pylori* infection by European gastroenterologists is heterogeneous, frequently suboptimal and discrepant with current recommendations. Clinical practice is constantly adapting to updated recommendations, although this shift is delayed and slow.

TABLE 1. Use and effectiveness of 7, 10 and 14--day triple regimens in Europe

	7 or 10 days		14 days		
	Mistake (%)[1]	mITT (%)	14--days use, N (%)	mITT, N (%)	95% CI
Spain	71	71	1,429 (29)	1,297 (86)	83-87
Russia	63	77	984 (37)	790 (90)	88-92
Slovenia	62	85	1,070 (38)	722 (91)	89-93
Italy	93	84	28 (7)	21 (67)	43-85
Lithuania	84	75	182 (16)	1 (100)	1.3-99
Total	69	81	3,693 (31)	2,831 (88)	87-89

CI, confidence interval; mITT, modified intention--to--treat; N, total number of patients; PP, per--protocol. [1]% of mistake accounted for 7 or 10 day--treatment durations.

TABLE 2. Acid inhibition potency of proton pump inhibitor use in triple regimens in Europe

	Low, N	% mistake[1]	95% CI	Standard, N (%)	95% CI	High, N	95% CI
Spain	1,368	41	39-42	1,223 (36)	35-38	782 (23)	22-25
Russia	1,173	56	54-58	754 (36)	34-38	169 (8)	6.8-9.2
Slovenia	1,385	52	50-54	50 (2)	1.3-2.4	1,241 (46)	44-48
Italy	106	85	78-91	14 (11)	5.3-17	5 (4)	1.3-9.1
Lithuania	480	46	43-49	326 (31)	28-34	234 (23)	20-25
Total	4,512	48	47-49	2,367 (25)	24-26	2,431 (26)	25-27

CI: confidence interval; Low dose: 4.5 to 27 mg omeprazole equivalents; Standard dose: 32 to 40 mg omeprazole equivalents; High dose: 54 to 128 mg omeprazole equivalents. [1]% mistake accounted for all PPIs dose less than 32 mg omeprazole equivalent (as the PPI given twice daily).

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EP2.12 | 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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Background: The impact of consensus, prescription choices and efficacy trends on clinical practice over time has not been studied in depth.

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 registered at AEG--REDCap e--CRF up to April 2020. Modified intention--to--treat (mITT) and time trend analyses were performed.

Results: So far 24,882 first--line empirical prescriptions from 29 European countries have been included. Overall, the most common prescribed treatments in 2013--20 were triple therapies; however, a shift in antibiotic regimens was identified. Triple therapies decreased from >50% of prescription in 2013/15 to less than 20% in 2018/20; concomitant therapy 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. No trend was identified regarding the effectiveness of each specific treatment (data now shown); however, an overall 5% improvement in first--line mITT effectiveness was observed (Table 1). **Conclusions**: 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.

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

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%	12.0%	24.5%	22.3%	17.6%	17.8%
Quadruple-M+Tc+B	2.3%	1.9%	0.4%	0.2%	0.3%	0.4%	1.6%	0.0%
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-A+L	2.1%	2.2%	3.2%	1.9%	0.3%	0.3%	0.4%	0.3%
Triple-A+M	4.1%	3.0%	1.7%	0.9%	0.9%	0.6%	2.3%	0.6%
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%
Length								
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	20.5%	19.2%	19.4%	36.8%	45.3%	54.2%	66.8%	58.3%
PPI acid inhibition*								
Low	62.0%	56.7%	47.1%	36.2%	39.2%	28.5%	24.0%	33.4%
Standard	18.7%	25.5%	26.5%	24.5%	23.7%	28.8%	34.6%	24.4%
High	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%

PPI, proton pomp inhibitor; mITT, modified intention--to--treat ; A, amoxicillin; C, clarithromycin; M, metronidazole; T, tinidazole; L, levofloxacin; B, bismuth salts; Tc, tetracycline. *Low dose PPI – 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.

O.P. Nyssen: None. D. Bordin: None. B. Tepes: None. A. Pérez--Aisa: None. D. Vaira: None. M. Caldas: None. L. Bujanda: None. M. Castro--Fernandez: None. F. Lerang: None. M. Leja: None. L. Rodrigo: None. T. Rokkas: None. L. Kupcinskas: None. J. Pérez--Lasala: None. L. Jonaitis: None. O. Shvets: None. A. Gasbarrini: None. H. Simsek: None. A. R. T. Axon: None. G. M. Buzás: None. J. Machado: None. Y. Niv: None. L. Boyanova: None. A. Goldis: None. V. Lamy: None. A. Tonkic: None. K. Przytulski: None. C. Beglinger: None. M. Venerito: None. P. Bytzer: None. L.G. Capelle: None. T. Milosavljevic: None. L. Veijola: None. J. Molina--Infante: None. L. Vologzhanina: None. G. Fadeenko: None. I. Ariño: None. G. Fiorini: None. A. Garre: None. J. Garrido: None. C.F. Pérez: None. F. Heluwaert: None. I. Puig: None. F. Mégraud: None. C. O'Morain: None. J.P. Gisbert: None.

EP2.13 | European Registry on *H. pylori* Management (Hp--EuReg): Analysis of empirical second--line treatments in Europe

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Background: After a failed eradication attempt, approximately 10--20% of patients will fail to obtain *H. pylori* eradication.

Aims: To evaluate the effectiveness of second--line empirical treatments.

Methods: A systematic prospective registry of the clinical practice of European gastroenterologists on *H. pylori* management was established. All infected adult patients were systematically registered at AEG--REDCap e--CRF until April 2020. Modified intention--to--treat (mITT) and per--protocol (PP) analyses were performed.

Results: Overall, 4,862 patients from 29 European countries were given an empirical second--line therapy. Overall effectiveness was 83.7% (by mITT) and 84% (by PP). Over 97% of patients were compli-ant. AEs were reported in 28% of the cases. 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, Pylera® or quadruple therapy with levofloxacin and bismuth. In patients receiving triple regimens containing levofloxacin or the standard bismuth quadruple regimen, cure rates were optimized with 14--day regimens using high doses of proton pump inhibitors (PPIs). However, Pylera® or quadru-ple therapy with levofloxacin and bismuth achieved reliable eradica-tion rates regardless of the PPI dose, duration of therapy, or previous first-line treatment.

