

Clinical Summary: Pressure-Enabled Drug Delivery™ Improves Tumor Targeting in Liver Radioembolization with Resin Microspheres

d'Abadie P, Walrand S, Goffette P, et al. Antireflux catheter improves tumor targeting in liver radioembolization with resin microspheres. *Diagn Interv Radiol* 2021; 27:768-773.

SUMMARY:

A retrospective analysis of 61 patients with liver cancer (190 lesions) treated with resin Y90 radioembolization (RE) showed that Pressure-Enabled Drug Delivery (PEDD™) significantly improved both tumor targeting and dose delivery.

In this study, each patient served as their own control. All patients underwent an MAA planning procedure delivered via a traditional microcatheter (TMC). Resin Y90 was then delivered via either a TMC (control group) or via PEDD, followed by PET/CT imaging. Each patient's post-Y90 PET/CT was co-registered to their post-MAA SPECT/CT to compare the tumor to normal liver ratio (T:N) and tumor dose (TD).

Overall, 38 patients (115 lesions) and 23 patients (75 lesions) were analyzed in the PEDD and control groups, respectively. The results showed that across all tumor types, PEDD increased the T:N by a median of 24%, and the TD by a median of 23%, with no significant difference seen in the TMC (control) group.

Tumor to Normal Ratio (T:N)

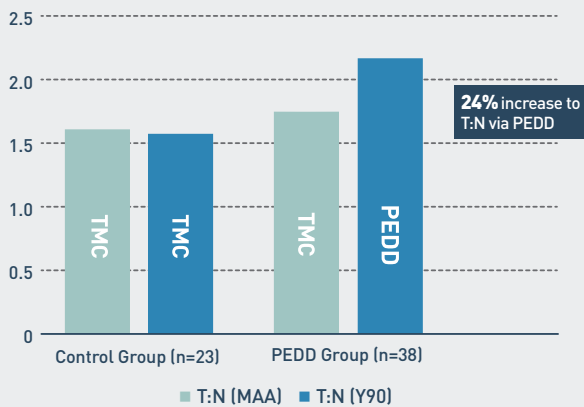


Figure 1. Across all tumor types, PEDD increased the T:N by a median of 24% ($p < 0.001$).

Tumor Dose

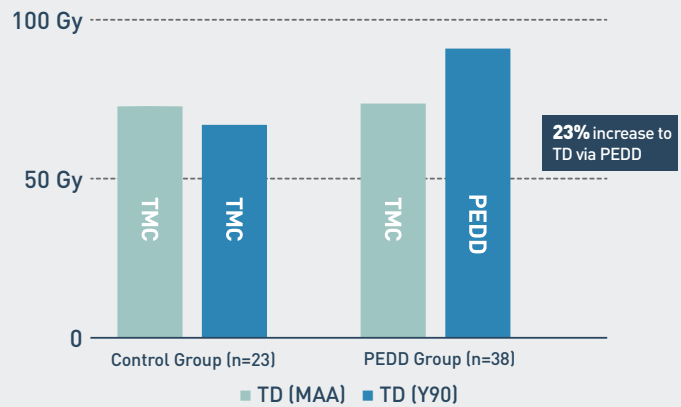


Figure 2. Across all tumor types, PEDD increased the TD by a median of 23% ($p < 0.001$).

STUDY DESIGN:

A retrospective analysis of 61 patients who underwent resin Y90 RE for primary or metastatic liver tumors. **Figure 3** shows the patient tumor characteristics by group, including tumor type: colorectal metastases (CRM), hepatocellular carcinoma (HCC), and neuroendocrine metastases (NEM).

All patients underwent a ^{99m}Tc-MAA planning infusion delivered via traditional catheter, followed by SPECT/CT imaging. One to three weeks after the planning angiography, resin Y90 microspheres were delivered via PEDD or via a TMC (control group) at the discretion of the treating interventional radiologist. PET/CT imaging was performed immediately following RE.

In this study design, each patient served as their own control. Tumors were first identified using patient's baseline CT or MRI imaging. The volumes of interest, tumor and normal liver, were fused with the post-MAA SPECT/CT and post-Y90 PET/CT using a rigid co-registration, so that each patient's own imaging could be compared. Angiograms with differences in catheter tip position greater than 2cm were excluded from the analysis. **Figure 4** shows example imaging for an NEM patient.

Patient Tumor Characteristics

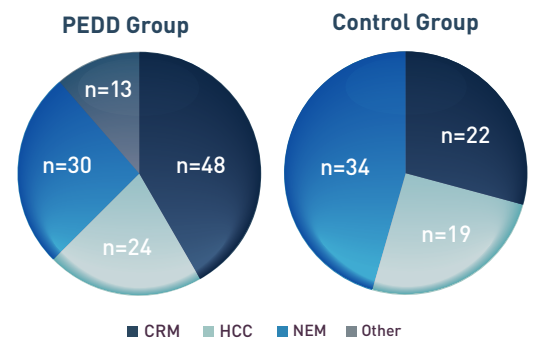


Figure 3. Analysis was performed on 38 patients with 115 lesions in the PEDD group and 23 patients with 75 lesions in the control group.

