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Effectiveness and Safety of Re-Treatment with ¹⁷⁷Lu-DOTATATE in Patients With Progressive NETs in the US: a Retrospective Real-World Study

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BACKGROUND

Advanced neuroendocrine tumors (NETs) are associated with poor prognoses. A 4-dose regimen of lutetium Lu 177 (¹⁷⁷Lu)-DOTATATE has been shown to improve progression-free survival (PFS) and overall survival (OS) in patients with advanced NETs. This is the first United States (US) study to evaluate the effectiveness and safety of additional doses in patients with progressive NETs.

METHODS

This was a retrospective chart review of 31 adults with advanced NETs who underwent initial treatment with ≤ 4 doses of ¹⁷⁷Lu-DOTATATE and who, following disease progression and a period of ≥ 6 months since the end of initial treatment, were re-treated with ≥ 1 additional dose at a single US center (2010–2020). Patient characteristics, treatment patterns, and clinical outcomes were evaluated descriptively. Response was evaluated per RECIST 1.1; toxicity was defined using CTCAE 5.0 criteria. Kaplan–Meier plots were used to evaluate PFS and OS.

RESULTS

Of the 31 patients who received ¹⁷⁷Lu-DOTATATE re-treatment, 19 (61%) were male and 29 (94%) were white. Overall, patients received a median of 6 doses (4 initial and 2 re-treatment doses). Mean \pm sd administered activity was 41.9 \pm 4.4 GBq. Two patients received additional re-treatment (1 and 2 doses, respectively) following a second period of ≥ 6 months and progression after re-treatment. Best responses of partial response and stable disease were observed in 11 (35%) and 20 (65%) patients after initial treatment and 7 (23%) and 14 (45%) patients after re-treatment (**Table**). Median PFS was 20.2 and 9.6 months after initial and re-treatment, respectively; median OS was 42.6 and 12.6 months. Hematological parameters decreased significantly during both initial and re-treatment but recovered, with no significant difference between the values, prior to initial treatment and re-treatment. Clinically significant hematotoxicity occurred in 1 and 3 patients following initial and re-treatment, respectively. No grade 3/4 nephrotoxicity (based on creatinine levels) was observed.

CONCLUSIONS

Re-treatment with ¹⁷⁷Lu-DOTATATE after progression appeared to be well tolerated and offered disease control in patients with progressive NETs following initial ¹⁷⁷Lu-DOTATATE treatment.

Table. Summary of Efficacy and Safety Outcomes

Outcome	Initial Treatment (N=31)	Re-treatment (N=31)
Response, n (%)		
Complete response	0	0
Partial response	11 (35%)	7 (23%)
Stable disease	20 (65%)	14 (45%)
Progressive disease	0	3 (10%)
Unknown	0	7 (23%)
Median PFS, months (95% CI)	20.2 (13.5–25.8)	9.6 (5.5–16.2)
Median OS, months (95% CI)	42.6 (31.2–53.8)	12.6 (9.6–18.9)
Grade 3/4 hematotoxicity (Including leukopenia, neutropenia, and thrombocytopenia), n (%)	1 (3%)	3 (10%)

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