Conclusion: Empirical second--line triple therapies generally provided low eradication rates except when prescribing 14 days of levofloxacin or moxifloxacin. However, high effectiveness was obtained with second--line bismuth--containing quadruple therapies.

TABLE 1. Frequency of second--line empirical treatment prescriptions and effectiveness by modified intention--to--treat and per--protocol analyses

Treatment	N	% Use	mITT, N (%)	95% CI	PP, N (%)	95% CI
Triple-A+L	1,522	33.2	1,341 (81)	79-83	1,320 (81)	79-83
Pylera® (single capsule)	692	15.1	622 (90)	87-92	607 (90)	88-93
Quadruple-A+L+B	529	11.5	478 (89)	86-92	462 (89)	86-92
Triple-C+A	477	10.4	231 (81)	76-86	226 (81)	76-86
Quadruple-M+Tc+B	204	4.4	183 (83)	77-89	177 (84)	78-90
Quadruple-C+A+M	179	3.9	169 (85)	79-90	167 (84)	79-90
Triple-A+Mx	143	3.1	135 (91)	86-96	135 (91)	86-96
Triple-A+M	93	2.0	76 (60.5)	49-72	76 (60.5)	49-72
Other	1,023	21.0	NA	NA	NA	NA
Total	4,862	100%	3,966 (84)	82-85	3,966 (84)	81-83

mITT, modified intention--to--treat; PP, per--protocol; 95% CI, 95% confidence interval; C, clarithromycin; M, metronidazole; T, tinidazole; A, amoxicillin; L, levofloxacin; B, bismuth salts; Tc, tetracycline; Mx, moxifloxacin; N, Total of patients receiving an empirical treatment; Other, Other second--line empirical treatments with less than 100 patients treated in each category.

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EP2.15 | Bismuth quadruple three--in--one single capsule: 3 or 4 times daily? Sub--analysis of the Spanish data of the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: Bismuth quadruple with the quadruple single capsule Pylera® (PPI, bismuth, tetracycline and metronidazole) includes the intake of 3 capsules four times a day (3c/6h), according to the technical sheet. This scheme may not be suitable for Spanish eating habits; therefore, some physicians prescribe the treatment in the form of 4 capsules three times a day (4c/8h).

Aim: To assess the effectiveness and safety of Pylera® administered three times a day (4c/8h).

Methods: Systematic prospective registry of the clinical practice of European gastroenterologists on the management of *H. pylori* infection (Hp--EuReg). All infected adult patients treated with Pylera® were sys-tematically collected at AEG--REDCap e--CRF until June 2019. Modified intention--to--treat (mITT) and per--protocol (PP) analyses were performed. **Results**: Of the 2,326 patients, 1,140 (74%) were treated with 3c/6h and 403 (17%) with the 4c/8h. Most of the cases (72%) were naïve to treatment. The PPI dose did not influence the eradication rate. Both treatment schedules showed equivalent compliance, tolerance, and effectiveness (table 1). One patient suffered a serious adverse event (*C. difficile* infection), in the group 3c/6h.

Conclusions: The prescription of quadruple therapy with single cap-sule bismuth (Pylera®) given as four capsules three times a day seems to have the same compliance, tolerance and effectiveness as the scheme included in the data sheet (three capsules four times a day).

TABLE 1. Effectiveness (by modified intention--to--treat and per--protocol analyses), compliance and safety of treatment with Pylera® in first-, second-, and third-line

			Modified intention--to--treat				Per--protocol			
Pylera®	Compliance	AEs	Total	1st line	2nd line	3rd line	Total	1st line	2nd line	3rd line
4c/8h	97%	22%	91%	95%	92%	86%	93%	96%	94%	92%
3c/6h	98%	24%	86%	93%	83%	84%	90%	95%	87%	86%

AEs: adverse events. 4c/8h: four capsules three times a day (every 8 hours); 3c/6h: three capsules four times a day (every 6 hours).

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EP2.16 | European Registry on *H. pylori* Management (Hp--EuReg): Experience with single capsule bismuth quadruple therapy in 3,439 patients

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Background: Bismuth--quadruple therapy (PPI, bismuth, tetracycline and metronidazole) has resurfaced in Europe thanks to a three--in--one single--capsule formulation (Pylera®).

Aim: To evaluate the effectiveness and safety of Pylera®.

Methods: International prospective registry of the clinical practice of European gastroenterologists on the management of *H. pylori* infection (Hp--EuReg). All infected adult patients treated with Pylera® according to data sheet (3 capsules/6h) were systematically collected at AEG--REDCap e--CRF until December 2019. Modified intention--to-- treat (mITT) analyses were performed.

Results: Overall, 2,100 patients were prescribed single--capsule bismuth--quadruple therapy (10 days, 3 capsules q.i.d.). The major-ity of these patients were naïve (63%) and 16% had peptic ulcer. Pylera® achieved a high eradication rate based on the mITT (91.9%). Effectiveness was higher when using Pylera® as a first--line treatment

(94.6%) but it had also high effectiveness as a rescue therapy, both in second--line (89.3%) or subsequent lines of therapy (3rd--6th line: 91.9%) (Table 1). Compliance was the factor most closely associated with the effectiveness of treatment. Adverse events (AEs) were generally mild--to--moderate and transient, only 3% of patients reporting a severe AE, leading to discontinuation of treatment in 1.7% of patients. Conclusions

The 10--day treatment with single--capsule bismuth--quadruple therapy (Pylera®) achieves *H. pylori* eradication in approximately 90% of patients by mITT in real--world clinical practice, both as a first--line and rescue treatment, with a favourable safety profile.

TABLE 1. Pylera® effectiveness (by modified intention--to--treat) in first--, and consecutive rescue treatment lines

	Use, N (%)	mITT, N (%)	95% CI	PP, N (%)	95% CI
Overall	2,100 (6*)	1,777 (92)	91-93	1,761 (93)	92-94
Naïve	1.335 (63)	1,166 (95)	93-96	1,158 (95.5)	94-97
2nd line	465 (22)	375 (89)	86-92	370 (90)	87-93
3rd line	212 (10)	174 (89)	84-93	177 (88)	83-93

* Of the total of treatments included in the Hp--EuReg up to December 2019 (i.e. N = 34,460); mITT: modified intention--to--treat; PP: per--protocol, N: total number of patients analysed.

