

Prospective, phase II study of chemoembolization with drug-eluting beads for hepatic neuroendocrine metastases: interim analysis

Purpose

To evaluate safety and efficacy of transarterial chemoembolization (TACE) with doxorubicin eluting beads (DEBs) in 30 patients with hepatic neuroendocrine metastases (NET) in a prospective, phase II study. Herein, we report analysis of initial 10 patients.

Material and Methods

Patients who met inclusion criteria (Child-Pugh:A-B, ECOG:0-1, treatment naïve) underwent up to 4 DEB-TACE sessions (100-300micron beads loaded with up to 100mg of doxorubicin). Statistical plan included interim analysis of initial 10 patients to assess therapeutic efficacy (defined as objective response \geq 50%). Tumor response assessed by MR imaging 1 month after treatment using contrast-enhancement (EASL) and size (RECIST). Safety assessed by NCI Common Terminology Criteria.

Results

DEB-TACE successfully performed in 10 patients (22 targeted lesions). Characteristics included mean age 65 yrs; ECOG 0/1 (6/4); carcinoid syndrome (n=2); tumor burden range (4-75%), and mean targeted tumor size 4.8 cm (range 1.2-10.2). One month follow-up (n=9), grade 3 toxicities were hyperglycemia (n=3), abdominal pain (n=3), fatigue (n=1), and elevated ALT (n=1). Bilomas (grade 2 (n=4) and grade 3 (n=1) constituted the other toxicities and occurred in small lesions or diffuse disease with low tumor burden, and single lesions \geq 5 cm. MR imaging at 1 month-follow-up showed treated lesions had a mean decrease in size of 7% (p=0.03). Using RECIST, partial response achieved in 1 patient (11%) and 8 patients (89%) had stable disease. Treated tumors demonstrated mean decrease in contrast-enhancement of 59% (p<0.0001). By EASL criteria, 7 patients (78%) had objective tumor response and 2 (12%) had stable disease.

Conclusion

Interim analysis shows therapeutic efficacy of DEB-TACE in NET. Early recommendation suggests DEB-TACE may be best suited for NET patients with multinodular disease or diffuse disease with large tumor burden.