TriNav® INFUSION SYSTEM

Clinical Summary: The Impact of Pressure-Enabled Drug Delivery™ on Target Volume Particulate Distribution in Liver-Directed Embolotherapy

Pasciak AS, McElmurray JH, Bourgeois AC, Heidel RE, Bradley YC. The impact of an antireflux catheter on target volume particulate distribution in liver-directed embolotherapy: a pilot study. *J Vasc Interv Radiol.* 2015;26(5):660-669. doi:10.1016/j.jvir.2015.01.029

SUMMARY:
A prospective study included 9 patients who were referred for Y90 radioembolization (RE) treatment of their liver tumors. Prior to RE treatment via Pressure-Enabled Drug Delivery (PEDD™), each patient received two same-day sequential lobar infusions of macroaggregated albumin (MAA) via endhole (EH) microcatheter and PEDD. Every infusion was performed from the same location, and post-MAA SPECT imaging was obtained. Differences in MAA distribution within the tumors and non-target sites were evaluated, and across a variety of tumor types the results showed:

- A 33% to 90% (mean=68%) increase in tumor deposition
- A 24% to 89% (mean=58%) decrease in nontarget embolization
- Increased on-target deposition in 100% of the tumors

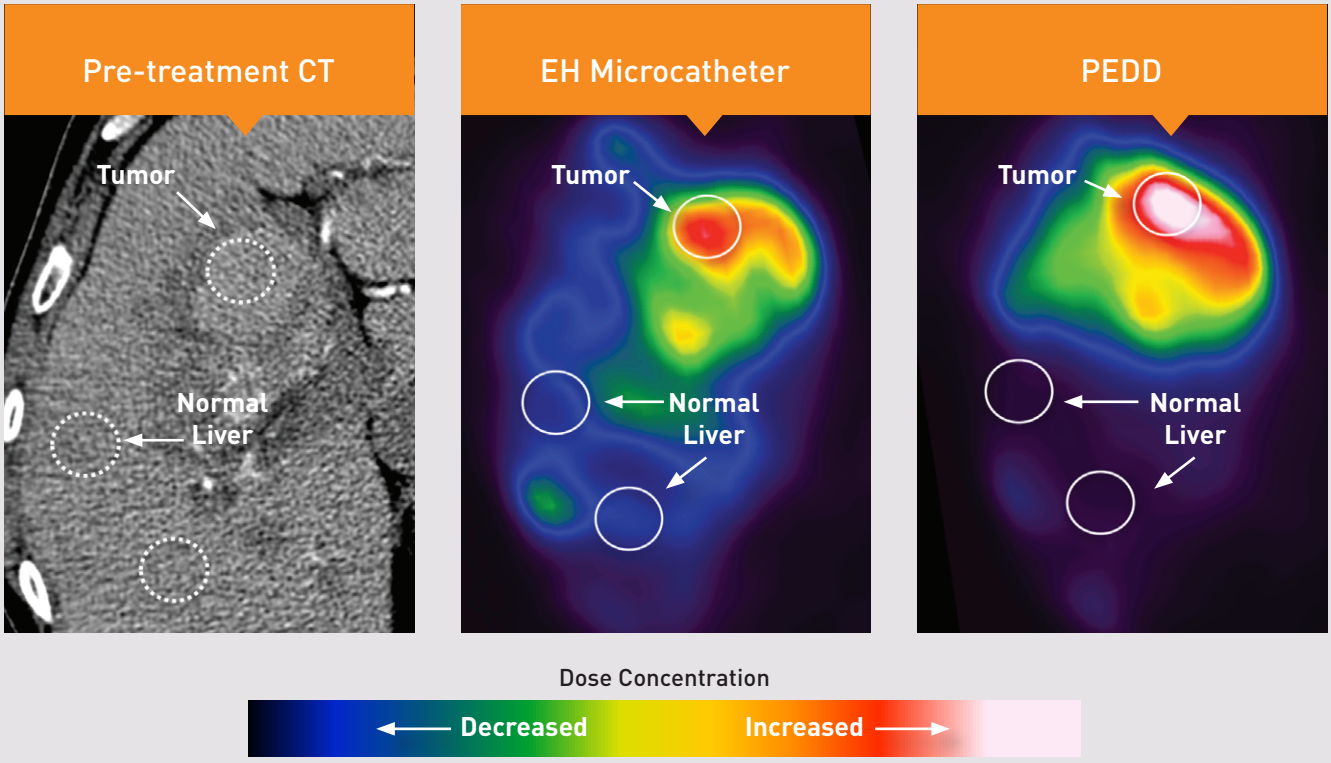


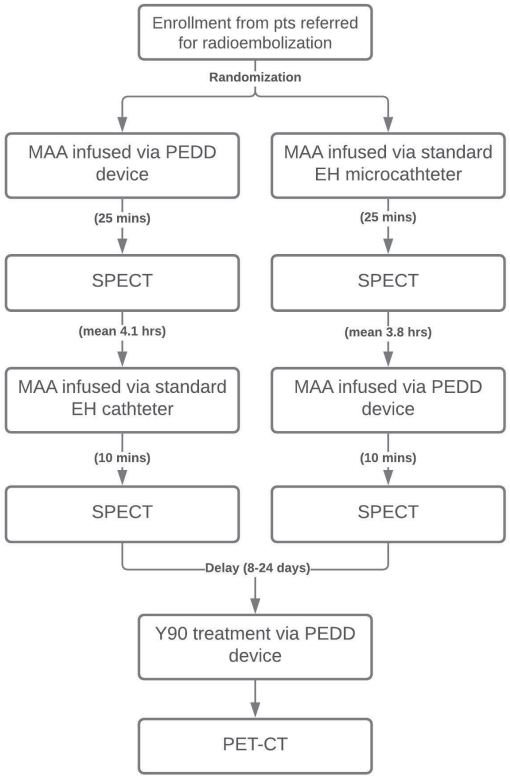
Figure 1. Imaging from study patient #9 demonstrates increased tumor deposition, with reduced non-target embolization.

STUDY DESIGN:

This prospective study included 9 patients with unresectable liver cancer who were referred for Y90 treatment of hepatocellular carcinoma (HCC, n = 6), liver-dominant metastatic disease (n = 2), or intrahepatic cholangiocarcinoma (n = 1).