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EP2.17 | Safety of the treatment of *H. pylori* infection: Experience from the European Registry on *H. pylori* Management (Hp--EuReg) on 22,000 patients

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Introduction: The safety of *Helicobacter pylori* eradication treatments and to what extent adverse events (AEs) may influence therapeutic compliance is unknown.

Objective: To assess the frequency, type, intensity and duration of AEs, and their impact on compliance.

Methods: Systematic prospective non--interventional registry of the clinical practice of European gastroenterologists on the management of *H. pylori* infection. All prescribed treatments and their corresponding safety profile were recorded in an e--CRF in AEG--REDCap until June 2019. AEs were classified depending on the intensity of symptoms as mild/moderate/severe, and as serious AEs (death, hos-pitalisation, disability, congenial anomaly and/or requires interven-tion to prevent permanent damage).

Results: The different treatments prescribed to a total of 22,492 naïve and non--naïve patients caused at least one AE in 22% of the cases (Table 1), the classic bismuth--based quadruple therapy being the worst tolerated (37% of AEs). Taste disturbance (7%), diarrhoea (7%), nausea (6%) and abdominal pain (3%) were the most frequent AEs. The majority of AEs were mild (57%), 6% were severe, and only 0.08% were serious, with an average duration of 7 days. The treatment compliance rate was 97%. Only 1.3% of the patients discontinued treatment due to AEs.

Conclusions: *H. pylori* eradication treatment frequently induces AEs, although they are usually mild and of limited duration. Its appearance does not interfere significantly with the compliance of treatment.

TA B L E 1 . Safety in naïve and non--naïve patients

Adverse events	Yes	%	95% CI
Triple-C+A	1,037	15	14-16
Quadruple-C+A+M	926	25	23-26
Pylera®	642	28	26-30
Quadruple -C+A+B	627	34	34-37
Triple-A+L	339	21	19-23
Triple-C+M	184	20	18-23
Quadruple -A+L+B	180	32	28-36
Triple-A+M	79	22	17-26
Sequential-C+A+M	50	19	14-24
Quadruple -M+Tc+B	84	37	30-43
Quadruple -A+B+	67	32	26-39
Quadruple -M+D+B	62	33	26-40
Sequential -C+A+T	5	6.8	2.2-15
Quadruple -C+A+T	16	17	9.1-26
Total	4,298	22	22-23

A, amoxicillin; B, bismuth; C, clarithromycin; CI, confidence interval; D, doxycycline; L, levofloxacin; M, metronidazole; T, tinidazole; Tc, tetracycline.

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EP2.18 | Bismuth quadruple regimen with tetracycline or doxycycline versus Pylera® as third--line rescue therapy for *H. pylori* infection: A prospective multicenter analysis of the European Registry on *Helicobacter pylori* Management (Hp--EuReg)

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Background: Different bismuth--quadruple therapies containing proton pump inhibitors, bismuth, metronidazole, and a tetracycline have been recommended as third--line *Helicobacter pylori* eradication treatment after failure with clarithromycin and levofloxacin.

Aim: To evaluate the effectiveness and safety of third--line treatments with bismuth, metronidazole and either tetracycline or doxycycline.

Methods: Sub--study of the European Registry on *H. pylori* Management (Hp--EuReg), an international multicenter prospec-tive non--interventional registry of the routine clinical practice of European gastroenterologists. After previous failure with clarithromycin-- and levofloxacin--containing therapies, patients receiving a third--line regimen with 10/14--day of PPI, bismuth, metronidazole and either tetracycline (T) or doxycycline (D), or 10--day Pylera® (P) were registered at AEG--REDCap.

Results: Overall, 454 patients were treated: 85 with T, 94 with D, and 275 with P. Overall modified intention--to--treat and per--protocol eradication rates were 81% (D: 65%, T: 76%, P: 88%) and 82% (D: 66%, T: 77%, P: 88%), respectively (Table 1). Higher eradication rates were associated with compliance (OR = 2.96; 95% CI = 1.01--8.84) and no prior metronidazole use (OR = 1.96; 95% CI = 1.15--3.33); P was superior to D (OR = 4.46; 95% CI = 2.51--8.27), and T marginally superior to D (OR = 1.67; 95% CI = 0.85--3.29).

Conclusion: Third--line (after failure with clarithromycin and levofloxacin) *H. pylori* eradication with bismuth quadruple treatment offers acceptable effectiveness and safety. Highest effectiveness was found in compliant patients and in those taking 10--day Pylera® or 14--day tetracycline. Doxycycline appears less effective and therefore should not be recommended.

TABLE 1. Effectiveness (by modified intention--to--treat and per--protocol) and compliance according to the treatment regimen and length

Effectiveness, N (%)		Compliance	mITT, N	mITT	95% CI	PP, N	PP	95% CI
Group T	All	82 (97%)	64	76%	66-86	63	77%	67-86
	10 days*	29 (97%)	19	66%	47-85	19	66%	47-85
	14 days	45 (96%)	45	82%	71-93	44	83%	72-94
Group D	All	85 (93%)	58	65%	55-76	56	66%	55-77
	10 days*	37 (90%)	25	63%	46-79	23	63%	45-79
	14 days	53 (96%)	32	70%	55-84	32	71%	57-85
Group P	10 days*	249 (96%)	222	88%	83-92	216	88%	84-92

Group T – tetracycline containing bismuth quadruple therapy, Group D – doxycycline containing bismuth quadruple therapy, Group P – single capsule bismuth quadruple therapy (Pylera®), 95% CI – 95% confidence interval. ITT: intention--to--treat, mITT: modified intention--to--treat; PP: per--protocol. The Chi^2 test showed statistically significant differences of treatment length in the mITT set between treatment groups (T, D and P) as reported in the table: *$P < 0.001$.

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EP2.19 | European Registry on *H. pylori* Management (Hp--EuReg): Clinical phenotypes through *machine learning* of first--line treated patients in Spain during the period 2013--2018

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Background: Patients' segmentation in homogeneous groups could help to improve the effectiveness of current *Helicobacter pylori* eradication therapy.

