

A phase III random assignment trial comparing percutaneous hepatic perfusion with melphalan (PHP-mel) to standard of care for patients with hepatic metastases from metastatic ocular or cutaneous melanoma.

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Abstract:

Background: Patients with hepatic metastases from primary melanoma have a median survival between 6 and 9 months. Few treatment strategies provide a meaningful impact on outcome. This report examines the efficacy of a minimally invasive regional therapy with melphalan (MEL) in patients with hepatic metastases from malignant melanoma. **Methods:** Between February 2006 and October 2009, 93 patients (M:F; 45:48) were accrued to a phase III, random-assignment trial comparing percutaneous hepatic perfusion (PHP-mel) (n=44) to standard of care (BAC) (n=49). This represents 100% of a planned 92 patient accrual. The primary endpoint was hepatic progression-free survival (H-PFS). Crossover to PHP-mel therapy was permitted at hepatic progression. Secondary endpoints included assessment of response rate (RR), duration of response (RES), and overall survival (OS) after PHP. A planned PHP treatment regimen included 4 to 6 PHP procedures at 28 to 35 day intervals. MEL (3.0 mg/kg) was delivered via the hepatic artery in a 30-minute hepatic artery infusion via a percutaneously placed catheter with hepatic venous hemofiltration using a retrohepatic, double balloon catheter (Delcath Systems, Inc.) and paired hemofiltration cartridges. Patients randomized to BAC were offered treatment considered to be the best alternative regimen by the treating physician. Staging evaluations were performed at baseline and then at 6 to 8 week intervals post baseline. All responses represent investigator-based results and were evaluated via standard RECIST criteria. Intent to treat based survival analysis was via the Kaplan-Meier

method, with a 2-sided $p < 0.05$ defining significance. **Results:** Median H-PFS was 245 days (CI:136, 267) for PHP-mel vs. 49 days (CI:43, 68) for BAC ($p < 0.001$). Overall response rate was 34.1 % (15/44) (CI: 20.5, 49.9) for PHP (15/44) vs. 2.0 % (1/49) (CI: 0.1, 10.9) for BAC ($p < 0.001$). Upon hepatic progression, crossover to PHP occurred in 27 patients (55%) randomized to BAC. **Conclusions:** For patients with metastatic melanoma to the liver, H-PFS is significantly improved with PHP-mel versus best available care.

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Faculty & Discussant Disclosures

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