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## 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 ( $\pm 15$ ) 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  $^{13}\text{C}$ -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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FIRST-LINE EMPIRICAL *H. PYLORI* ERADICATION THERAPY IN EUROPE: RESULTS FROM 30,000 CASES OF THE EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG)

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

**Aims & Methods:** 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 February 2021. *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 41,562 patients from 31 European countries were evaluated and 29,634 (70%) first-line empirical *H. pylori* treatments were included for analysis. Triple therapy with amoxicillin and clarithromycin was most commonly prescribed (39%), followed by non-bismuth concomitant treatment (18%) and bismuth quadruple (three-in-one single capsule) (12%), achieving 84%, 90% and 94% mITT eradication rate, respectively. Over 90% effectiveness was obtained only with 10 and 14-day bismuth quadruple or with 14-day concomitant treatment (Table). Longer treatment duration, higher acid inhibition and compliance were associated with higher eradication rates.

First-line treatment	Length (days)	mITT, N (%)	(95% CI)	PP, N (%)	(95% CI)
Triple-C+A	7	2,129 (82)	(81-84)	2,111 (83)	(81-85)
	10	3,346 (83)	(82-85)	3,304 (84)	(82-85)
	14	3,032 (87)	(86-88)	3,005 (87)	(87-89)
Triple-A+M	7	127 (80)	(72-87)	126 (79)	(72-87)
	10	173 (86)	(80-91)	171 (85)	(80-91)
	14	70 (88)	(80-97)	70 (88)	(80-97)
Triple-C+M	7	744 (84)	(82-87)	741 (85)	(73-85)
	10	122 (66)	(58-75)	120 (67)	(59-76)
	14	212 (87)	(83-92)	210 (87)	(82-92)
Triple-A+L	7	182 (79)	(73-85)	180 (79)	(72-85)
	10	150 (85)	(79-91)	144 (86)	(80-92)
Sequential-C+A+M/T	10	655 (82)	(79-85)	615 (84)	(81-87)
Concomitant-C+A+M/T	10	2,463 (88)	(87-90)	2,397 (89)	(88-90)
	14	2,687 (92)	(91-93)	2,629 (92)	(91-93)
Quadruple-C+A+B	10	644 (86)	(83-89)	637 (87)	(84-90)
	14	2,031 (92)	(91-93)	2,005 (92)	(91-93)
Quadruple-M+Tc+B	10	151 (91)	(87-96)	149 (92)	(87-97)
	14	85 (98)	(92-100)	88 (94)	(87-98)
Single capsule (M+Tc+B)	10	3,104 (94)	(93-95)	3,038 (95)	(94-96)

A – amoxicillin, C – clarithromycin; M – metronidazole; T – tinidazole; L – levofloxacin B; – bismuth salts; Tc – tetracycline.

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

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

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## P0102

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

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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 2013 to February 2021.

**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 41,562 patients from 31 European countries have been included, and 29,634 (70%) were first-line empirical prescriptions. 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; likewise, non-bismuth concomitant therapy use decreased from 21% in 2013/14 to 13% in 2019/20, while three-in one single capsule increased from 0-1% in 2014/2015 to 19% in 2019/20.

An increase in the average duration of treatments from 11 days in 2013 to 13 days in 2020, and of the daily dose of PPI, was identified (detailed description of most common treatments is shown in Table 1 on the following page).

Regarding the effectiveness of each specific treatment, no trend was identified (data now shown); however, there was an 8% overall improvement in first-line mITT overall effectiveness from 2013 to 2020 (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 progressive improvement in overall effectiveness.

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Dr. Gisbert has served as a speaker, a consultant and advisory member for or has received research funding from Mayoly, Allergan, Diasorin, Phathom and Gebro Pharma.