Objectives: 1) To group patients from the European Registry on *Helicobacter. pylori* management (Hp--EuReg) according to their demographic and clinical characteristics and to the treatment types through multivariate categorical analysis and subsequent cluster decomposition. 2) To evaluate treatments' effectiveness.

Methods: Categorical variables used: sex, ethnicity, diagnosis, symp-toms, therapeutic indication, treatment and its duration, proton-- pump inhibitor (PPI) dose, compliance, adverse events, and region of the prescribing center.

Results: Overall, 8,322 patients were analysed from 2013 to 2018. Table 1 shows the increase of effectiveness, ranging from 78.4% in 2013 to 92.2% in 2018. The lowest effectiveness, for clusters with over 100 patients, was obtained in cluster 1 (2015), with an eradication rate of 82.8%. This cluster comprised: triple therapy with PPI--clarithromycin--amoxicillin and concomitant therapy with PPI--clarithromycin-amoxicillin-metronidazole/tinidazole, lasting both 10 days in most of cases. High PPI dose, 10--day Pylera® treatment obtained over 95% effectiveness in cluster 3 (2018), uniformly distributed among Malaga, Valencia, Ciudad Real, Sevilla, Madrid, and Valladolid. High PPI dose, 14--day concomitant therapy achieved 90.7% effectiveness in cluster 1 (2018), among Malaga, Ciudad Real and Madrid.

Conclusion: The cluster analysis allows both identifying homogeneous groups of patients as well as assessing the effectiveness of the different first--line treatments evaluated.

TABLE 1. Trends in the overall effectiveness (by modified intention--to--treat, per cluster) between 2013 and 2018 in Spain

		Effectiveness % (number of patients) per cluster				
year	Number of clusters	1	2	3	4	5
2013	3	89.6 (280)	83.2 (619)	80.0 (80)		
2014	3	88.2 (1685)	69.6 (46)	83.3 (6)		
2015	5	91.6 (83)	89.4 (839)	82.9 (615)	70.8 (24)	88.2 (17)
2016	3	94.7 (359)	86.1 (853)	92.6 (296)		
2017	3	94.3 (630)	90.6 (636)	91.6 (153)		
2018	3	91.8 (122)	90.7 (161)	96.5 (338)		

Simple underlining highlights the lowest effectiveness for groups of more than 100 patients and double underlining the highest effectiveness.

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EP2.21 | Real--world comparative effects of three--in--one single capsule bismuth quadruple therapy vs non--bismuth quadruple concomitant therapy: Interim analysis of the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: RCTs have strict selection criteria that render results not fully transferable to the clinical practice.

Objective: To assess the comparative effects of first--line bismuth-single-capsule (PPI-bismuth-tetracycline-metronidazole) vs non--bismuth quadruple concomitant therapy (PPI-amoxicillin-clarithromycin-nitroimidazole).

Methods: The European Registry on *H. pylori* management (Hp--EuReg) data from Spain, Italy and Portugal was used to emulate a target trial with prospective observational data, comparing the relative effectiveness (modified intention--to--treat, mITT; and per--protocol, PP) and safety (adverse events, AEs) of first--line bismuth--single--capsule [10 days, 3 PPI dosages] and concomitant therapy [10/14 days; 3 PPI dosages], rendering 9 prescription strategies Regression analysis controlling for confounders was used to estimate the relative effects of each strategy.

Results: Overall, 2,340 individuals were included. Compared to 10--day concomitant therapy at low PPI doses (n = 484), all bismuth--single--capsule combinations presented an eradication incremental benefit by mITT ranging from 7.3% (95% CI: 1.1--13%; $P = 0.024$) with low dose PPI to 12.1% (95% CI: 5.1--19%; $P < 0.001$) with standard PPI dose. High PPI dosages in the concomitant therapy resulted in an eradication incremental benefit by mITT ranging from 7.7% (95% CI: 2.5-12.8; $P = 0.003$) to 8.8% (95% CI: 1.1--16.5; $P = 0.025$) when administered for 14 and 10 days, respectively (Table 1). No differences were found with respect to AEs or severe AEs in any of the assessed strategies.

Conclusions: Single--capsule bismuth quadruple therapy and non--bismuth quadruple concomitant therapy appear to have similar risk--benefit ratios when prescribed with high PPI doses

TA B L E 1 . Adjusted estimates* for eradication with respect to non--bismuth quadruple concomitant therapy during 10 days and low dose PPI

Strategies	mITT absolute risk difference (95% CI)	*P* value	PP absolute risk difference (95% CI)	*P* value
Bismuth--single--capsule, 10 days, low dose PPI	7.4 (1.8-13.1)	0.010	8.9 (3.4-13.5)	0.002
Bismuth--single--capsule, 10 days, standard dose PPI	12.1 (5.1-19.0)	<0.001	12.6 (5.8-9.4)	<0.001
Bismuth--single--capsule, 10 days, high dose PPI	7.3 (0.9-13.6)	0.025	8.3 (2.0-14.5)	0.009
Non--bismuth quadruple concomitant therapy, 10 days, standard dose PPI	8.2 (2.1-14.2)	0.008	8.0 (2.2-13.9)	0.007
Non--bismuth quadruple concomitant therapy, 10 days, high dose PPI	8.8 (1.1-16.5)	0.025	10.0 (2.5-17.6)	0.009
Non--bismuth quadruple concomitant therapy, 14 days, low dose PPI	4.5 (-1.8-10.8)	0.166	4.6 (-1.6-10.8)	0.145
Non--bismuth quadruple concomitant therapy, 14 days, standard dose PPI	7.5 (-0.6-15.5)	0.069	6.8 (-1.0-14.6)	0.088
Non--bismuth quadruple concomitant therapy, 14 days, high dose PPI	7.7 (2.5-12.8)	0.003	7.5 (2.4-12.5)	0.004

Low dose PPI: ranging from 4.5 to 27 mg omeprazole equivalents, b.i.d. Standard dose PPI: ranging from 32 to 40 mg omeprazole equivalents, b.i.d. High dose PPI: ranging from 54 to 128 mg omeprazole equivalents, b.i.d. Bismuth--single--capsule (PPI--bismuth--tetracycline--metronidazole). Non-- bismuth quadruple concomitant therapy (PPI--amoxicillin--clarithromycin--nitroimidazole). *Estimates controlling for: age, sex, ethnicity, indication, concomitant allergy drug, hospital fixed effects and year fixed effects

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EP2.22 | Antibiotic resistance trends of *Helicobacter pylori* naïve patients in the period 2013--2019: Analysis of the European Registry on *H. pylori* Management (Hp--Eu--Reg)

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Background: Bacterial antibiotic resistance changes over time based on multiple factors. It is essential to study these trends to apply pre-ventive strategies to help reducing such resistances.

