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Efficacy and Toxicity Analysis of Capecitabine and Temozolomide in Neuroendocrine Neoplasms

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BACKGROUND: The capecitabine/temozolomide regimen has significant activity in advanced NETs. Questions exist regarding activity in pancreatic vs. non-pancreatic NETs, risk of opportunistic infections, long-term myelotoxicity, and safety of prolonged treatment duration. Analysis of large patient cohorts is needed for the evaluation of rare toxicities and assessment of risk factors.

METHODS: Retrospective study of all patients with advanced NETs seen at Moffitt Cancer Center between 1/2008 and 6/2019 treated with CAPTEM.

RESULTS: 462 patients met eligibility criteria for evaluation. ORR was 46% and DCR was 81%. Median PFS was 16 months (95% CI, 12.4 – 19.6 months), and median OS was 51 months (95% CI, 42.8 – 59.2): 62 months in well-differentiated NETs vs. 14 months in poorly-differentiated NECs ($p < 0.0001$). Patients with primary pancreatic tumors had the highest PR rates and longest median PFS. Patients with grades 1, 2, and 3 tumors had a median OS of 81 months, 57 months, and 23 months respectively ($p < 0.0001$). Incidences of grade 4 thrombocytopenia and neutropenia were 7% and 3% respectively: substantially higher in females vs. males ($p=0.02$ and $p=0.004$, respectively). Only one case (0.2%) of suspected PCP was observed in a patient taking corticosteroids. Three patients developed myelodysplastic disease, all of whom had also received prior PRRT with ^{177}Lu-Dotatate. There were no acute treatment-related deaths, although one patient died 2 months after a thrombocytopenic bleed.

CONCLUSION: The CAPTEM regimen is exceptionally safe, with a treatment-associated mortality rate of 0.2%. Efficacy is particularly robust in well-differentiated pancreatic NETs.

Severe myelotoxicity is rare, but risks of grade 4 thrombocytopenia and neutropenia are significantly increased in females: gender-based dosing should be considered. There were no cases of MDS except among patients who also had received PRRT, a known risk factor. Risk of PCP is negligible.

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