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## Phase II study of sunitinib malate following hepatic artery embolization for metastatic neuroendocrine tumors

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

**Methods:** Patients with metastatic neuroendocrine tumors 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. PFS and OS were calculated using Kaplan-Meier methodology.

**Results:** 39 patients with metastatic NETs were enrolled. Primary tumor sites included the small intestine (26), pancreas (10), rectum (2) and lung (1). The initial starting dose of sunitinib was 50 mg, however all five patients enrolled at this dose required dose reductions, and the starting dose was subsequently lowered to 37.5 mg. The majority of patients required further dose reductions to 25mg. Twenty eight patients (72%) experienced a partial radiographic response (PR), eight patients (20%) had stable disease and three patients (8%) had progressive disease as their best response. Median PFS was 18 months and the rate of 1-year PFS was 72%. The rates of overall survival (OS) at one-year and two-years were 94% and 78%. Serum VEGF levels increased by an average of 51pg/ml (34%) after embolization.

**Conclusions:** Hepatic artery embolization is a highly active treatment option for patients with metastatic neuroendocrine tumors to the liver. Embolization stimulates release of VEGF into

the circulation. Sunitinib can be administered following hepatic artery embolization. The high rates of progression-free survival and overall survival associated with this sequence of therapies are encouraging.