Objective: To conduct a time--trend analysis of the antibiotic re-sistance to *H. pylori* infection in the European Registry on *H. pylori* (Hp-EuReg).

Patients and Methods: International multicenter prospective non--interventional European Registry on *H. pylori* Management (Hp--EuReg) aiming to evaluate the decisions and outcomes of *H. pylori* infection by European gastroenterologists. All infected adult pa-tients diagnosed with culture and with a result of the antibiotic re-sistance test were registered at AEG--REDCap e--CRF from 2013 to 2019.

Results: A total of 32,447 patients were included, and culture was performed in 3,474 (11%), where 2,483 näive patients were included for analysis. Resistance to at least one antibiotic was described in 57% of the patients. Resistance to metronidazole (27%) was most frequent, whereas resistance to tetracycline and amoxicillin was below 1%. Clarithromycin resistance remained above 15% through-out the studied years (Table 1). A significant decrease in the met-ronidazole resistance rate was observed between 2013 (38%) and 2018 (21%).

Conclusion: In naïve patients, resistance to clarithromycin re-mained above 15% in the period 2013--2019. A progressive de-crease in metronidazole resistance was observed. No increasing or decreasing trend was observed in the bacterial resistance to other antibiotics.

TABLE 1. Antibiotic resistance trends (2013--2019) of *Helicobacter pylori* naïve patients in Europe

N (%)	2013	2014	2015	2016	2017	2018	2019	Variation range
Nº Cultures	435	522	469	286	355	282	310	282-522
No resistance	210 (48)	259 (50)	197 (42)	93 (33)	162 (46)	106 (38)	104 (33.5)	33-50
Clarithromycin (C)	86 (20)	120 (23)	117 (25)	59 (21)	68 (19)	65 (23)	57 (18)	18-25
Metronidazole (M)	165 (38)	156 (30)	140 (30)	72 (25)	64 (18)	60 (21)	66 (21)	18-38
Levofloxacin (L)	58 (13)	100 (19)	103 (22)	46 (16)	59 (17)	55 (20)	41 (13)	13-22
Amoxicillin	6 (1)	0 (0)	0 (0)	0 (0)	10 (3)	1 (0.4)	0 (0)	<1
Tetracycline	3 (0.7)	1 (0.2)	0 (0)	1 (0.3)	5 (1.4)	0 (0)	1 (0.3)	<1.4
Dual (C+M)	56 (13)	65 (13)	62 (13)	33 (12)	30 (9)	28 (10)	29 (9)	9-13
Triple (C+M+L)	22 (5)	31 (6)	32 (7)	16 (6)	12 (3)	12 (4)	8 (3)	3-7

C, clarithromycin; L, levofloxacin; M, metronidazole.

L. Bujanda: None. O. P. Nyssen: None. D. S. Bordin: None. A. Cosme: None. B. Tepes: None. A. Perez--Aisa: None. D. Vaira: None. M. Caldas: None. M. Castro--Fernandez: None. F. Lerang: None. M. Leja: None. L. Rodrigo: None. T. Rokkas: None. L. Kupcinskas: None. J. Perez--Lasala: None. L. Jonaitis: None. O. Shvets: None. A. Gasbarrini: None. H. Simsek: None. A. Axon: None. G. Buzas: None. J. Machado: None. Y. Niv: None. L. Boyanova: None. A. Goldis: None. V. Lamy: None. A. Tonkic: None. W. Marlicz: None. C. Beglinger: None. M. Venerito: None. P. Bytzer: None. L. Capelle: None. T. Milosavljevic: None. L. Veijola: None. J. Molina--Infante: None. L. Vologhzanina: None. G. Fadeenko: None. I. Ariño: None. G. Fiorini: None. E. Resina: None. R. Muñoz: None. I. Puig: None. C. O'Morain: None. F. Megraud: None. J.P. Gisbert: None.

EP2.24 | *Helicobacter pylori* antibiotic resistance: Data from the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: Antibiotic resistance is the major factor affecting our ability to cure *Helicobacter pylori* infection. Understanding the different *H. pylori* antibiotic resistances could be the key to improve treatment effectiveness.

Objective: To evaluate the *H. pylori* antibiotic resistance both prior and after one or several eradication treatments, in order to provide the most appropriate recommendations for the eradication of *H. pylori*.

Methods: International multicenter prospective non--interventional European Registry on *H. pylori* Management (Hp--EuReg) aiming to evaluate the decisions and outcomes of *H. pylori* infection by European gastroenterologists. Infected adult patients diagnosed with culture and with a result of the antibiotic resistance test registered at AEG--REDCap e--CRF from 2013 to 2019. Per--protocol (PP) analysis was performed. The antibiotic bacterial resistances were described by treatment line.

Results: A total of 32,447 patients were included, and culture was performed in 3,474 (11%). In naïve patients, 21% reported single clarithromycin resistance, and 11% dual (clarithromycin and metronidazole) resistance. Antibiotic resistance increased markedly from the first treatment, reaching over 37% dual resistance in second--line treatment (Table 1).

Conclusion: In Europe, culture testing to determine antibiotic resistance against *H. pylori* is scarce. *H. pylori* single clarithromycin resist-ance remains high (>15%) in all treatment lines, and greater than 20% in naïve patients. Dual or triple resistances are frequent and increase remarkably after the first treatment failure. Resistance to amoxicillin or tetracycline is exceptional.

