

Purpose: Hepatic arterial infusion (HAI) combined with systemic chemotherapy is used to treat patients with advanced liver cancers in a staged operative approach. At the time of HAI pump placement, upwards of 60% of patients require ligation of aberrant hepatic arteries. We sought to characterize the safety and efficacy of portal vein embolization (PVE) for inducing liver hypertrophy in patients who underwent HAI with and without hepatic arterial ligation.

Materials and Methods: An IRB-approved retrospective review was conducted on all patients who underwent PVE between the years of 2015 and 2022, with and without preceding or subsequent HAI. Segmental liver volumes, the standardized future liver remnants (sFLR), percent volumetric changes, and the kinetic growth rates (KGR) were calculated using semi-automatic liver segmentation (IntelliSpace, Version 11.1, Philips Medical Systems, Netherlands) performed on multiphase liver computed tomography scans prior to and 4-12 weeks after PVE. The impact of hepatic artery ligation was assessed by analyzing hepatic resection outcomes following PVE.

Results: Between January 2015 and August 2022, 48 patients underwent technically successful PVE with 12 (25%) having a HAI pump as part of their operative clearance strategy. There were 9 HAI pumps (19%) placed before PVE and 3 (6%) after PVE. Among the 9 patients who underwent PVE after HAI, sFLR increased from $21.1 \pm 6.8\%$ (mean \pm std) to $34.8 \pm 6.0\%$, with KGR of $2.2 \pm 1.8\%$ (3 patients had KGRs below 2% but sFLR $>30\%$ prior to hepatectomy). Seven (78%) of these patients had hepatic artery ligation during HAI pump placement including 5 replaced right hepatic arteries and 5 accessory left hepatic arteries (4 patients required ligation of both). All patients with ligated right hepatic arteries developed robust intrahepatic left-to-right collateralization prior to PVE. Of these 9 patients, 5 (56%) proceeded to an extended right hepatectomy, 1 (11%) to a right hepatectomy. Three patients did not undergo hepatic resection due to interval development of extrahepatic disease. The median time from PVE to hepatic resection was 59 days. There were no biliary complications in the patients treated with PVE after HAI.

Conclusion: PVE to induce liver hypertrophy in sequence with HAI for patients with advanced liver cancer was not associated with increased biliary complication or compromised hepatic function. HAI with or without prior hepatic arterial ligation should not be used to exclude patients from PVE.

Abstract No. 139

■ FEATURED ABSTRACT Transarterial Chemoperfusion Treatment of Unresectable Pleural Mesothelioma: A Phase 2 Prospective Study

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Purpose: Transarterial chemoperfusion treatment selectively delivers relatively high concentration of chemotherapy to the targeted tissue's arterial bed maximizing antitumoral effect and minimizing systemic side effects. Advanced malignant pleural mesothelioma (MPM) carries a very poor prognosis. The current prospective study (ClinicalTrials.gov Identifier: NCT02611037) investigated the disease control rate, overall survival and adverse events of transarterial chemoperfusion treatment in patients with relapsed unresectable MPM.

Materials and Methods: 32 patients, 5 female and 27 males (age 71.7 ± 6.9 years), with MPM were enrolled between 3/2016-4/2021. ECOG performance status was 0 and 1 (12.5% and 87.5%, respectively). Patients had transarterial chemoperfusion treatment in every 4 weeks with cisplatin (35 mg/m^2), methotrexate (100 mg/m^2) and gemcitabine (1000 mg/m^2) via the ipsilateral internal mammary artery and/or descending thoracic aorta. All patients had received and progressed on prior chemotherapy. 5 patients also had prior radiation therapy and 3 patients had pleurectomy. The number of prior systemic chemo- and immunotherapy was 1.96 ± 1.3 (range, 1-6). Response rate was evaluated by modified RECIST for mesothelioma.

Results: At the data cutoff date (October 10, 2022) 30 of the 32 patients had died. A total of 199 chemoperfusion treatments were performed. The median number of treatments was 3/patient (range, 1-53). The disease control rate was 75% (1 PR, 23 SD, 8 PD). Median progression-free survival from the enrollment was 4.7 months (95% CI 2.5-7.4). Median OS was 8.9 months (95% CI 5.7-15). OS at 6, 12, 18, 24 and 36 months were 69%, 41%, 14%, 7%, and 5%, respectively. There was no treatment related mortality. Major complication rate (grade 3 adverse events) was 1% (2 events). The most common grade 1 or 2 adverse events were nausea and anemia (both occurred in 47% of patients), followed by hypomagnesemia (44%), hyperkalemia (41%) and lymphopenia (31%).

Conclusion: Transarterial chemoperfusion treatment with cisplatin, methotrexate and gemcitabine in every 4 weeks is feasible and safe. The treatment has promising disease control rate and OS in this group of heavily pretreated patients with relapsed MPM.

