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Retreatment With 177Lu-DOTATATE in Well-Differentiated Neuroendocrine Tumors: Interim Analysis of a Multicenter Registry

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BACKGROUND

177Lu-DOTATATE is an established peptide receptor radionuclide therapy (PRRT) for somatostatin receptor (SSTR)-positive, well-differentiated neuroendocrine tumors (WDNETs). In patients with clinical benefit from an initial course of 177Lu-DOTATATE, retreatment (rePRRT) is increasingly utilized at disease progression; however, data guiding patient selection remain limited. We present an interim analysis of rePRRT outcomes from a multicenter US registry.

METHODS

We analyzed data from 543 patients with WDNETs; 98 (18%) underwent rePRRT. Patient demographics, tumor characteristics, toxicity, radiographic response (by clinical report), PFS (time from rePRRT initiation to progression/death) were evaluated.

RESULTS

Median age 56 years. Tumor grade: 1 (n=29, 30%), 2 (n=51, 52%), 3 (n=10, 10%), unknown n=8, 8%). Primary site of origin: pancreas (n=40, 41%), small bowel (n=28, 29%), bronchial (n=6, 6%), rectal (n=5, 5%), gastric (n=2, 2%), other (n=7, 7%), unknown (n=10, 10%). Patients received a mean of 2.4 rePRRT cycles (1 cycle, n=25; 2 cycles, n=31; 3 cycles, n=15; 4 cycles, n=27).

47/98 patients (48%) experienced a TRAE during rePRRT, most commonly hematologic toxicities (n=39, 83%; grade >3 in one patient (1%)). Sixteen patients (16%) experienced leukopenia (15 grade 1/2; 1 grade 3), 17 patients (17%) experienced grade 1/2 anemia, 24 patients (24%) experienced grade 1/2 thrombocytopenia. One patient developed therapy-related MDS (3 initial PRRT followed by 2 rePRRT; total cumulative activity 996.7 mCi); this patient presented with new onset leukocytosis, prompting further workup. MDS developed 4.6 months after last rePRRT dose.

In the 77 patients with radiographic response data, best response to rePRRT was: CR (2 patients, 3%), PR (19 patients, 25%), SD (45 patients, 58%), PD (11 patients, 14%); disease

control rate (86%). Median re-PRRT PFS was 14.2 months (95% CI 13.0-21.1 months). Median PFS after initial PRRT was 25.5 months (95% CI 21.8-31.4 months). Stratification by initial PRRT median PFS demonstrated a significant difference in rePRRT outcomes: patients with initial PFS >25.5 months achieved a median rePRRT PFS of 22.2 months (95% CI 13.4-29.0 months), compared with 13.1 months (95% CI 10.7 - 16.0 months) for those with initial PFS ≤25.5 months (p=0.005).

CONCLUSIONS

In this interim analysis of the largest US multicenter rePRRT cohort reported to date (n=98), rePRRT demonstrated a disease control rate of 86% with a favorable safety profile (grade >3 TRAEs 1%). PFS after initial 177Lu-DOTATATE was significantly associated with rePRRT PFS, suggesting that first-line treatment duration may be a clinically useful predictor for rePRRT patient selection.

ABSTRACT ID #36552