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.

Sub-category:
Melanoma

Category:
Melanoma/Skin Cancers

Meeting:
2010 ASCO Annual Meeting

Session Type and Session Title:
Oral Abstract Session, Melanoma/Skin Cancers

Abstract No:
LBA8512

Citation:
J Clin Oncol 28:18s, 2010 (suppl; abstr LBA8512)

Author(s):
J. F. Pingpank, M. S. Hughes, M. B. Faries, J. S. Zager, H. R. Alexander, R. Royal, E. D. Whitman, C. W. Nutting, G. P. Siskin, S. S. Agarwala; University of Pittsburgh, Hillman Cancer Center, Pittsburgh, PA; Surgery Branch, National Cancer Institute, Bethesda, MD; John Wayne Cancer Institute, Santa Monica, CA; H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL; University of Maryland School of Medicine, Baltimore, MD; University of Texas M. D. Anderson Cancer Center, Houston, TX; Atlantic Melanoma Center, Morristown, NJ; Radiology Imaging Associates, Englewood, CO; Albany Medical Center Hospital, Albany, NY; St. Luke's Hospital and Health Network, Bethlehem, PA

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.

**Abstract Disclosures**

**Faculty & Discussant Disclosures**

**Annual Meeting Planning Committee Disclosures**

Abstracts that were granted an exception in accordance with ASCO's Conflict of Interest Policy are designated with a caret symbol (^) here and in the printed Proceedings.

**Associated Presentation(s):**

1. 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.

Meeting: 2010 ASCO Annual Meeting  
Presenter: James F. Pingpank  
Session: Melanoma/Skin Cancers (Oral Abstract Session)

**Other Abstracts in this Sub-Category:**

1. A phase III, randomized, double-blind, multicenter study comparing monotherapy with ipilimumab or gp100 peptide vaccine and the combination in patients with previously treated, unresectable stage III or IV melanoma.

Meeting: 2010 ASCO Annual Meeting  
Abstract No: 4  
First Author: S. O'Day  
Category: Melanoma/Skin Cancers - Melanoma

2. A phase II trial of riluzole, an antagonist of metabotropic glutamate receptor 1 (GRM1) signaling, in metastatic melanoma.

Meeting: 2010 ASCO Annual Meeting  
Abstract No: TPS309  
First Author: J. M. Mehner  
Category: Melanoma/Skin Cancers - Melanoma

3. Treatment of melanoma with wild-type p53 (wt-p53) and detectable S100B using pentamidine: A phase II trial with correlative biomarker endpoints.

Meeting: 2010 ASCO Annual Meeting  
Abstract No: TPS310  
First Author: J. M. Mehner  
Category: Melanoma/Skin Cancers - Melanoma

More...
Abstracts by J. F. Pingpank:

1. 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.

Meeting: 2010 ASCO Annual Meeting  Abstract No: LBA8512  First Author: J. F. Pingpank
Category: Melanoma/Skin Cancers - Melanoma

2. Impact of high-dose melphalan (MEL) administered via hepatic arterial infusion for patients with unresectable hepatic metastases (LM) from ocular melanoma (OM).

Category: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract - Translational research

3. A pilot study of local injection of TNFerade biologic in addition to neo-adjuvant chemoradiation for the treatment of primary and recurrent rectal cancer.

Meeting: 2007 ASCO Annual Meeting  Abstract No: 14585  First Author: K. A. Camphausen
Category: Gastrointestinal (Colorectal) Cancer - Colorectal Cancer

More...

Presentations by J. F. Pingpank:

1. 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.

Meeting: 2010 ASCO Annual Meeting
Presenter: James F. Pingpank, MD, FACS
Session: Melanoma/Skin Cancers (Oral Abstract Session)

2. Impact of high-dose melphalan (MEL) administered via hepatic arterial infusion for patients with unresectable hepatic metastases (LM) from ocular melanoma (OM).

Meeting: 2008 Gastrointestinal Cancers Symposium
Presenter: James F Pingpank, MD
Session: General Poster Session B (Poster Discussion Session)

3. A phase I dose-escalation study of hepatic arterial melphalan infusion with hepatic venous hemofiltration using percutaneously placed catheters in patients with unresectable hepatic malignancies.

Meeting: 2004 Gastrointestinal Cancers Symposium
Presenter: James F Pingpank, MD
Session: Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract - General Poster Session (Poster Discussion Session)

More...

► Educational Book Manuscripts by J. F. Pingpank:

No items found.