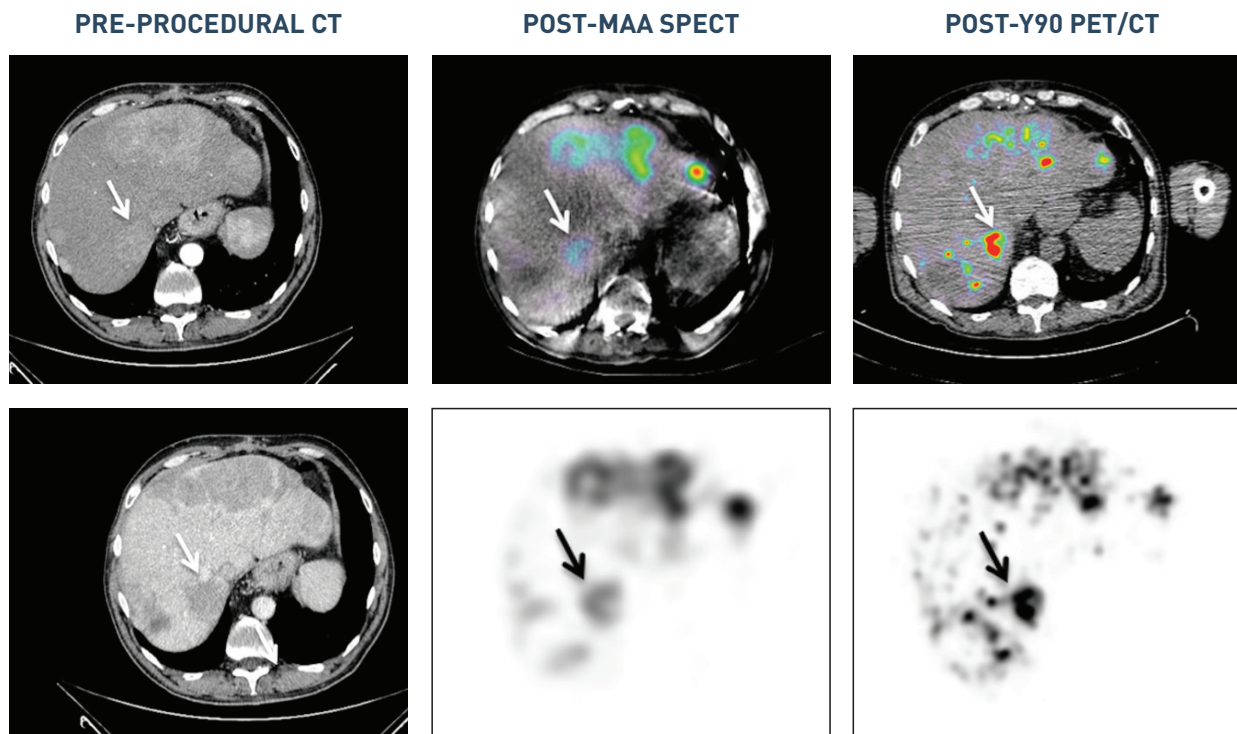


Figure 4. Example of a patient with a hypervascular NEM tumor in segment 7. (left column) Arterial and portal phase CT. (centre column) Post-MAA SPECT imaging. ^{99m}Tc-MAA planning infusion delivered via TMC resulted in a T:N of 2.9 and a tumor dose of 69 Gy. (right column) Post-Y90 PET/CT imaging. Resin Y90 RE delivered via PEDD resulted in a T:N of 8.4 and a tumor dose of 172 Gy. This corresponds to a 189% increase in T:N and a 149% increase in tumor dose for this patient compared to the MAA delivery.

RESULTS:

The analysis showed that PEDD significantly increased T:N_{Y90} and TD_{Y90} compared to T:N_{MAA} and TD_{MAA} (Figure 5). PEDD increased the T:N by a median of 24%, and the TD by a median of 23% in all tumor types studied (NEM, HCC and CRM). There was no significant difference in either T:N or TD in the group treated with a standard traditional microcatheter (control group).

Groups	Characteristics (Median)	MAA	Y90	p
PEDD n=115	T:N	1.74	2.16	<0.001*
	Dose (Gy)	73.72	90.96	<0.001*
Control n=75	T:N	1.60	1.57	0.892
	Dose (Gy)	72.92	66.88	0.950

Wilcoxon signed rank test was used for the analysis of patient-paired difference between MAA and Y90.
*Indicates a significant result at a 5% type 1 error.

Figure 5. Tumor to Normal Ratio and Tumor Dose in groups.

CONCLUSION:

This study demonstrates that compared to a traditional microcatheter, using PEDD to deliver resin Y90 RE significantly improves dose delivery across a variety of tumor types. The results support the use of PEDD in resin Y90 RE to improve tumor targeting and to reduce the risk of extrahepatic deposition of the microspheres.

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

INDICATIONS FOR USE: The TriNav Infusion System is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the peripheral vascular system.

CONTRAINDICATIONS: TriNav is not intended for use in the vasculature of the central nervous system (including the neurovasculature) or central circulatory system (including the coronary vasculature).

Rx ONLY. For the safe and proper use of the TriNav device, refer to the Instructions for Use.