

Chemosaturation using percutaneous hepatic perfusion: pre-embolization of GI branches in a phase 3 clinical trial

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Purpose: Chemosaturation therapy with percutaneous hepatic perfusion (CS-PHP) is a novel regional chemotherapy for non-resectable hepatic metastases that isolates the liver from the systemic circulation and allows direct infusion of drug into the liver. Pre-embolization of adjacent gastrointestinal (GI) branches may be needed to avoid inadvertent reflux of the chemotherapeutic agent into non-target vascular territories. We report on the need for, and patterns of, GI arterial branch embolization in a Phase 3 clinical study.

Materials and Methods: In a multicenter Phase 3 trial, patients (pts) were randomized to either CS-PHP with melphalan or best alternative care. Up to 6 cycles of CS-PHP were performed under general anesthesia with standard interventional radiology techniques at 4–6 week intervals. Arterial branches were embolized prior to CS-PHP infusion.

Results: 44 pts were randomized to CS-PHP and an additional 28 pts were eligible for CS-PHP at crossover. To date, angiographic records are available for 61 of 72 CS-PHP-eligible pts. 44 pts (72%) had embolizations at their first CS-PHP cycle, 6 at cycle 2 (10%) and 1 pt had a cycle 3 embolization (data missing for 6 pts). The proximal GDA and branches were the most frequently embolized vessels (47 embolizations in 43 pts [70%]), followed by right gastric (8 embolizations in 7 pts [11%]) and left gastric arteries or their branches (5 embolizations in 5 pts). Ten pts (16%) had the GDA and one or more of right (7) or left gastric (2) or replaced right hepatic (1) or extrahepatic branch of left hepatic artery embolization (3). No embolization was performed in 11/61 pts (18%). There was one complication: coil migration to the right hepatic artery (n=1). One procedure was prolonged due to tortuous hepatic artery anatomy (n=1); and one GDA procedure aborted due to venous malformations (n=1).

Conclusions: CS-PHP is a non-invasive, repeatable procedure. Pre-embolization of the adjacent gastrointestinal vasculature is an important preparatory step necessary to avoid unwanted exposure of the GI tract to chemotherapy. Pre-embolization and subsequent CS-PHP procedures offer a central role for interventional radiologists in this novel treatment for non-resectable liver metastases.

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