Year	2013	2014	2015	2016	2017	2018	2019	2020
Quadruple-C+A+B	2.0%	2.7%	6.8%	20.5%	13.7%	21.7%	10.8%	9.8%
Single capsule*	0.1%	0.0%	0.5%	13.2%	24.5%	18.7%	21.7%	16.5%
Quadruple-M+Tc+B	2.1%	1.9%	0.5%	0.2%	0.4%	0.5%	1.4%	1.2%
Concomitant-C+A+M/T	21.8%	21.5%	27.0%	22.7%	20.9%	8.0%	13.4%	12.8%
Sequential-C+A+M/T	11.8%	3.5%	1.9%	0.9%	0.5%	0.7%	0.11%	0.1%
Triple-A+L	2.3%	2.2%	3.1%	1.8%	0.3%	0.3%	0.4%	0.3%
Triple-A+M	3.6%	3.0%	1.7%	0.8%	0.9%	0.5%	1.9%	0.7%
Triple-C+M	3.4%	6.4%	8.8%	6.3%	1.4%	0.7%	1.1%	10.2%
Triple-C+A	48.5%	54.6%	44.7%	29.2%	32.1%	31.0%	35.2%	34.6%
Length								
7 days	27.5%	28.1%	24.4%	16.2%	7.9%	1.7%	2.1%	4.5%
10 days	55.1%	52.6%	55.1%	46.5%	47.2%	41.6%	34.7%	29.4%
14 days	17.4%	19.3%	20.4%	37.3%	44.9%	56.7%	63.2%	66.1%
PPI acid inhibition**								
Low	66.6%	56.6%	47.3%	37.9%	39.7%	25.0%	30.1%	45.3%
Standard	16.9%	25.5%	26.7%	24.1%	23.7%	41.3%	30.9%	19.5%
High	16.5%	17.9%	26.0%	38.0%	36.6%	33.7%	39.0%	35.2%
Eradication rate (mITT)	85.0%	85.1%	85.7%	87.6%	87.7%	91.4%	91.5%	92.7%

PPI: proton pump inhibitor; mITT: modified intention-to-treat; A – amoxicillin, C – clarithromycin; M – metronidazole; T – tinidazole; L – levofloxacin B; – bismuth salts; Tc – tetracycline. \*: three-in-one single capsule containing metronidazole, tetracycline and bismuth; \*\*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.

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

## P0103

### EXPERIENCE WITH SINGLE CAPSULE BISMUTH QUADRUPLE THERAPY IN 5,000 PATIENTS FROM THE EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG)

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**Introduction:** There has been a resurgence in the use of bismuth-quadruple therapy (PPI, bismuth, tetracycline and metronidazole) in Europe with the commercialization of a three-in-one single-capsule formulation, but the experience with this regimen is still limited.

**Aims & Methods:** To evaluate the effectiveness and safety of the single capsule in the European Registry on *Helicobacter pylori* management (Hp-EuReg). International multicenter prospective non-interventional registry aimed to evaluate the decisions and outcomes of *H. pylori* management by European gastroenterologists. All infected adult patients treated with 10-day single capsule according to data sheet (3 capsules/6h) or alternative three times a day (4 capsules/8h) prescriptions were systematically registered at AEG-REDCap e-CRF until 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:** Of the 41,562 patients in the Hp-EuReg, 5,068 (12%) received single-capsule bismuth-quadruple therapy. The majority of these patients were naïve (70%), with an average age of 52 years, 63% female and 13% with peptic ulcer. Overall, the single capsule achieved a high eradication rate based on the mITT (92%) and PP (93%) analyses. Effectiveness (mITT) was higher when using the single capsule as a first-line treatment (94%) but it had also high effectiveness as a rescue therapy, both in second-line (90%) or subsequent lines of therapy (3<sup>rd</sup>-6<sup>th</sup> lines: 86%) (Table 1). Compliance was the factor most closely associated with the effectiveness of treatment. Adverse events were generally mild-to-moderate and transient, only 3% of patients reporting a severe adverse event, leading to discontinuation of treatment in 1.7% of patients.

	Use, N (%)	mITT, N (%)	95% CI	PP, N (%)	95% CI
Overall	5,068 (12*)	4,687 (92)	(91-93)	4,586 (93)	(92-94)
1 <sup>st</sup> line (naïve)	3,538 (70)	3,286 (94)	(93-95)	3,218 (95)	(94-95)
2 <sup>nd</sup> line	948 (19)	865 (90)	(88-92)	848 (90)	(88-92)
3 <sup>rd</sup> line	437 (9)	403 (89)	(86-92)	392 (89.5)	(86-93)
Rescue (3 <sup>rd</sup> to 6 <sup>th</sup> line)	582 (11.5)	536 (86)	(82-89)	520 (87)	(84-90)

\*Of the total of treatments included in the Hp-EuReg up to February 2021 (i.e. N= 41,562); mITT: modified intention-to-treat; PP: per-protocol, N: total number of patients analysed.