Before Y90 treatment, each subject received two same-day sequential lobar infusions of technetium-99m (99mTc) MAA via a standard EH microcatheter and via PEDD. The order of the devices used was randomized, and identical catheter positioning was confirmed via angiography (Figure 2). SPECT imaging was performed immediately following each infusion. Prior to RE treatment via PEDD, catheter position was verified to be identical to that used during the MAA infusions.

A board-certified nuclear medicine radiologist reviewed the post-MAA SPECT images, blinded to which device was used, to evaluate for tumor and nontarget MAA distribution. Following treatment, the PEDD post-MAA SPECT was compared to the post-Y90 PET-CT to confirm the validity of 99mTc MAA as a resin microsphere surrogate.



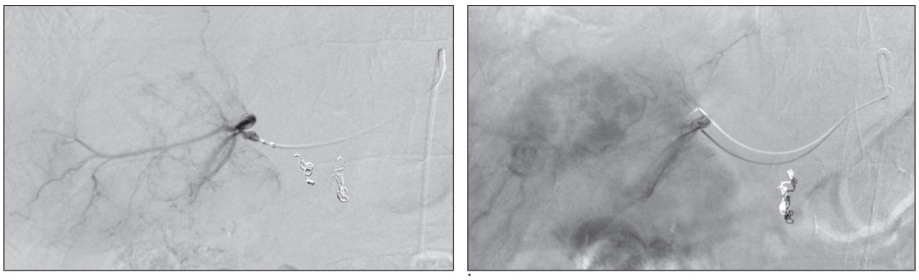


Figure 2. Digitally subtracted angiography of a study subject with HCC shows identical catheter position (PEDD, left and EH, right) for each infusion of MAA before RE treatment.

RESULTS:

In all 9 patients, regardless of tumor type, the post-MAA SPECT imaging qualitatively showed more uniform and extensive tumor coverage when the PEDD device was used. (See Clinical Summary Imaging Annex.) Semiquantitative analysis showed a statistically significant 33%-90% increase (mean 68%, $P < 0.05$) in tumor deposition when PEDD was used, versus the EH microcatheter. A statistically significant 24%-89% decrease (mean 58%, $P < 0.05$) in nontarget MAA deposition was also seen when using PEDD versus the EH microcatheter. Comparison of the post-Y90 PET-CT following RE treatment showed excellent agreement between the distribution of Y90 and the distribution of MAA when the PEDD device was used. One of the 9 enrolled patients did not complete RE treatment due to elevated liver function test results between the MAA day and RE treatment day. Figure 1 shows the imaging from study patient #9, and imaging from all 9 study patients can be found in the Clinical Summary Imaging Annex.

