RESULTS: The GEMINI LDTs de novo cohort included 421 patients (UC 190; CD 231) with a mean disease duration of 8.7 (UC) and 10.6 (CD) years, 6.0 mean partial Mayo Score (UC) and 11.1 mean Harvey-Bradshaw Index; 61% of patients with UC and 74% with CD had prior anti-TNF failure. Up to 5 years follow-up, 276 patients (68%) total discontinued VDZ. 18% with UC and 17% with CD due to AEs, and 24% with UC and 33% with CD due to lack of efficacy. Survival probabilities for VDZ treatment persistence at 54 months were 53% for UC and 41% for CD. These VDZ 54-month survival probabilities were higher in patients with VDZ treatment response at Week 12 vs without (UC, 60% vs 26%, respectively, P < 0.0001; CD, 42% vs 53%, respectively, P = 0.001) and in patients without prior anti-TNF failure vs with (UC, 43% vs 47%, respectively, P = 0.046; CD, 47% vs 42%, respectively, P = 0.016). Among patients with baseline anti-TNF failure, survival probabilities for VDZ treatment persistence at 54 months were higher in UC patients who were secondary nonresponders vs those who were primary nonresponders (65% vs 13%, respectively, P < 0.0001); this difference was not observed in CD patients (50% vs 40%, respectively, P = 0.573). There were no differences in survival probabilities of continuing VDZ at 54 months among patients with UC or CD who initiated VDZ therapy with vs without any concomitant medications.

CONCLUSION(S): More than half of patients with UC and 4 of every 10 patients with CD persisted on VDZ for 54 months. Treatment persistence rates in UC and CD cohorts were significantly higher in Week 12 responders and patients without prior anti-TNF failure, whereas there were no differences in persistence rates with baseline use of concomitant medications. Vedolizumab discontinuation rates due to AEs were low. These findings from GEMINI LSTS support the long-term effectiveness and safety of VDZ in patients with moderately to severely active UC and CD.

METHODS: Male Wistar Han/sub rats (200-300 g) were divided into five groups: SAL (non-colitic control), SAL + TNBS (colitic control), IND3 + TNBS (colitic test), IND10 + TNBS (colitic test) and IND30 + TNBS (colitic test). After a ketamine (50 mg/kg) and xylazine (10 mg/kg) anesthesia, the SAL + TNBS and IND + TNBS groups received a single dose of TNBS (10 mg) dissolved in 0.25 mL of 50% ethanol (v/v) by rectal application. The SAL group rectally received 0.25 mL of physiological saline. The physiological saline (10 mL/kg) and Indigo (3, 10 and 30 mg/kg) were administered 72, 48, 24, and 2 hours before and 24 hours after colitis induction by gavage. Animals were euthanized by cervical dislocation (under halothane anesthesia) 48 h after induction inflammation, and colons were removed for measuring the macroscopic inflammation, the weight/length ratio of colon, and the COX-1, COX-2 and nuclear factor-kappa B expressions, as well as for quantifying IL-10 by ELISA. The occurrence of adhesions (score 0-2) and/or diarrhea (score 0-1) was also evaluated. Data are expressed as median (minimum-maximum) or mean ± SEM. Statistical analysis: Kruskal-Wallis test, followed by Dunn or one-way ANOVA, followed by Tukey. The experiments were approved by the Ethics Commission in Animal Use - CEUA/Unisamp (CEUA number 2399-1).

RESULTS: The TNBS group was characterized by increased colonic wall thickness, edema and diffuse inflammatory cell infiltration. In contrast, the Indigo (3 mg/kg) treatment significantly reduced the macroscopic inflammation score (P-value less than 0.005) and reduced the histological damage promoted by TNBS treatment. Indigo (30 mg/kg) prevented the increase in the weight/length ratio of the rat colon (as an indicator of inflammation; P-value less than 0.001), but did not prevent the presence of adhesions to adjacent organs and diarrhea. COX-1 expressions remained unchanged in all groups, indicating that COX-1 protein was constitutively expressed in the colonic tissue and was not significantly changed after TNBS induction or in the presence of Indigo treatment. On the other hand, COX-2 protein was significantly increased by the hapten, indicating that the inducible isoenzyme expression could be induced at the early stage of colonic lesion caused by TNBS. Nonetheless, further analysis did not reveal a decrease in Indigo expression or COX-2 expression. Nuclear factor-kappa B expression was higher in the SAL + TNBS group, which was not prevented after treatment with Indigo. Colon damage caused by TNBS treatment was also characterized by a decrease in the level of anti-inflammatory cytokine IL-10 compared to the SAL group treatment with Indigo (3 mg/kg) did not prevent this reduction.

CONCLUSION(S): Indigo decreased the macroscopic inflammation score and decreased weight/length ratio of the colon. Indigo action on colitis should mainly involve inhibiting or reducing the release of inflammatory mediators such as COX-2. These results suggest a potential role of Indigo in colitis therapy.

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Online Feedback: Perceptions About Family Planning in Men and Women With IBD in Brazil

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BACKGROUND: Inflammatory Bowel Disease (IBD) predominantly affects young and reproductive age patients. Fears that IBD itself and/or its medication may inadvertently affect stroke, pregnancy outcome and lactation safety are significant concerns for IBD patients. Myths and lack of proper education can make patients voluntarily choose not to have children, stop treatment during pregnancy and refuse lactation. The voluntary lack of children and the constitution of smaller families has been observed and reported in IBD. There is a lack of studies on the perceptions of patients in this scenario in Brazil. The objective was to evaluate what are the perceptions about family planning in men and women with inflammatory bowel disease.

METHODS: This prospective study was conducted by a self-completed cross-sectional online questionnaire answered by 951 female and male IBD patients over 18 years of age throughout Brazil in 2019 for 10 weeks.

RESULTS: A total of 951 patients answered the questionnaire, 80% (761) of the questionnaires were usable. The respondent population was 76.34% female, of these 76.38% aged between 18 and 38 years old; 69.67% were diagnosed with Crohn’s disease, 27.96% ulcerative colitis and 2.37% indeterminate colitis. In both genders, female and male consecutively, 49.14/42.48% were using contraception, 30.77/28.78% did not consider having one child, 30.77/28.78%, the disease disrupted family planning, 67.08/70.37% did not consider having more children, 73.22/87.56% reported that their doctors never addressed family planning during treatment and 43.73/13.81% proactively approached the issue with their doctors.

CONCLUSION(S): It can be seen from the data presented that the theme of family planning is little explored by both doctors and patients, and that inflammatory bowel disease can influence family planning with regard to not having children or considering having more children.

What Are the Biggest Concerns About Family Planning in Female and Male Perception?

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BACKGROUND: The GEMINI LSTS support the longer-term effectiveness and safety of VDZ in patients with moderately to severely active UC and CD. The objectives were to evaluate the effect of Indigo in experimental ulcerative colitis. Indigo is a bis-indolic alkaloid that has antitumorogenic, antioxidant and anti-inflammatory activities.