Abstract No. 140

Hepatic Arterial Infusion of the Class C TLR9 Agonist SD-101 in Pressure Enabled Regional Immuno-Oncology (PERIO) Phase 1 Trials for Liver Tumors

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Purpose: Patients with primary and metastatic liver tumors experience limited benefit with immune checkpoint inhibitor (ICI) monotherapy in part due to a highly immunosuppressive tumor-microenvironment (TME) and in part due to high hepatic pressures. Hepatic arterial infusion (HAI) of the class C Toll-like receptor-9 agonist (TLR-9A) SD-101 using the TriNav Pressure-Enabled Drug Delivery (PEDD) device has the potential to enhance TME sculpting through improved intrahepatic delivery and minimization of systemic exposure to the drug. This approach may overcome limitations in the use of TLR-9A associated with direct needle injection or systemic delivery.

Materials and Methods: PERIO-01 and PERIO-02 are open-label first-in-human Phase 1b trials of SD-101 given by HAI using PEDD in uveal melanoma with liver metastases (UMLM), advanced hepatocellular carcinoma (HCC), and advanced intrahepatic cholangiocarcinoma (ICC) (NCT04935229 and NCT05220722). The studies consist of dose-escalation cohorts of single agent SD-101 alone and with ICI. SD-101 is delivered over 2 cycles via HAI using TriNav and standard intra-arterial access, with 3 weekly doses per cycle. Procedural data for the first 12 months of the PERIO program was collected and analyzed. Enrollment in these studies is ongoing.

Results: Over the first 12 months of the PERIO program 23 participants were treated at 5 clinical trial sites, and 87 infusions were completed. 74% of participants were treated via sectoral approach; 22% via segmental approach; and 4% via a whole liver approach (single infusion location). 92% of procedures required a single TriNav device to infuse to all target locations. The average infusion time was 40 minutes. There were no procedure-related serious adverse events reported, with 15 procedure-related adverse events. Minor adverse events included puncture site pain, bruising, or hematoma. Thirteen immune-related adverse events were reported, including fever and chills. There were no severe (Grade 3 or higher) immune-related events, specifically cytokine release syndrome, in the procedure rooms or during follow-up.

Conclusion: These are the first clinical trials to study HAI of a TLR-9A with PEDD and suggest safety, tolerability and feasibility of this approach in the multicenter setting.

Abstract No. 141

Development and Characterization of Patient-Derived Rat Models of Hepatocellular Carcinoma for Interventional Oncology



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Purpose: Hepatocellular carcinoma (HCC) carries high morbidity and mortality worldwide. To advance treatment strategies in interventional radiology, animal models that can undergo endovascular locoregional therapy would be valuable. Although rats with autochthonous models of HCC exist,

models featuring patient-derived xenografts (PDX) offer powerful benefits in advancing our understanding and treatment of HCC.

Materials and Methods: Ultrasound-guided percutaneous HCC biopsies were implanted heterotopically into the flanks of immunodeficient mice (NSG, Jackson Labs). Mice-bearing tumors reaching >300 mm³ were euthanized and tumors were harvested for analysis and in vivo passaging. After two passages, mice were euthanized and tumor tissue was implanted orthotopically into immunocompromised rats (SRG, Charles River Laboratories) in the left and right medial liver lobes. Two weeks following implantation and weekly thereafter, rats underwent T2-weighted MRI to confirm successful implantation and evaluate tumor size. Blood samples were obtained weekly to quantify serum concentrations of alpha-fetoprotein by ELISA. Once tumors exceeded 300 mm³, rats underwent T1-weighted contrast-enhanced MRI and angiography to evaluate the feasibility of endovascular intervention as described previously.

Results: Two cohorts ($n = 4$ /cohort) of rats were implanted with PDX tissue with each cohort sharing tumor tissue derived from a unique patient. Overall, these models demonstrated a tumor engraftment rate of 87% on a per tumor basis and a 100% engraftment rate on a per rat basis. Average specific tumor growth rates were 15.81 ± 8.73 mm³/day in the first cohort, and 1.91 ± 3.36 mm³/day in the second. Serum AFP levels increased consistently by 982 ng/mL/day to 45,954 ng/mL at 68 days post-implantation ($n = 3$). Dynamic contrast-enhanced T1-weighted MR imaging as well as proper hepatic arteriography via a transfemoral approach in two animals (1 from each cohort) demonstrated hypervascular masses corresponding to the tumors identified on MRI.

Conclusion: Patient-derived orthotopic xenotransplantation can produce a robust rat model of HCC amenable to endovascular locoregional therapy using techniques that mimic clinical protocols. This novel model holds the promise to enable the advancement of tumor-specific treatment strategies in the practice of interventional radiology.

Scientific Session 15

Women's & Men's Health 1

Monday, March 6, 2023

3:00 PM–4:30 PM

Abstract No. 142

Impact of Virtual Injection Software on Radiation Exposure and Operative Time during Prostate Artery Embolization



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