TABLE 1. *Helicobacter pylori* antibiotic resistances (by treatment line) in Europe

Treatment line	Naïve (%)	Second (%)	Third (%)	Fourth (%)	Fifth (%)	Sixth (%)	*P*--value
Number of patients	2,485	521	311	97	31	11	
No resistance	1,054 (42)	74 (14)	26 (8)	7 (7)	4 (13)	1 (9)	<0.001
Clarithromycin (C)	531 (21)	298 (57)	217 (70)	72 (74)	23 (74)	5 (45)	<0.001
Metronidazole (M)	674 (27)	251 (48)	192 (62)	59 (61)	19 (61)	7 (64)	<0.001
Levofloxacin (L)	438 (18)	134 (26)	130 (42)	44 (45)	12 (39)	3 (27)	<0.001
Amoxicillin	17 (1)	4 (1)	5 (2)	0 (0)	0 (0)	0 (0)	<0.001
Tetracycline	11 (0.4)	3 (1)	2 (0.6)	1 (1)	0 (0)	0 (0)	>0.05
Dual (C+M)	279 (11)	195 (37)	165 (53)	52 (54)	17 (55)	5 (46)	<0.001
Triple (C+M+L)	128 (5)	91 (18)	99 (32)	34 (35)	9 (29)	3 (27)	<0.001

C, clarithromycin; L, levofloxacin; M, metronidazole.

L. Bujanda: None. O.P. Nyssen: None. A. Cosme: None. D. Bordin: None. B. Tepes: None. A. Perez--Aisa: None. D. Vaira: None. M. Caldas: None. M. Castro--Fernandez: None. F. Lerang: None. M. Leja: None. L. Rodrigo: None. T. Rokkas: None. L. Kupcinskas: None. J. Perez--Lasala: None. L. Jonaitis: None. O. Shvets: None. A. Gasbarrini: None. H. Simsek: None. A. T. R Axon: None. G. Buzas: None. J. Machado: None. Y. Niv: None. L. Boyanova: None. A. Goldis: None. V. Lamy: None. A. Tonkic: None. W. Marlicz: None. C. Beglinger: None. M. Venerito: None. P. Bytzer: None. L. Capelle: None. T. Milosavljevic: None. L. Veijola: None. J. Molina--Infante: None. L. Vologhzanina: None. G. Fadeenko: None. I. Ariño: None. G. Fiorini: None. E. Resina: None. R. Muñoz: None. I. Puig: None. F. Megraud: None. C. O'Morain: None. J.P. Gisbert: None.

EP2.25 | Impact of *Helicobacter pylori* clarithromycin resistance on the treatment effectiveness: Data of the European Registry on *H. pylori* Management (Hp--EuReg)

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Background: Antibiotic resistance is the major factor affecting our ability to cure *Helicobacter pylori* infection. Quadruple therapy is currently recommended; however, triple therapy with two antibiotics may be sufficient in those patients without clarithromycin resistance.

Objective: To evaluate the effectiveness of the treatments according to the clarithromycin *H. pylori* resistance in Europe.

Methods: International multicenter prospective non--interventional European Registry on *H. pylori* Management (Hp--EuReg) aiming to evaluate the decisions and outcomes of *H. pylori* infection. Infected adult patients diagnosed with culture registered at AEG--REDCap e--CRF from 2013 to 2019. Per--protocol (PP) analysis was performed based on the presence or absence of clarithromycin bacterial resistance.

Results: Overall, 5,036 patients were included: 1,747 (35%) were resistant and 3,289 (65%) sensitive to clarithromycin. The overall eradication rate was higher in clarithromycin--susceptible patients (91% vs 84%; $P < 0.001$). Triple therapy with a PPI, clarithromycin and amoxicillin achieved over 90% eradication rates in clarithromycin--susceptible patients. However, in those with clarithromycin--resistance, optimal effectiveness was only achieved when treated with quadruple therapy with a PPI, clarithromycin, amoxicillin and bismuth (Table 1).

Conclusions: Classic triple therapy with a PPI, clarithromycin and amoxicillin achieves optimal results (>90%) in patients susceptible to clarithromycin. However, when clarithromycin resistance is unknown, quadruple therapy with a PPI, clarithromycin, amoxicillin and bismuth may be a better treatment option.

TABLE 1. Effect of the clarithromycin *Helicobacter pylori* on the effectiveness in Europe

	Clarithromycin resistant			Clarithromycin susceptible		
Treatment schemes	**E**	**N**	**%**	**E**	**N**	**%**
Overall	754	897	84	1.512	1.658	91
Triple-C+A	11	14	79	392	431	91
Triple-A+L	165	191	86	47	55	85
Triple-A+M	46	55	84	147	166	89
Triple-A+R	91	102	89	9	11	82
Triple-C+M	NA	NA	NA	17	19	89
Quadruple-C+A+M/T	43	54	80	88	100	88
Quadruple-C+A+B	10	11	91	36	40	90
Sequential-C+A+T	242	286	85	627	664	94
Sequential-C+A+M	17	23	74%	41	53	77%
Hybrid-C+A+M	27	34	79%	36	38	95%
Single capsule	66	80	83%	53	54	98%

A, amoxicillin; B, bismuth; C, clarithromycin; E, number of eradicated patients; M, metronidazole; N, total number of patients analysed; T, tinidazole; Single capsule: three--in--one single capsule containing bismuth, tetracycline and metronidazole (marketed as Pylera®).

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EP2.32 | Effectiveness of first--line *H. pylori* eradication therapy according to the daily statin--use: Analysis of the European Registry on *H. pylori* Management (Hp--EuReg)

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Introduction: The use of statins with antibiotics and proton pump inhibitors has been suggested as a strategy to increase the effectiveness of *Helicobacter pylori* treatments, mainly based on their anti--inflammatory characteristics. However, evidence published so far still remains scarce.

Aim: To analyse the impact of the daily use of statins in the effective-ness of *H. pylori* first--line therapies.

Methods: Multicentre prospective non--interventional registry of the clinical practice of European gastroenterologists of the European Registry on *H. pylori* Management (Hp--EuReg). Patients were col-lected at AEG--REDCap e--CRF from 2013 to December 2019. Records of naïve patients containing information about the statins' use were included for current analysis. Modified intention--to--treat (mITT) analysis was performed to evaluate the treatment effectiveness. **Results**: Overall, 7,687 patients received an empirical first--line therapy: 60.5% were women and median age was 56 years. From those, 1,895 (25%) were daily statins--users: 45% used simvastatin, 35% atorvastatin, 11% rosuvastatin and 9% other statins. Univariate analysis showed no differences in the treatment effectiveness of the statin--users group versus no statin--users (Table).

Conclusions: The daily use of statins does not seem to increase the effectiveness of *H. pylori* eradication treatment.

