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Xermelo Patient Registry: Improvements in Clinical Outcomes, Patient Satisfaction, and Weight with Telotristat Ethyl in the Real-World

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BACKGROUND: This ongoing registry evaluates clinical and patient-reported outcomes in a larger cohort of patients receiving telotristat ethyl (TE) for carcinoid syndrome (CS) diarrhea over a longer duration of treatment than observed in clinical trials.

METHODS: The RELAX registry offers online surveys to patients with CS when they initiate TE and every 6 months for up to 3 years. Baseline assessments include demographic and clinical characteristics and satisfaction with current treatment before starting TE. Follow-up assessments include overall and specific CS symptom control, patient global impression of change (PGIC), weight change, TE treatment satisfaction, and somatostatin analog (SSA) use. Demographic, clinical characteristics and 6-month treatment satisfaction and clinical outcomes were evaluated using descriptive statistics.

RESULTS: This cohort included 109 patients who initiated TE (baseline) and 51 patients with 6-month follow-up data. Mean (SD) age was 60.9 (11.1); 5.3 (4.5) years since CS diagnosis; 56% female; 66% primary tumor in small intestine. Background treatment included SSA, radionuclide therapy, chemotherapy, radiation, and embolization. Overall, patients reported improved CS symptoms and increased satisfaction with CS treatment after 6 months of TE (Table). The majority of patients reported reductions in daily bowel movements (41/51, 80%) and 75% (95% CI 63–87%) showed weight gain or maintenance over 6 months

of TE treatment, a clinically relevant indicator of health for patients with CS. Use of short-acting SSA rescue therapy and long-acting SSA decreased or stayed the same for nearly all patients (Table).

CONCLUSION: These findings are consistent with previous demonstrations of the effectiveness of TE. Improvement in clinical outcomes despite diverse treatment histories, including maintenance of weight and background SSA therapy, together with patient satisfaction suggest benefits of TE in clinical practice.

Table 1. Baseline Characteristics and 6-month Outcomes

	Baseline, SSA only (n=109)	6 Months, TE (n=51)
CS symptom control, somewhat or very satisfied, n (%)	41 (38)	36 (71)
Diarrhea control, somewhat or very satisfied, n (%)	33 (30)	39 (77)
Flushing control, somewhat or very satisfied, n (%)	44 (40)	21/42 (50)
Weight maintenance or gain; weight gain, n (%)	–	38 (75); 11 (22)
PGIC – CS symptoms somewhat/much/very much improved, n (%)	–	38 (75)
PGIC – CS symptoms (1–7), mean (SD); median	–	5.1 (1.3); 5.0
Short-acting SSA use, less frequent or about the same, n (%)	–	34/42 (81)
Long-acting SSA dose, decreased or stayed the same, n (%)	–	49 (96)
Long-acting SSA frequency, decreased or stayed the same, n (%)	–	47/50 (94)