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VONOPRAZAN IS HIGHLY EFFECTIVE AND SAFE AS AN ADJUVANT IN DIFFERENT REGIMES IN FIRST- AND RESCUE-LINE THERAPIES FOR *H. PYLORI* INFECTION IN BRAZIL

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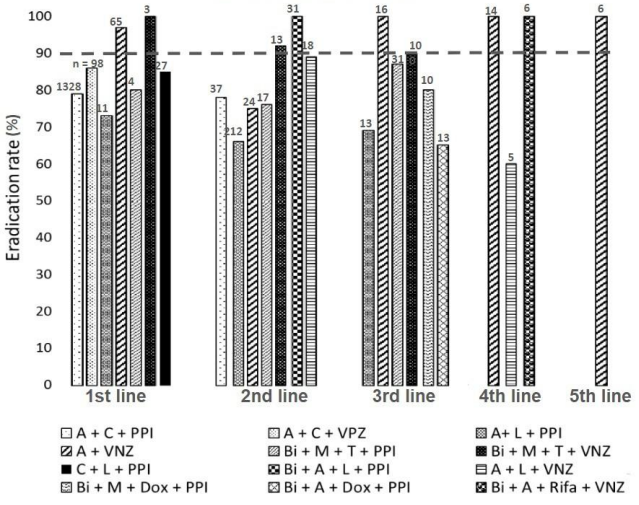
ABSTRACT BODY: Introduction: Data about the effectiveness and safety of vonoprazan (VPZ) as an adjuvant for treating *H. pylori* are lacking in Brazil. Previous studies suggest that greater acid suppression might improve effectiveness, with an acceptable eradication rate around 90%. ***Aim:*** To evaluate VPZ in eradication therapy in Brazil, as part of the Hp-BrazilReg, partner of Hp-WorldReg. **Methods:** Multicenter and prospective real-life registry evaluating outcomes of *H.* pylori management by Brazilian gastroenterologists. Data were registered at e-CRF AEG-REDCap from March 2022 to October 2024. The effectiveness was assessed by modified intention-to-treat (mITT) analysis. Data were subject to quality review. **Results:** 2,144 Brazilian patients, with a mean age of 52 years, 61% of whom were women, were included in the mITT analysis. The main treatment indications were: 63% dyspepsia, 10% gastroduodenal ulcers, and 5% premalignant gastric lesions. Endoscopy was performed in 95% of the cases, using histology (90%) and/or the rapid urease test (15%) for diagnosing the infection. No pre-treatment bacterial resistance test was performed. First-line treatments were administered to 73% (n=1,560) of cases, second-line to 18% (n=396), and rescue to 9% (n=188), with 94% of patients receiving 14-day prescriptions. Low-dose, standard-dose, and high-dose PPIs, as well as VPZ, were used in 39%, 38%, 23%, and 15% of treatment cases, respectively. Probiotics were used as adjuvant in 15% of patients. Compliance (>90% drug intake) was reported in 99% of the patients. Eradication was mostly confirmed by endoscopy in 88% (histology [74%] and/or rapid urease test [14%]). The ^{14}C-urea breath test was used in 8% of the cases. At least one adverse event was reported by 25% of patients, mainly nausea (13%), dysgeusia (8%) and diarrhea (7%). The regimens reaching 90% eradication were: dual-VPZ+amoxicillin for first-line and rescue treatments (96% and 100%, respectively), quadruple VPZ+bismuth+tetracycline+metronidazole for second- and third-line treatments (92% and 90% respectively), and quadruple PPI+bismuth+levofloxacin+amoxicillin (100%) for second-line treatment (Table and Figure). Prescribing VPZ (vs PPI) was an independent factor associated with higher effectiveness both in first-line (OR 2.95; IC 95%: 1.71-5.09) and in second-line and rescue treatments (OR 3.01; IC 95%: 1.43-6.3). There was no difference in adverse effects between VPZ and PPI-based regimens (p<0.01). **Conclusions:** VPZ, when prescribed as an adjuvant for treating *H. pylori* infection, shows highly effective results as part of dual therapy with amoxicillin for first-line and rescue treatments, as well as in quadruple therapy with bismuth+metronidazole+ tetracycline or bismuth+amoxycillin and rifabutin for rescue treatments.

Figure - Effectiveness of different schemes for treatment of H. pylori
HpBrazilReg (N mITT = 2,144)



PPI–proton pump inhibitor, C–clarithromycin, A–amoxicillin, L-levofloxacin, Bi–bismuth salts, VPZ-vonoprazan, T-tetracycline, M-metronidazole, Dox-Doxycycline, Rifa-Rifabutin
CI - Confidence interval, mITT - Modified Intention-to-treat

Table - Effectiveness of different schemes for treatment of *H. pylori* – HpBrazilReg (N = 2,144)

Therapeutic schemes	N (%)	Effectiveness mITT, % (IC 95%)
First-line (n = 1560)		
A + C + PPI	1328 (85.2%)	77.9 (76-80)
A + C + VPZ	98 (6.3%)	85.7 (77-92)
A + VPZ	65 (4.2%)	**96.9 (89-99)**
C + L + PPI	27 (1.7%)	85.2 (66-96)
A + L + PPI	11 (0.7%)	72.7 (39-94)
Bi + M + T	7 (0.4%)	85.7 (42-99)
Other	24 (1.5%)	-
Second-line (n = 386*)		
A + L + PPI	212 (54.9%)	65.6 (59-72)
A + C + PPI	37 (9.6%)	75.7 (59-88)
Bi + A + L + PPI	31 (8%)	**100 (88-100)**
A + VPZ	24 (6.2%)	75 (53-90)
A + L + VPZ	18 (4.7%)	88.9 (65-98)
Bi + M + T + PPI	17 (4.4%)	76 (50-93)
Bi + M + T + VPZ	13 (3.4%)	**92.3 (64-100)**
Other	34 (8.8%)	-
Third-line (n = 130)**		
Bi + M + T + PPI	31 (23.8%)	87 (70-96)
Bi + A + Dox + PPI	20 (15.4%)	65 (41-85)
A + VPZ	16 (12.3%)	**100 (80-100)**
A + L + PPI	13 (10%)	69 (38-90)
Bi + M + T + VPZ	10 (7.7%)	**90 (55-99)**
Bi + M + Dox + PPI	10 (7.7%)	80 (44-97)
Other	30 (20.3%)	-
Fourth-line (n = 42)		
A + VPZ	14 (33.3%)	**100 (77-100)**
Bi + A + Rifa + VPZ	6 (14.3%)	**100 (54-100)**
A + L + VPZ	5 (11.9%)	60 (15-95)
Bi + M + T + PPI	2 (4.8%)	**100 (16-100)**
Other (6 different)	15 (36%)	-
Fifth-line and + (n = 14)		
A + VPZ	6 (42.9%)	**100 (54-100)**
Other (8 different)	8 (57.1%)	

Cases excluded due to drug allergy: 10 (*) and 2 cases (**)

PPI–proton pump inhibitor, C–clarithromycin, A–amoxicillin, L-levofloxacin, Bi–bismuth salts, VPZ-vonoprazan, T-tetracycline, M-metronidazole, Dox-Doxycycline, Rifa-Rifabutin
CI - Confidence interval, mITT - Modified Intention-to-treat