Table 1. Three-in-one single capsule effectiveness in first-line and consecutive rescue treatment lines.

**Conclusion:** The 10-day treatment with single-capsule bismuth-quadruple therapy 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.

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## P0104

### 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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**Introduction:** Bismuth quadruple with the single capsule (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).

**Aims & Methods:** To assess the effectiveness and safety of quadruple single capsule bismuth therapy administered three times a day (4c/8h) in the European Registry on the management of *Helicobacter pylori* (Hp-EuReg). Systematic prospective registry of the clinical practice of European gastroenterologists on the management of *H. pylori* infection and its treatment. All infected adult patients were systematically registered at AEG-REDCap e-CRF from June 2013 to February 2021. Extraction and analysis of all Spanish cases treated with the single capsule were subject to quality control. Effectiveness was provided for both the modified intention-to-treat and per-protocol sets.

**Results:** Of the 5,068 patients treated with the single capsule in the Hp-EuReg, 3,624 (71%) cases were from Spain and validated for analysis. Of those, 2,459 (68%) were treated with 3c/6h and 1,165 (32%) with the 4c/8h scheme. The average age was 52 years, 63% were women, and 15% had a peptic ulcer. Most of the cases (72%) were naïve to treatment. The dose of PPI did not influence eradication rates. Both treatment schedules showed equivalent compliance, adverse events, and eradication rates (table 1). In the group 3c/6h, 4 patients suffered a serious adverse event requiring hospitalisation: 1 with mild hypertension, 1 with *Clostridium difficile* infection

causing diarrhea, 1 with treatment-related nausea and abdominal pain, and 1 with initial dizziness and stroke in the 4<sup>th</sup> day of treatment (which was interrupted).

	N	Compliance	AEs	Modified intention-to-treat				Per protocol			
				Overall	1 <sup>st</sup> line	2 <sup>nd</sup> line	3 <sup>rd</sup> line	Over-all	1 <sup>st</sup> line	2 <sup>nd</sup> line	3 <sup>rd</sup> line
4c/8h	1,165	97%	28%	94%	96%	89%	89%	95%	96%	89%	89%
3c/6h	2,405	97%	26%	91%	93%	88%	88%	92%	93%	89%	89%

N: number of treatments. AEs: adverse events. 4c/8h: four capsules three times a day; 3c/6h: three capsules four times a day.

*Table 1. Effectiveness (by modified intention-to-treat and per-protocol analyses), compliance and safety of treatment with three-in-one single capsule in first-, second-, and third-line.*

**Conclusion:** The prescription of quadruple therapy with three-in-one single capsule bismuth 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) with the benefit of being more convenient for the patient.

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## P0105

### ANTIBIOTIC RESISTANCE TRENDS OF *HELICOBACTER PYLORI* NAÏVE PATIENTS IN THE PERIOD 2013-2020: ANALYSIS OF THE EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG)

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**Introduction:** Bacterial antibiotic resistance frequently changes over time. It is essential to study these trends to apply preventive strategies to help reducing such resistances. To conduct a time-trend analysis of the antibiotic resistance to *H. pylori* infection in the European Registry on *H. pylori* (Hp-EuReg).

**Aims & 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 patients diagnosed with culture and with a result of the antibiotic resistance test were registered at AEG-REDCap e-CRF from 2013 to February 2021.

**Results:** A total of 41,562 patients were included, and culture was performed in 3,974 (10%), where 2,852 naïve patients were included for analysis. Resistance to at least one antibiotic was described in 27% of the patients. Resistance to metronidazole (30%) was most frequent, whereas resistance to tetracycline and amoxicillin was below 1%. Clarithromycin resistance remained above 15% throughout the studied years (Table 1).

A significant decrease in the metronidazole resistance rate was observed between 2013 (39%) and 2020 (18%),  $p < 0.001$ . Likewise, a decrease in the levofloxacin resistance rate (from 14% to 7%,  $p < 0.001$ ) or in dual (clarithromycin and metronidazole) resistance rate (from 13% to 7%,  $p < 0.05$ ) were observed in the same period.

