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Real-World Evidence of Lenvatinib Use for Treatment of Metastatic Neuroendocrine Neoplasms

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BACKGROUND

Metastatic neuroendocrine neoplasms (NENs) constitute a heterogeneous group of incurable cancers with limited treatment options. Lenvatinib is an oral multiple kinase inhibitor that showed activity in gastroenteropancreatic neuroendocrine tumors in the phase II Talent Trial at a starting dose of 24 mg per day. Although a confirmatory phase III study was never conducted, the drug is available for use off-label.

METHODS

We retrospectively reviewed real-world data from patients with metastatic NENs treated with lenvatinib via compassionate use in British Columbia and Ontario, Canada. Descriptive statistics and Kaplan-Meier curves were used to summarize baseline characteristics and outcomes.

RESULTS

From January 2019 to June 2023, 32 patients with metastatic NENs were treated with lenvatinib. Patient characteristics are shown in Table 1. The median prior lines of systemic therapy were 2.5 (range 1-5). Median initial, maximal, and minimal doses (mg) were 12 (range 4-24), 12 (range 8-24), and 8 (range 4-24). The median progression-free survival was 10 months (95% CI, 7.3-12.7) and median overall survival was 18 months (95% CI, 9.9-26.1). Of the 29 (91%) patients who had response assessment, 6 (21%) experienced some tumor burden response, 19 (66%) had tumor stabilization, and 4 (14%) had an increase as the best response. RECIST evaluation will be assessed in the future. The most frequent all-grade side effects reported were hypertension (59%), fatigue (38%), hypothyroidism (22%), diarrhea (19%), hand-foot syndrome (12%), mucositis (12%), and proteinuria (9%). Dose reductions were reported in 11 (34%) patients and treatment interruptions or discontinuation due to toxicity in 7 (22%) and 5 (16%), respectively.

Table 1 – Patient Characteristics at Baseline (N=32)

Median Age, years (range)	56 (34-81)
ECOG PS No. (%): 0-1 vs.2 vs. 3	28 (87.5) vs. 3 (9.4) vs. 1 (3.1)
Primary Site No. (%): Pancreas vs. Small Intestine vs. Other	16 (50.0) vs. 11 (34.3) vs. 5 (15.6)
WHO Differentiation No. (%): Well-differentiated: G1 vs G2 vs G3 Poorly differentiated	3 (9.4) vs. 22 (68.8) vs. 5 (15.6) 2 (6.3)
Functional Status No. (%): Functional vs Non-functional	15 (46.9) vs. 17 (53.1)
Prior Systemic Treatment No. (%)	32 (100.0)
Somatostatin Analogue	27 (84.4)
Chemotherapy; Targeted Therapy	27 (84.4); 17 (53.1)
PRRT	11 (34.4)

CONCLUSIONS

This real-world cohort demonstrates encouraging evidence of lenvatinib activity in pre-treated metastatic NENs even when used on a more heterogeneous population and at a reduced dose compared to the TALENT trial. The toxicity profile was consistent with prior reports with lenvatinib.

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