TriNav® INFUSION SYSTEM

Clinical Summary—Imaging Annex: The Impact of Pressure-Enabled Drug Delivery™ on Tumor to Normal Microsphere Distribution in Transarterial Radioembolization

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

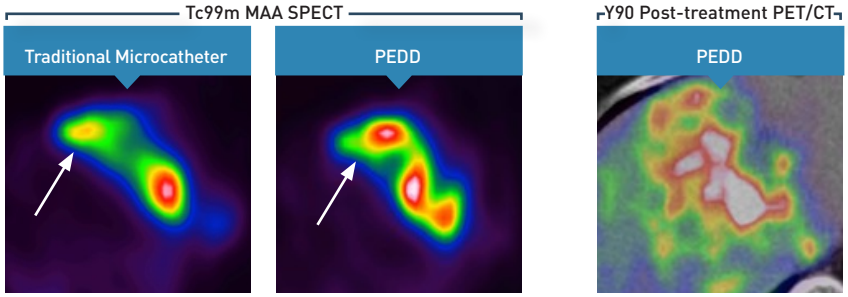
SUMMARY:
In this prospective, single-center study, PEDD™ was shown to increase targeting while reducing non-target embolization across a variety of tumor types. In all nine patients, the post-MAA SPECT imaging qualitatively showed more uniform and extensive tumor coverage when the PEDD device was used. 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 non-target MAA deposition when using PEDD versus the traditional 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

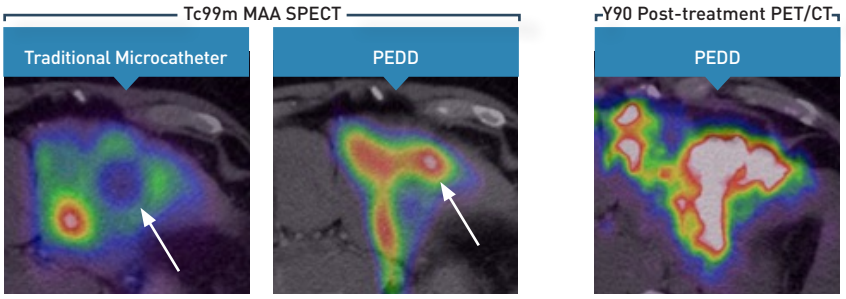


PATIENT 2 Cholangiocarcinoma Liver Mets

Activity deposition with PEDD:

33% Increase in tumor deposition

55% Decrease in non-target deposition

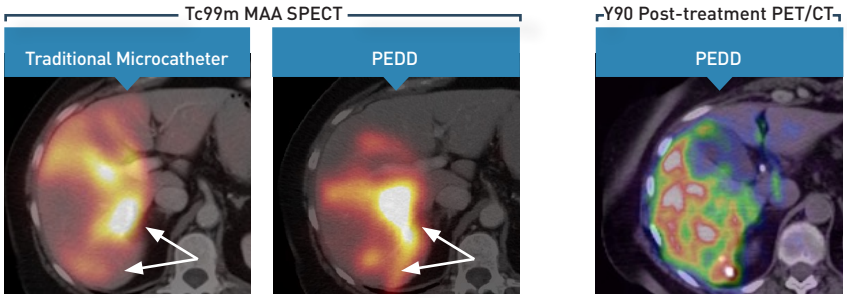


PATIENT 3 Breast Liver Mets

Activity deposition with PEDD:

56% Increase in tumor deposition

89% Decrease in non-target deposition



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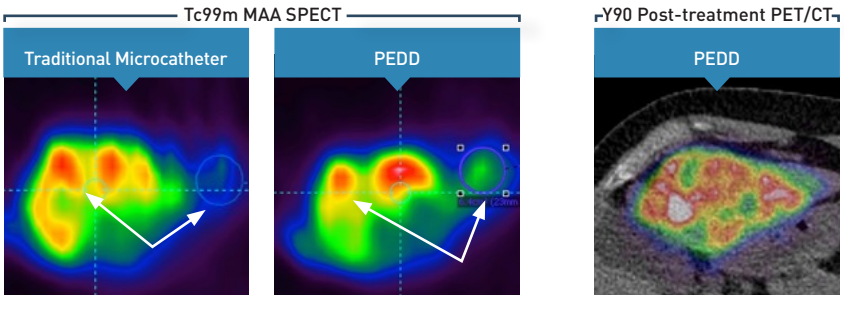
PATIENT 4 HCC

