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Patient-Reported Symptom Burden of Carcinoid Syndrome Diarrhea Inadequately Controlled by Somatostatin Analog Therapy

TAP TO GO BACK TO KIOSK MENU

Jonathan Strosberg[1], Vijay N. Joish[2], Chad McKee[2], Susan Giacalone[2], Raul Perez-Olle[2], Ann Fish-Steagall[3], Kanika Kapoor[4], Sam Dharba[5], Al B. Benson[6]

[1]Moffitt Cancer Center, Tampa, FL, USA;[2]Lexicon Pharmaceuticals, Inc., The Woodlands, TX, USA; [3]Biologics McKesson Inc., Raleigh, NC, USA; [4]Diplomat, Flint, MI, USA; [5]Datawave Solutions, Cranbury, NJ, USA; [6]Feinberg School of Medicine, Northwestern University, Chicago, IL, USA

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Table 1

Table 2

Background

- Patients with carcinoid syndrome may continue to experience increased bowel movement frequency even after treatment with somatostatin analog (SSA) therapy[1]
- Telotristat ethyl (TE) is indicated for the treatment of carcinoid syndrome diarrhea (CSD) in combination with SSA therapy in adults inadequately controlled by SSA therapy[2]
- The objective of this study was to evaluate changes in patient-reported CSD symptoms after initiating TE in clinical practice

This presentation reports baseline characteristics and symptom burden in participating patients with CS inadequately controlled with SSA therapy.

Methods

- Patients initiating TE between March and November 2017 were invited to participate in a nurse support program
- Participating patients provided CS symptom burden prior to TE initiation (baseline) and at the end of months 1, 2, and 3 by telephone interview
- Demographic (e.g., age, sex, insurance) and clinical characteristics (e.g., background treatment, frequency and dose of SSA) were collected at baseline
- Patient-reported CS symptoms included:
  - daily bowel movement (BM) frequency
  - flushing episodes frequency
  - stool form on a scale of 1 (“very hard”) to 10 (“watery”)
  - nausea
  - urgency and abdominal pain on a scale of 0 (“no/not at all”) to 100 (“worse imaginable/very urgent”)
  - functional status using the ECOG score (0 to 4)
- Summary statistics were used to describe patient-reported symptom burden prior to initiating TE

Results

- 791 CSD patients opted in to the TE nurse support program
- On enrollment, median age was 65 years, 55% of patients were females, and 42% and 37% had commercial or Medicare insurance, respectively (Table 1)
- CSD patients had been diagnosed with CS for an average of 6.0 ± 5.8 years
- Most patients (88%, n=697) reported using long-acting SSA (70% octreotide, 30% lanreotide) and 8% (n=63) reported using short-acting octreotide (Table 1)
  - Mean octreotide LAR and lanreotide doses reported were 41 ± 25.6mg and 117 ± 27.3 mg, respectively
- Patient-reported CS symptom burden and functional status are provided in Table 2

Table 1. Baseline demographic and clinical characteristics

Characteristic	Participants (N = 791)
Sex, n (%)	
Female	433 (54.7)
Male	358 (45.3)
Age, median (IQR)	65.5 (58-90)
Primary Insurance, n (%)	
Commercial	336 (42.5)
Medicare	292 (36.9)
Cash	48 (6.1)
Tricare/VHA	34 (4.3)
Medicaid	30 (3.79)
Other or Unknown	51 (6.4)
Time since CS diagnosis, years, mean (SD)	6.0 (5.8)

IQR, interquartile range; CS, carcinoid syndrome; SD, standard deviation; BM, bowel movements.

Somatostatin Analog Use	Participants (N = 791)
Short-acting SSA therapy (octreotide IR), n (%)	**63 (8.0)**
≥ 2 times/day	24 (38.1)
Daily	5 (7.9)
Weekly	1 (1.6)
Monthly	14 (22.2)
Continuously	2 (3.2)
As needed	16 (2.5)
Varies	1 (1.6)
Long-acting SSA therapy (SSA LAR), n (%)	**697 (88.1)**
Lanreotide	206 (29.6)
Octreotide	491 (70.4)

Frequency of LAR therapy	Lanreotide (n = 206)	Octreotide (n = 491)
Weekly	0	1 (0.2)
Every 2 weeks	6 (2.9)	21 (4.3)
Every 3 weeks	10 (4.9)	64 (13.0)
Monthly (every 4 weeks)	186 (90.3)	396 (80.7)
Unknown or missing	4 (1.9)	9 (1.8)

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Table 2. Patient-reported CS symptom burden and functional status

Patient-reported CS symptoms	Mean (SD)	Min – Max	Survey Responses n (%)
Diarrhea Symptoms			
BM per day	6.3 (3.47)	1 – 30	770 (97%)
Stool Form	6.7 (2.02)	1 – 10	777 (98%)
Urgency	29.7 (34.59)	1 – 100	744 (94%)
Nausea	39.4 (26.29)	1 – 100	144 (18%)
Abdominal Pain	19.7 (25.41)	1 – 100	527 (67%)
Flushing per day	2.9 (3.13)	1 – 30	631 (80%)
Functional status (ECOG)	1.4 (0.65)	0 – 4	650 (82%)

CS, carcinoid syndrome; SD, standard deviation; BM, bowel movements.

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Conclusions

- Prior to initiating TE, CSD patients inadequately controlled by SSA therapy had significant CS symptom burden
- Future analyses will evaluate the real-world patient-reported effectiveness of TE over the first three months of treatment

References
1. Kulke et al. *JCO 2017;35(1): DOI:*10.1200/JCO.2016.69.2780
2. Xermelo PI; September 2017. PP-LX1606-US-0205

Disclosures
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Presented at the NANETS Annual Multidisciplinary NET Disease Symposium, October 4-6, 2018, Seattle, WA

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*Reported as number of events/episodes per day
†Reported on a scale of 1 “very hard” to 10 “watery”
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