

C-36

Radiographic Predictors of Response to ¹⁷⁷Lu-DOTATATE

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BACKGROUND: Peptide receptor radionuclide therapy with ¹⁷⁷Lu-DOTATATE was recently approved to treat somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (NETs). The precise role of ¹⁷⁷Lu-DOTATE in the evolving NET treatment landscape is unclear, so there is value in early identification of patients most likely to benefit. We investigated whether maximum standardized uptake value (SUVmax) or mid-treatment imaging predicted response to ¹⁷⁷Lu-DOTATATE.

METHODS: We identified patients at UCSF who received ¹⁷⁷Lu-DOTATATE through the expanded access protocol (N=18, age 59±13 years, 44% male, 78% midgut). This was an open-label trial (NCT02705313) for patients with inoperable, well-differentiated NETs progressing despite somatostatin analog therapy. Patients received up to 4 cycles of ¹⁷⁷Lu-DOTATATE and underwent restaging CT or MRI scans mid-treatment after 2 cycles, following completion of therapy, and then per routine clinical follow-up. We determined SUVmax for the 16 patients with baseline ⁶⁸Ga-DOTATATE/TOC PET scans. Overall response rate (ORR) was determined using RECIST 1.1 criteria. Spearman correlations were used to determine associations between continuous variables.

RESULTS: We observed high baseline ⁶⁸Ga-DOTA-TATE/TOC uptake in this population, with a median SUVmax of 28±18. The ORR following therapy completion was low (6%), but most patients achieved at least stable disease (83%). We found a strong association between the percentage changes in tumor size on the mid-treatment scan and the scan performed immediately following

therapy completion (Spearman rho 0.92, $p < 0.001$). There was also a strong association between the percentage changes in tumor size on the mid-treatment scan and last follow-up scan (rho 0.82, $p = 0.002$). Patients with higher baseline SUVmax tended to have more disease shrinkage on the last follow-up scans, although not significantly so (rho -0.45, $p = 0.17$).

CONCLUSION: The response to ^{177}Lu -DOTATATE on mid-treatment scan was strongly correlated with treatment response on subsequent scans. Further investigation in larger studies is merited to determine whether baseline SUVmax predicts treatment response.

Table 1:

Percentage Change in Target Lesion Size with Treatment for Patients with Progressive Disease

Subject ID	Mid-Treatment Scan	Post-Treatment Scan	Last Follow-Up Scan
8	+31.8%	+31.1%	+30.5%
9	+51.0%	NA	NA
15	+20.2%	+20.2%	+15.7%

Individual patient-level response data are shown for the patients (N=3) with progressive disease. Each of these patients had already progressed at the time of their mid-treatment scan. Subject 9 died from rapidly progressive disease shortly after completing 2 cycles of therapy. In contrast, patients who had either stable disease or a partial response (N=15) had median percentage change in tumor size of 0.0%, -4.0%, and -17.7% at mid-treatment, post-treatment, and last follow-up scans, respectively. NA, not available.