TABLE 1. Impact of the statins' use on the effectiveness of most frequently used first--line empirical treatments in Europe.

	Daily use of statins	mITT, N (%)	Differences (*P*--value)
Overall	No	4,835 (88)	0.44
	Yes	1,729 (88.5)	
PPI+C+A	No	1,790 (86)	**0.05**
	Yes	544 (82)	
PPI+C+M	No	380 (82)	0.52
	Yes	95 (79)	
PPI+Bi+Tc+M	No	616 (94.5)	0.69
	Yes	287 (95)	

	Daily use of statins	mITT, N (%)	Differences (*P*--value)
PPI+C+A+M (Sequential)	No	53 (81)	0.32
	Yes	27 (93)	
PPI+C+A +M (Concomitant)	No	1,189 (88)	0.08
	Yes	527 (91)	
PPI+Bi+C+A	No	612 (88)	0.12
	Yes	186 (92.5)	

mITT: modified intention--to--treat. N: number of patients included. %: proportion of patients showing effectiveness. PPI: proton pump inhibitor. C: clarithromycin. A: amoxicillin. M: metronidazole. Bi: bismuth. Tc: tetracycline. Sequential: sequential administration of the treatment components. Concomitant: concomitant administration of the treatment components.

M. Caldas: None. Á. Pérez--Aisa: None. B. Tepes: None. M. Castro--Fernández: None. L. Bujanda: None. G. Fadeenko: None. A. J. Lucendo: None. D. Vaira: None. L. Jonaitis: None. N. Brglez Jurecic: None. J. Pérez--Lasala: None. L. Fernández--Salazar: None. L. Rodrigo: None. J. Huguet: None. M. Leja: None. M. Areia: None. J. Barrio: None. J. Ortuño: None. S. Alekseenko: None. J. Molina--Infante: None. P. Bogomolov: None. V. Ntouli: None. M. Domínguez--Cajal: None. R. Ruiz--Zorrilla: None. R. Pellicano: None. M. Espada: None. I. Puig: None. O. P. Nyssen: None. F. Megraud: None. C. O´Morain: None. J. P. Gisbert: None.

EP2.33 | Effectiveness of first--line *H. pylori* eradication treatments in Spain: Results from the European Registry on *H. pylori* management (Hp--EuReg)

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Introduction: Updated data in Spain is needed to design the best strategy to treat *Helicobacter pylori* infection.

Aim: To analyse the effectiveness of *H. pylori* first--line eradication therapies in Spain.

Methods: Systematic multicentre prospective registry of the clini-cal practice of gastroenterologists on the management of *H. pylori* infection (Hp--EuReg). All infected adult patients were registered at AEG--REDCap e--CRF from February 2013 to June 2019. Data were subject to quality control. Effectiveness (by modified intention--to--treat) and multivariate analysis were performed. Independent fac-tors evaluated: age, gender, presence of ulcer, proton pump inhibitor (PPI) dose, therapy duration and compliance.

Results: Overall, 10,633 naïve patients from 53 Spanish hospitals were included: median age was 51 years and 61% were women. From those, 10,267 patients received an empirical prescription. Over 90% mITT eradication rate was obtained with first--line 14--day quadruple therapies or 10--day bismuth three--in--one single--capsule (Table). Adverse events occurred in 25% of the cases, 0.2% being serious ad-verse events (Table). Multivariate analysis reported that 10--14 days therapies (OR = 4), good compliance (>90% drug intake; OR = 4) and high PPI doses (OR = 2) were associated with higher mITT eradica-tion rates.

Conclusions: In Spain, optimal effectiveness (>90%) in first--line treatment was obtained with the non--bismuth concomitant therapy, the bismuth quadruple therapy with amoxicillin and clarithromycin (both for 14 days), and the 10--day bismuth quadruple (single capsule).

TABLE 1. Effectiveness and safety of the most--frequently prescribed first--line therapies in Spain

	Effectiveness					
	mITT		PP		Adverse events	
	N (%)	C.I. 95%	N (%)	C.I. 95%	N (%)	C.I. 95%
Overall 1st line therapies	9,726 (88)	88-89	9,497 (89)	88-89	9,937 (25)	25-26
7 days	159 (60)	52-68	158 (61)	53-68	159 (3.1)	1-7
10 days	6.011 (88)	87-89	5,858 (89)	88-90	6,167 (22)	21-23
14 days	3,522 (90)	89-91	3,449 (90)	89-91	3,574 (33)	31-34
PPI + C + A + M (Concomitant)	3,880 (90)	89-91	3,781 (90)	89-91	3,963 (28)	26-29
10 days	2,232 (88)	87-90	2,175 (89)	88-90	2,296 (26)	24-28
14 days	1,629 (92)	91-93	1,588 (92)	91-94	1,648 (30)	28-32
PPI + C + A	2,544 (83)	82-85	2,498 (84)	82-85	2,617 (15)	13-16
7 days	146 (59)	51-67	145 (59)	51-67	146 (2.7)	1-7
10 days	1,686 (84)	82-86	1,657 (84.5)	83-86	1,737 (10)	9-12
14 days	699 (86)	84-89	683 (87)	84-89	719 (28)	25-31
PPI + Single capsule	1,540 (95)	94-96	1,514 (96)	95-97	1,566 (25)	23-27
10 days	1,533 (95)	94-96	1,507 (96)	95-97	1,558 (25)	23-27
PPI + Bi + C + A	1,015 (91)	89-93	1,002 (91)	89-93	1,019 (40)	37-44
14 days	1,004 (91)	89-93	992 (91)	89-93	1,008 (41)	38-44
PPI + C + A + M (Sequential)	222 (81.5)	76-86	192 (84)	79-89	230 (49)	42-55
10 days	221 (81)	76-86	191 (84)	78-89	229 (49)	42-56

mITT: modified intention--to--treat. PP: per protocol. N: number of patients included. %: proportion of patients showing the event (effectiveness or the adverse event). C.I.: confidence interval. PPI: proton pump inhibitor. C: clarithromycin. A: amoxicillin. M: metronidazole. Single capsule: three--in--one single capsule containing bismuth, tetracycline and metronidazole. Bi: bismuth. Concomitant: concomitant administration of the drugs. Sequential: sequential administration of the drugs.

