

C-4

Real-World Effectiveness of Telotristat Ethyl among Patients with Mild Baseline Diarrhea

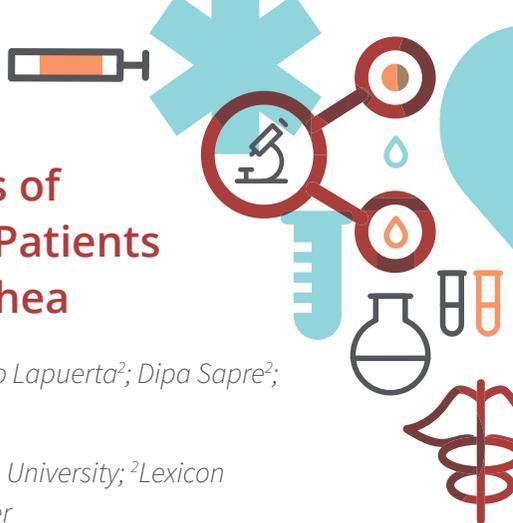
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BACKGROUND: Clinical trials demonstrated the efficacy of telotristat ethyl (TE) in patients with carcinoid syndrome (CS) with ≥ 4 and < 4 daily bowel movements (BM). This subgroup analysis of the TELEPRO study evaluated the real-world effectiveness of TE in patients reporting < 4 daily BM at baseline.

METHODS: Design and methodology of TELEPRO have been published elsewhere. Patients initiating TE between March–November 2017 who participated in a nurse support program collecting symptom-related data at initiation and at least one follow-up month up to 3 months were included. Pre/post t-tests assessed CS symptom changes from TE initiation through 3 months in a subgroup of patients reporting < 4 BM/day at TE initiation using last observation carried forward for missing values.

RESULTS: Approximately 20% (n=68) of patients participating in the nurse support program reported < 4 BM/day at baseline. Demographic and clinical characteristics were similar between patients reporting < 4 and ≥ 4 daily BM, respectively: 50% and 57% female; 6.0 and 5.5 mean years since CS diagnosis; 68% and 64% receiving long-acting somatostatin analog (SSA) therapy but three times higher SSA rescue use (18% vs 6%). CS symptom burden at baseline in patients with < 4 BM/day were as follows: BM/day (2.4 \pm 0.7) mean urgency (28.7 \pm 33.2), stool consistency (5.5 \pm 1.8), abdominal pain (22.5 \pm 26.6), nausea severity (50.7 \pm 28.4), flushing episodes/day (3.6 \pm 4.3). At the end of Month 3, patients experienced significant ($p < 0.05$) improvements in urgency (-13.2), stool consistency (-1.3), abdominal pain (-13.7), nausea (-30.9), and flushing episodes/day (-1.7). Improvements in mean BM/day frequency from baseline were minimal



(-0.2, $p=0.12$), however 30% ($n=21$) of patients reported $\geq 30\%$ reduction, a meaningful reduction to patients reported elsewhere.

CONCLUSION: Patients with mild CS diarrhea exhibited improvements in CS symptoms from treatment with TE. Addressing the burden of CS diarrhea beyond BM frequency such as stool consistency and urgency including other concomitant CS symptoms may be warranted.