CONCLUSION:

In this prospective, single-center study, PEDD was shown to increase targeting while reducing non-target embolization across a variety of tumor types. Blinded review of the imaging showed that 100% of the tumors demonstrated increased deposition with PEDD versus the standard EH microcatheter.

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

INTENDED 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.

TriSalus LIFE SCIENCES® | TriNav® INFUSION SYSTEM

TriNav® INFUSION SYSTEM

Clinical Summary—Imaging Annex: The Impact of Pressure-Enabled Drug Delivery™ on Target Volume Particulate Distribution in Liver-Directed Embolotherapy

Pasciak AS, McElmurray JH, Bourgeois AC, Heidel RE, Bradley YC. The impact of an antireflux catheter on target volume particulate distribution in liver-directed embolotherapy: a pilot study. *J Vasc Interv Radiol.* 2015;26(5):660-669. doi:10.1016/j.jvir.2015.01.029

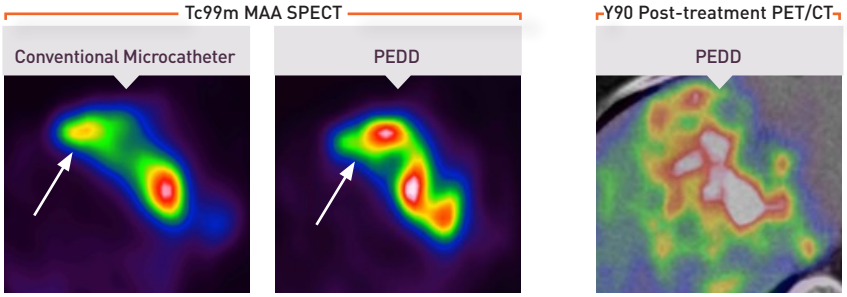
SUMMARY:
In this prospective, single-center study, PEDD™ was shown to increase targeting while reducing non-target embolization across a variety of tumor types. In all 9 patients, the post-MAA SPECT imaging qualitatively showed more uniform and extensive tumor coverage when the PEDD device was used. Semiquantitative analysis showed a statistically significant 33%-90% increase (mean 68%, P < 0.05) in tumor deposition and a 24%-89% decrease (mean 58%, P < 0.05) in nontarget MAA deposition when using PEDD versus the EH microcatheter. Comparison of the post-Y90 PET-CT following treatment showed concordance between the distribution of Y90 and the distribution of MAA when the PEDD device was used.

PATIENT 1 Colorectal Liver Mets

Activity deposition with PEDD:

75% Increase in tumor deposition

35% Decrease in non-target deposition

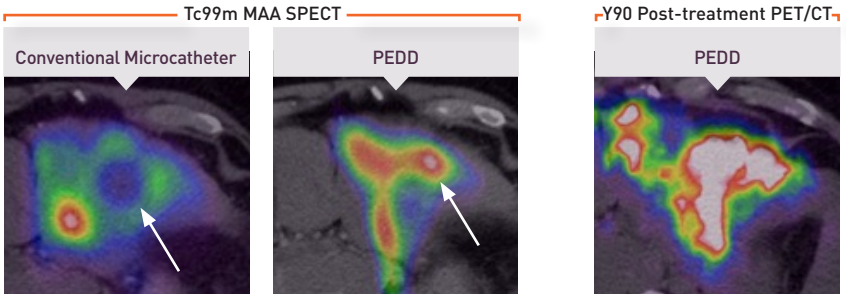


PATIENT 2 Cholangiocarcinoma Liver Mets

Activity deposition with PEDD:

33% Increase in tumor deposition

55% Decrease in non-target deposition

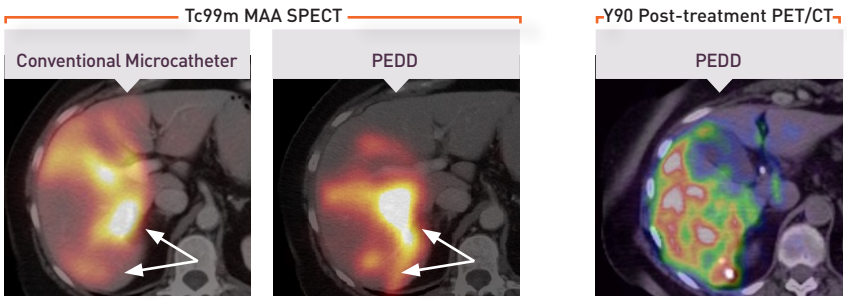


PATIENT 3 Breast Liver Mets

Activity deposition with PEDD:

56% Increase in tumor deposition

89% Decrease in non-target deposition



TriSalus LIFE SCIENCES® | TriNav® INFUSION SYSTEM

PATIENT 4 HCC

Activity deposition with PEDD™:

90% Increase in tumor deposition

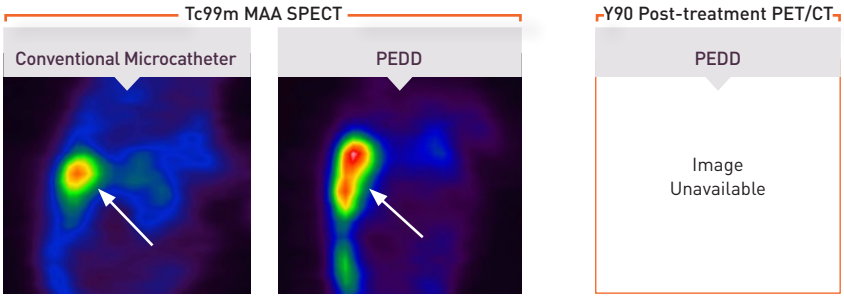
78% Decrease in non-target deposition

PATIENT 5 HCC

Activity deposition with PEDD:

45% Increase in tumor deposition

52% Decrease in non-target deposition

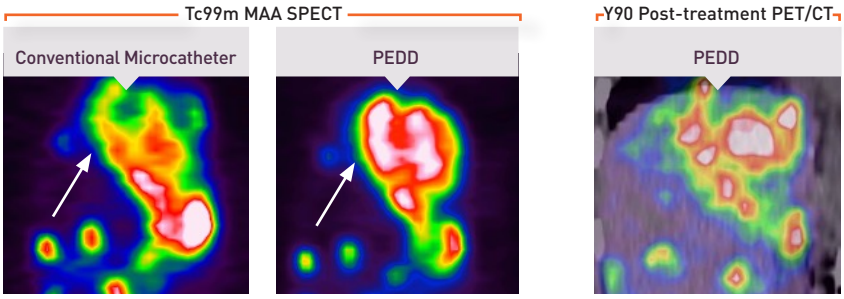


PATIENT 6 HCC

Activity deposition with PEDD:

67% Increase in tumor deposition

63% Decrease in non-target deposition

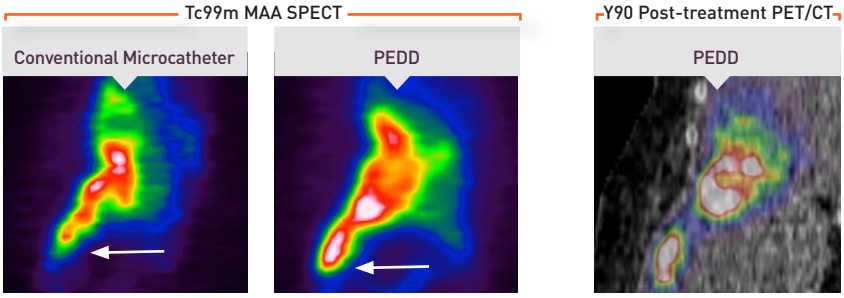


PATIENT 7 HCC

Activity deposition with PEDD:

84% Increase in tumor deposition

62% Decrease in non-target deposition



PATIENT 8 Imaging not available

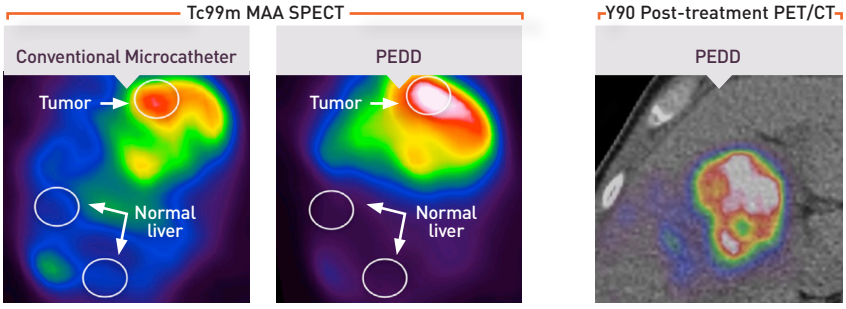
Activity deposition with PEDD: **85%** increase in tumor deposition. **24%** decrease in non-target deposition.

PATIENT 9 HCC

Activity deposition with PEDD:

77% Increase in tumor deposition

60% Decrease in non-target deposition



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

INTENDED 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.

TriSalus LIFE SCIENCES® | TriNav® INFUSION SYSTEM