N (%)	2013	2014	2015	2016	2017	2018	2019	2020	Variation range
N° Cultures	423	521	501	271	343	282	270	218	270-521
No resistance	209 (49)	260 (50)	245 (49)	120 (44)	188 (55)	135 (48)	130 (48)	78 (36)	36-55
Clarithromycin (C)	85 (20)	119 (23)	136 (27)	91 (34)	83 (24)	76 (27)	76 (28)	35 (16)	16-34
Metronidazole (M)	165 (39)	155 (30)	162 (32)	90 (33)	84 (25)	78 (28)	77 (29)	40 (18)	18-39
Levofloxacin (L)	58 (14)	100 (19)	121 (24)	73 (27)	75 (22)	69 (25)	48 (18)	16 (7.3)	7-27
Amoxicillin	6 (1)	0 (0)	0 (0)	0 (0)	4 (1.2)	1 (0.4)	0 (0)	0 (0)	<1
Tetracycline	2 (0.5)	1 (0.2)	0 (0)	1 (0.4)	0 (0)	0 (0)	1 (0.4)	0 (0)	<1.4
Dual (C+M)	56 (13)	64 (12)	77 (15)	45 (17)	41 (12)	34 (12)	35 (13)	16 (7.3)	7-17
Triple (C+M+L)	22 (5.2)	31 (6)	45 (9)	26 (10)	19 (5.5)	16 (6)	11 (4.1)	2 (1)	1-10

Table 1. Antibiotic resistance trends (2013-2020) of *H. pylori* naïve patients in Europe

**Conclusion:** In naïve patients, *H. pylori* resistance to clarithromycin remained above 15% throughout the period 2013-2020. A progressive decrease in metronidazole (as well as dual clarithromycin and metronidazole) and levofloxacin resistance was observed.

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## P0106

### EXPERIENCE WITH RIFABUTIN-CONTAINING THERAPY IN 426 PATIENTS FROM THE EUROPEAN REGISTRY ON *H. PYLORI* MANAGEMENT (HP-EUREG)

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**Introduction:** First-line *H. pylori* treatments have been relatively well evaluated; however, there is a need to identify effective rescue treatment strategies to be prepared to face possible failures.

**Aims & Methods:** To evaluate the effectiveness and safety of rifabutin-containing regimens in the management of *H. pylori* infection. 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 patients treated with rifabutin were registered at AEG-REDCap e-CRF from 2013 to February 2021. Modified intention-to-treat (mITT) and per-protocol (PP) analyses were performed. Data were subject to quality review.

**Results:** A total of 41,562 patients were included in the Hp-EuReg, and 426 (1%) were treated with rifabutin. Most of the cases were from Italy (64%), Spain (25%) and Israel (8%). Mean age was 51 years old, 70% were female, 58% suffered from dyspepsia and 4% from peptic ulcer. Culture (before rifabutin treatment) was performed in 63% of the cases: dual resistance (to both clarithromycin and metronidazole) was reported in 43% of the cases, and triple resistance (to clarithromycin, metronidazole and levofloxacin) in 38%. Rifabutin was mainly used in second-line (32%), third-line (26%), and fourth-line (29%) regimens, achieving 83%, 81% and 63% mITT effectiveness, respectively (Table 1). In 91% of cases rifabutin was used as part of a triple therapy together with amoxicillin and a proton-pump-inhibitor,

and in an additional 7% of the patients bismuth was added to this triple regimen. Compliance with treatment was 89%. Triple therapy with amoxicillin and rifabutin achieved a mITT effectiveness of 84% (110 patients treated) in second-line, 80% (70 patients treated) in third-line and 64.5% (72 patients treated) in fourth-line. At least one adverse event was registered in 28% of the patients (most frequently nausea and asthenia) and one serious adverse event (0.2%) was reported in one patient with leucopenia and thrombopenia with fever requiring hospitalisation.

