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## Phase II Study of Sunitinib Following Hepatic Artery Embolization for Metastatic Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

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**Background:** Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) frequently metastasize to the liver. Hepatic artery embolization is an important therapeutic modality in patients with liver-predominant metastases. NETs are highly vascular and are known to express both VEGF and VEGFR. We hypothesize that administration of sunitinib malate, a VEGFR inhibitor, following hepatic artery embolizaiton will delay tumor revascularization and extend progression-free survival.

**Methods:** Patients with differentiated GEP-NETs metastasized to the liver underwent a series of selective arterial embolizations followed by sunitinib (one week after each embolization, and continued until disease progression or up to a maximum of 8 cycles). Radiographic response rates were assessed by RECIST criteria.

**Results:** Fourteen patients have been enrolled to date. Primary tumor sites include the small-intestine (11), rectum (2), and pancreas (1). The initial starting dose of sunitinib was 50mg, however all five patients enrolled at this dose required dose reductions. Consequently, the starting dose was reduced to 37.5mg resulting in improved tolerance. Nine patients (64%) had a partial radiographic response (PR), four patients (28%) had stable disease (SD) and one patient (7%) had progressive disease (PD) as best response. At a median follow-up of 8 months, progression-free survival (PFS) is 79%. Seven grade 3 toxicity events were reported in six patients. Serum VEGF levels increased by an average of 107pg/ml (88%) after embolizations.

**Conclusions:** Hepatic artery embolization is a highly active treatment option for patients with metastatic GEP-NETs. Embolization stimulates release of VEGF into the circulation. Sunitinib can be safely administered following hepatic artery embolization at a dose of 37.5mg. Longer follow-up is needed to assess whether this strategy results in prolonged time to tumor progression.