Activity deposition with PEDD™:

90% Increase in tumor deposition

78% Decrease in non-target deposition

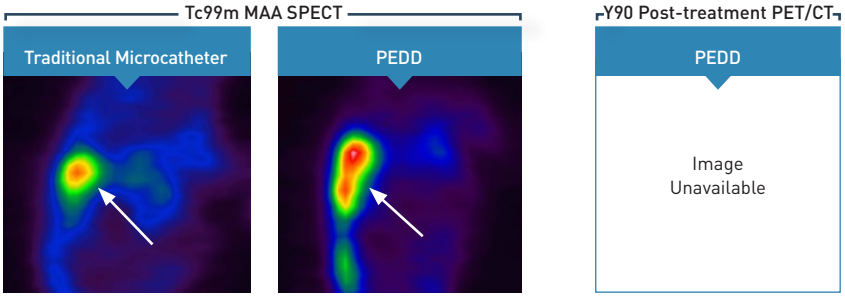


PATIENT 5 HCC

Activity deposition with PEDD:

45% Increase in tumor deposition

52% Decrease in non-target deposition

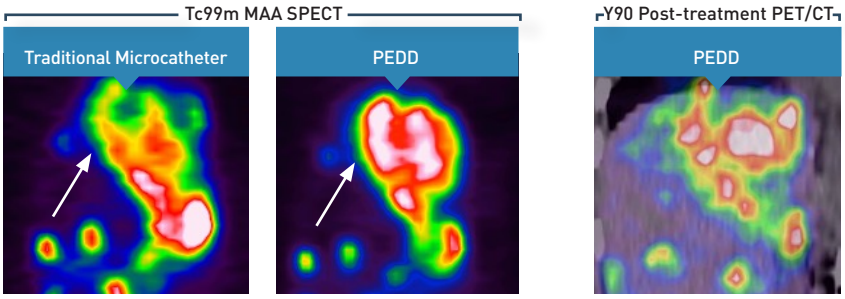


PATIENT 6 HCC

Activity deposition with PEDD:

67% Increase in tumor deposition

63% Decrease in non-target deposition

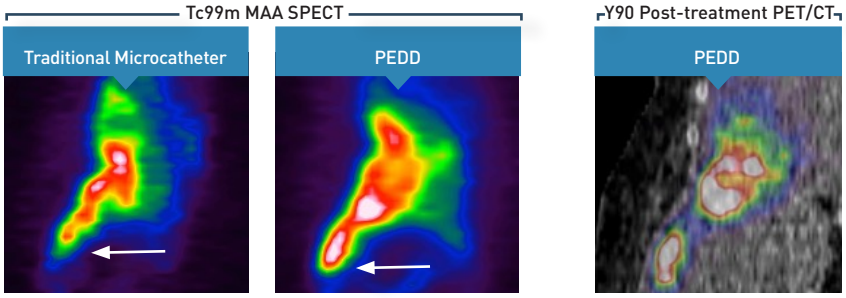


PATIENT 7 HCC

Activity deposition with PEDD:

84% Increase in tumor deposition

62% Decrease in non-target deposition



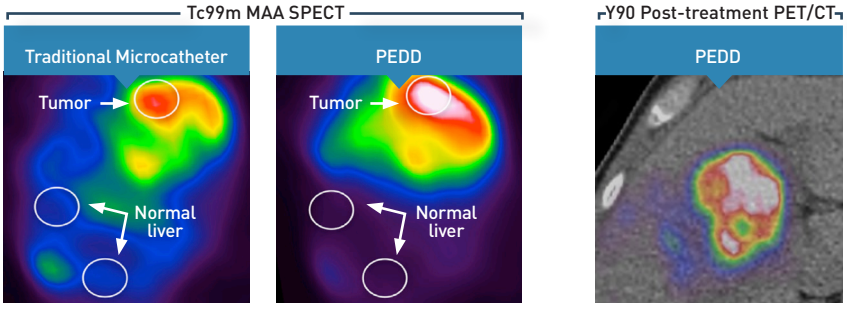
PATIENT 8 Imaging not available Activity deposition with PEDD: **85%** increase in tumor deposition. **24%** decrease in non-target deposition.

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.

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.

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