TriNav® INFUSION SYSTEM

Clinical Summary: Pressure-Enabled Drug Delivery™ Significantly Increases Intra-Arterial Delivery of Embolic Microspheres to Liver Tumors in a Porcine Model

Jaroch DB, Liu Y, Kim AY, Katz SC, Cox BF, Hullinger TG. Pressure-Enabled Drug Delivery Significantly Increases Intra-Arterial Delivery of Embolic Microspheres to Liver Tumors in a Porcine Model. *J Vasc Interv Radiol* 2025;36:499-504.e1

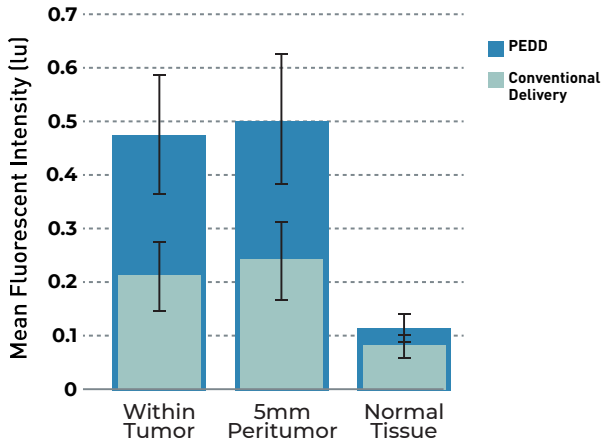
SUMMARY:

A preclinical study in transgenic pigs (Oncopigs) with induced liver tumors demonstrated that Pressure-Enabled Drug Delivery (PEDD™) with a **TriNav® Infusion System significantly increased the tumor penetration of embolic microspheres, with improved sparing of normal tissue,** compared to a traditional microcatheter (TMC).

In this head-to-head comparison study, hepatic arterial infusion of fluorescently labeled embolic microspheres (100-300 µm) was performed via PEDD with the TriNav device, or via conventional techniques using a traditional MC (n=8 each). Liver tissue was harvested and imaged immediately following infusion, and blinded quantitative analysis of signal intensity was performed with a custom deep learning algorithm.The study showed that compared to a traditional MC:

- **3.3x increase in microsphere tumor penetration via TriNav with PEDD (Figure 1)**
- **3.1x increase in penetration to 5mm tumor margin via TriNav with PEDD (p=.045) (Figure 1)**
- **1.6x increase to the tumor-to-normal ratio via TriNav with PEDD (Figure 2)**

Microsphere Distribution



3.3x

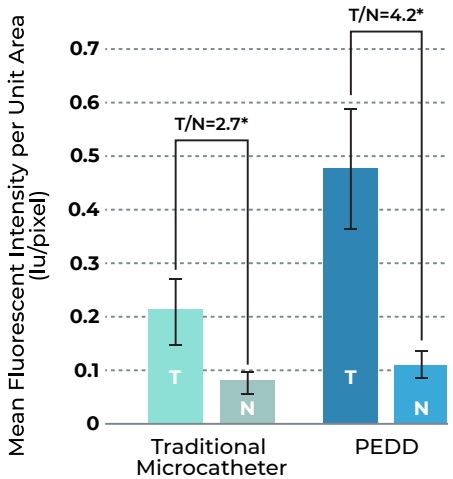
Increase in Tumor Penetration (n=16, p=.029)

3.1x

Increase in Penetration to 5mm Tumor Margin (n=16, p=.045)

Figure 1.*Microsphere tumor penetration in subjects treated via PEDD and TMC.*

Tumor-to-Normal Ratio



1.6x

Increase to the mean T:N Ratio by PEDD

Figure 2. *Mean tumor-to-normal ratios in subjects treated via PEDD and TMC. Tumor (T) defined as -1 to -10 mm within tumor margin. Normal tissue (N) defined as >30mm away from tumor margin.*

STUDY DESIGN:

This study was designed to test the hypothesis that, compared to a traditional MC, using a TriNav would improve the delivery of embolic microspheres into and around a tumor.

Oncopigs have genetic mutations which facilitate the development of cancerous, hypovascular tumors. In this study, Oncopigs had induced tumors which measured 1-3 cm at the time of the experiments. Fluorescently labeled microspheres (100–300 µm Embospheres, Merit Medical) were suspended in contrast and infused into 1.5-2.5 mm diameter second- or third-order vessels supplying approximately 50% of the targeted hepatic lobe. **(Figure 3)**

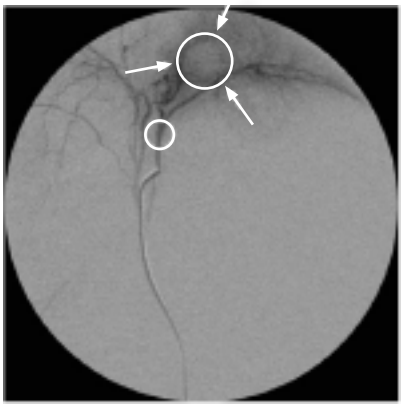


Figure 3. *Fluoroscopic image of a typical hypovascular lesion in a lobe of a porcine liver (white arrows). The white circle denotes the location of selective delivery to the tumor.*

The infusions were grouped by delivery method (PEDD using the TriNav or TMC, n=8 each). The standard embolization endpoints shown in Figure 4 were used for each device:

GROUP	EMBOLIZATION ENDPOINT
Traditional Microcatheter	Stasis observed (defined as the absence of flow into the target vessel with the development of reflux visible on angiography)
TriNav Infusion System	Leaching of contrast medium retrograde through the expandable tip **OR** Development of an intrahepatic collateral vessel leading away from the target tumor **OR** Visualization of the portal vein

Figure 4*. Embolization endpoints used in the hepatic arterial infusions.*

Livers were collected and processed immediately after dosing and Near-Infrared (NearIR) imaging was performed to identify patterns of therapeutic uptake. A deep learning image analysis algorithm (Visiopharm A/S) was then used to quantify the signal intensity in the tumors and surrounding tissue. To control for bias, the analysis portion of the study was blinded to what device was used, and the tumor and liver characteristics were statistically equivalent in both groups.

RESULTS:

High-resolution analysis of microsphere distribution within and around the tumor demonstrated that PEDD produced statistically significant (P ≤ .05) increases in microsphere signal intensity in concentric zones extending from –10 mm into the tumor to the tumor border relative to a traditional microcatheter.

- **3.3x increase in microsphere tumor penetration via TriNav with PEDD (Figure 1)**
- **3.1x increase in penetration to 5mm tumor margin via TriNav with PEDD (p=.045) (Figure 1)**

Macroscale tissue analysis of normal tissue (defined as >1 cm from tumor, but within the angiosome) was also performed in each liver. When analyzing the normal tissue in each group **TriNav with PEDD demonstrated a trend toward reduced microsphere delivery and a T:N ratio of 4.2 versus 2.7 for the TMC group, representing a 1.6x increase.**

CONCLUSION:

The results of this preclinical study are important for demonstrating how TriNav can improve the penetration of microspheres into peritumoral and tumor vasculature during embolization. Together, these data demonstrate that changing pressure and flow with PEDD may result in targeted therapeutic delivery to the rapidly growing rim of tumors while sparing normal liver tissue.

This summary is sponsored by TriSalus Life Sciences®.
Results are not predictive of outcomes in other cases.