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Multicenter Phase 2 Trial of Yttrium-90 Radioembolization with Capecitabine-Temozolomide for Grade 2 Liver-Dominant Metastatic Neuroendocrine Tumors: interim report

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BACKGROUND

Capecitabine and temozolomide (CapTem) are classic radiosensitizers used in combination with radiation therapy for many cancers. A feasibility study of integrated CapTem and Y90 transarterial radioembolization (TARE) for Grade 2 neuroendocrine tumors (NETs) demonstrated tolerance and suggested synergy with PFS of 36 months. This multicenter phase 2 study was initiated to estimate the efficacy of this regimen.

METHODS

Patients with hepatic dominant well-differentiated Grade 2 NET were treated with capecitabine 600 mg/m² twice daily for 14 days and temozolomide 150-200 mg/m² in 2 divided doses on day 10-14 (CapTem regimen), with 14 days between cycles. Simulation angiography with Tc99m-MAA SPECT was performed in the first cycle of CapTem. The dominant lobe was treated on day 7 of the second cycle. Resin Y90 microspheres (SIR-Spheres; Sirtex Medical) were administered using the body surface area method. For bilobar disease, the other lobe was treated in the third or fourth cycle. CapTem is continued until progression or intolerance. Clinical and laboratory assessment are done monthly while on chemotherapy. Imaging is performed every 3 months for 2 years.

RESULTS

Planned accrual of 50 patients at 4 centers was completed between 2022-2025. All patients completed their planned cycle of radioembolization while on CapTem. Median duration on CapTem was 12 months (range 4-16 mo) with 17 patients still on treatment. There have been four grade 4 cytopenias, leading to CapTem hold and dose reduction. Grade 3 toxicities include hematologic (13), GI (6), mucositis (1) and PPE (1).

CONCLUSIONS

Integrated CapTem chemotherapy and radioembolization showed acceptable toxicity, not greater than expected in this cohort of Grade 2 NET patients. Assessment of response and PFS is ongoing.

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