M. Caldas: None. Á. Pérez--Aisa: None. M. Castro--Fernández: None. L. Bujanda: None. A. J. Lucendo: None. J. Huguet: None. J. Molina--Infante: None. L. Fernández--Salazar: None. J. Ortuño: None. M. Domínguez--Cajal: None. P. Almela: None. J. Botargués: None. J. Gómez: None. C. De la Coba: None. L. Pozzati: None. M. Barenys: None. M. Fernández--Bermejo: None. J. Alcedo: None. M. Mego: None. J. Domínguez--Jiménez: None. N. Fernández: None. M. Pabón--Carrasco: None. H. Alonso--Galán: None. I. Ariño: None. A. Garre: None. I. Puig: None. O. P. Nyssen: None. F. Megraud: None. C. O´Morain: None. J. P. Gisbert: None.

EP2.34 | Effectiveness of second--line *H. pylori* eradication treatments in Spain: Results from the European Registry on *H. pylori* management (Hp--EuReg)

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Introduction: Optimal second--line regimens in *Helicobacter pylori* in-fection are required based on local previous results.

Aim: To analyse the effectiveness of second--line therapies in Spain.

Methods: Systematic multicentre prospective registry of clinical practice of gastroenterologists on the management of *Helicobacter pylori* infection (Hp--EuReg). All infected adult patients were registered at AEG--REDCap e--CRF from February 2013 to June 2019. Data were subject to quality control. Effectiveness (by modi-fied intention--to--treat) and multivariate analysis were performed. Independent factors evaluated: age, gender, presence of ulcer, proton pump inhibitor (PPI) dose, therapy duration, use of clarithromycin in the previous line, and compliance.

Results: Overall, 2,481 patients received a second--line therapy: me-dian age was 50 years and 66% were women. From those, 2,448 patients received an empirical prescription. Nearly 90% mITT eradication rate was obtained with either moxifloxacin--or levofloxacin containing triple therapy, or with quadruple therapy with levofloxa-cin and bismuth (all given for 14 days) or with 10--day bismuth three-- in--one single capsule (Table). Only 1 patient (0.2%) showed a serious adverse event. Multivariate analysis showed that compliance (>90% drug intake; OR = 3), high PPI dose (OR = 2) and 14--day therapy (OR = 1.5) were associated with higher mITT eradication rates.

Conclusions: In Spain, optimal effectiveness (approximately 90%) in second--line treatment was obtained with triple quinolone or quadruple bismuth--quinolone regimens (both for 14 days) or with the 10--day bismuth quadruple (single capsule).

TABLE 1. Effectiveness and safety of the most frequently prescribed second--line therapies in Spain.

	Effectiveness					
	mITT		PP		Adverse events	
	N (%)	C.I. 95%	N (%)	C.I. 95%	N (%)	C.I. 95%
Overall 2nd line therapies	2,295 (84)	82-85	2,247 (84)	82-86	2,348 (28)	27-30
10 days	1,265 (79)	77-81	1,241 (80)	77-82	1,303 (18)	16-20
14 days	1,007 (89)	87-91	986 (90)	88-92	1,020 (42)	39-45
PPI + L +A	893 (78.5)	76-81	881 (79)	76-82	919 (26)	23-29
10 days	647 (74)	70-77	636 (74)	70-77	668 (11)	9-14
14 days	241 (92)	88-95	240 (92.5)	88-96	246 (65)	59-71
PPI + Bi + L +A	451 (89)	86-92	435 (90)	87-93	454 (33)	28-37
14 days	444 (90)	86-92	428 (90)	87-93	448 (33)	28-37
PPI + Single capsule	409 (88)	85-91	398 (89)	85-92	422 (31)	27-36
10 days	399 (88.5)	85-91	390 (89)	86-92	411 (30)	26-35
PPI + Mx+ A	129 (91)	84-95	129 (91)	84-95	134 (19)	13-27
10 days	20 (100)	–	20 (100)	–	21 (5)	0-24
14 days	109 (89)	82-94	109 (89)	82-94	112 (21)	14-30
PPI + C + A + M (Concomitant)	110 (82)	73-89	109 (82)	73-88	112 (24)	17-33
10 days	47 (81)	67-91	46 (80)	66-91	48 (15)	6-28
14 days	62 (84)	72-92	62 (84)	72-92	63 (32)	21-45

mITT: modified intention--to--treat. PP: per--protocol. N: number of patients included. %: proportion of patients showing the event (effectiveness or the adverse event). C.I.: confidence interval. PPI: proton pump inhibitor. L: levofloxacin. A: amoxicillin. Bi: bismuth. Single capsule: three--in--one single capsule containing bismuth, tetracycline and metronidazole. Mx: moxifloxacin. C: clarithromycin. M: metronidazole. Concomitant: concomitant administration of the drugs.

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EP2.36 | 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: To evaluate the use and effectiveness of empirical rescue therapies on third and subsequent lines in Europe.

Methods: Sub--study of the European Registry on *H. pylori* Management, an international multicenter prospective non--interventional registry aimed to evaluate *H. pylori* management in Europe. All cases with ≥3 eradication attempts were extracted until June 2019. Only the empirically prescribed therapies 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, respec-tively. Mean age was 51, 69% of patients were women and 5% were allergic to penicillin. Sixty--three different therapies 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 achieved an optimal eradication rate (≥90% by mITT): Pylera®, quadruple PPI-bismuth-tetracycline-metronidazole and triple PPI--amoxicillin--levofloxacin, the two latter only when high PPI doses and 14 days' duration were used. The use of doxycycline instead of tetracycline was associated with lower eradication rates in classical bismuth quadruple therapies ($P < 0.05$).

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

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

		Modified intention--to--treat		Per--protocol	
Rescue therapy	**Use, N (%)**	**n**	**Effectiveness (95% CI)**	**n**	**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 (5381)	45	69 (53-82)
Triple PPI-C-A	43 (2.4%)	33	67 (48-82)	30	67 (47-83)
Quadruple PPI-C-A-B	28 (1.6%)	24	75 (53-90)	21	86 (64-97)
Triple PPI-A-Mx	27 (1.5%)	26	69 (48-86)	26	69 (48-86)
Quadruple PPI-A-R-B	24 (1.3%)	22	59 (36-79)	21	57 (34-78)

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

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