	Use, N (%)	mITT, N (%)	95% CI	PP, N (%)	95% CI
<b>Overall</b>	426 (100)	357 (75)	(70-79)	346 (76)	(71-80)
<b>1<sup>st</sup> line</b>	22 (5)	22 (86)	(65-97)	22 (86)	(65-97)
<b>2<sup>nd</sup> line</b>	137 (32)	116 (83)	(75-90)	113 (83)	(76-90)
<b>3<sup>rd</sup> line</b>	109 (26)	87 (81)	(71-89)	84 (82)	(73-91)
<b>4<sup>th</sup> line</b>	122 (29)	102 (63)	(53-73)	97 (64)	(54-74)
<b>5<sup>th</sup> line</b>	27 (6)	23 (57)	(34-79)	23 (56)	(34-79)
<b>6<sup>th</sup> line</b>	9 (2)	7 (71)	(29-96)	7 (71)	(29-96)

mITT: modified intention-to-treat; PP: per-protocol, N: total number of patients analysed.

Table 1. Prescriptions and effectiveness of rifabutin-containing regimens by line of treatment

**Conclusion:** Rifabutin-containing therapy represents a safe and encouraging strategy when one or even multiple previous *H. pylori* eradication treatments have failed.

**Disclosure:** Dr. Nyssen has received research funding from Mayoly, Allergan. Dr. Gisbert has served as a speaker, a consultant and advisory member for or has received research funding from Mayoly, Allergan, Diasorin, Phathom and Gebro Pharma.

## P0108

### ASSESSMENT OF FIRST-LINE TREATMENT IN GREECE: DATA FROM THE EUROPEAN REGISTRY ON *HELICOBACTER PYLORI* MANAGEMENT (HP-EUREG)

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**Introduction:** *Helicobacter pylori* (*H.pylori*) is the most common chronic bacterial infection in the world, affecting over 50% of the world's population. The management of *H. pylori* infection has to rely on local effectiveness due to the geographical variability of bacterial antibiotic resistance.

**Aims & Methods:** The aim was to evaluate treatment effectiveness in naïve patients in Greece as part of the European Registry on the management of *Helicobacter pylori* (Hp-EuReg).

**Patients and methods:** Data derived from the systematic prospective registry of the clinical practice of European gastroenterologists on the management of *H. pylori* infection and its treatment. All infected adult patients were systematically registered at AEG-REDCap e-CRF from June 2013 to February 2021. Extraction and analysis of all Greek cases with a first-line treatment were included for analysis. Modified intention to treat (mITT) analysis was reported for the effectiveness analysis.

**Results: Results:** Overall, five medical institutions reported data for *H. pylori* first-line eradication treatments including 547 patients. These patients were treated with the following regimens: Concomitant clarithromycin, amoxicillin and metronidazole (Concomitant-C+A+M) (38%), Hybrid clarithromycin, amoxicillin and metronidazole (Hybrid-C+A+M) (20%), Sequential clarithromycin, amoxicillin and tinidazole (Sequential-C+A+T) (12%), Sequential clarithromycin, amoxicillin and metronidazole (Sequential-C+A+M) (12%), Concomitant clarithromycin, amoxicillin and tinidazole (Concomitant-C+A+T) (8%), Triple clarithromycin, amoxicillin (Triple-C+A) (7%) and other (3%). Bismuth is not available in Greece and therefore regimens including this drug were not used. Overall compliance, i.e. >90% drug intake, was 99% (95% CI 97.5-99.4). Triple-C+A, Sequential-C+A+T, Sequential-C+A+M and Concomitant-C+A+T were used from 2013 to 2015/16. The respective mITT cure rates (%; 95% CI) were 92 (78-98), 87 (76-94), 67 (54-78) and 91 (79-98). Since 2015 patients were also treated with, Concomitant-C+A+M and Hybrid-C+A+M regimens, with respective mITT cure rates of 90 (85-94) and 88 (80.5-94). Adverse events were reported in 31% of the naïve patients, dysgeusia being the most frequent (15%). No serious adverse events were reported.

**Conclusion: Conclusions.** "Optimized" *H. pylori* therapies should achieve  $\geq 90\%$  cure rates. In Greece, only non-bismuth quadruple concomitant regimen (with a PPI, clarithromycin, amoxicillin and a nitroimidazole) achieves this target and therefore can be recommended as first-line treatment.

**Disclosure:** None.