Lipiodol Deposition in Neuroendocrine Tumor Liver Metastases during TACE using Pressure-Enabled versus Endhole Catheters: Pilot Data from a Randomized, Internally-Controlled Trial

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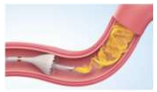
BACKGROUND

- Intratumoral lipiodol deposition during transarterial chemoembolization (TACE) is an imaging biomarker for response and survival in hepatocellular carcinoma.
- Improving delivery of liquid therapeutics during TACE may also help improve neuroendocrine tumors (NETs) outcomes.
- Pressure-enabled delivery catheters (PED) are designed to overcome the high resistance and interstitial pressure within the tumor microvasculature compared to end-hole catheters (EH).
- PED have been shown to increase deposition of solid particles in tumors.

End-hole catheter



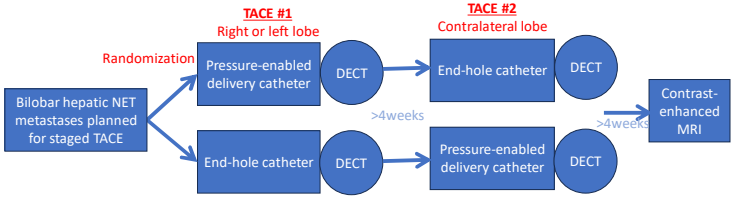
Pressure-enabled delivery catheter (TriNav)

Purpose:

- This study aims to evaluate deposition of a liquid agent such as emulsified lipiodol in TACE using enhole catheters and pressure-enabled delivery catheters.

METHODS

- Single-center, randomized, internally controlled comparison of end-hole versus PED catheter for TACE of NET liver metastases.
- Patients with bilobar NET metastases planned for staged TACE
  - Randomized for which catheter would be used for their first TACE
  - Other catheter used for second TACE→ serves as internal control for lipiodol deposition and response
- February 2024- October 2024



- TACE performed with 2:1 ratio lipiodol:chemoemulsion, 100-300 um Embospheres
- Pre-embolization CTA of the treated distribution was performed to delineate tumors
- After TACE, a dual energy CT scan (DECT) was performed at tube voltage 100/Sn150 kVp, and reconstructions of 40, 70, and 190 keV virtual mono-energetic images and iodine maps were created
- Lipiodol deposition in tumors was analyzed using iodine maps
- Comparison of lipiodol deposition and tumor response between catheters
  - Across all patients
  - Within each patient

RESULTS

Patient Characteristics

N = 5 patients treated with bilobar TACE. 4/5 patients have completed follow-up MRI

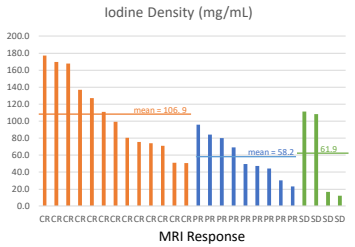
Patient	Site of Primary NET	Sex	Ki67 (%)	Grade	Years Since Dx
1	Small bowel (jejunal)	M	5.5	2	7
2	Large bowel (rectal)	M	6	2	8
4	Small bowel (ileal)	F	10.6	2	3
5	Small bowel (jejunal)	M	26.2	3	<1
6	Pancreas	M	14	2	1

Follow-up MRI mRECIST response

	EH	PED	Total
CR	8	7	15
PR	2	5	7
SD	3	1	4
PD	0	0	0
ORR	77%	92%	85%

CR= complete response, PR = partial response, SD = stable disease, PD = progressive disease, ORR = Overall response rate

ORR between EH and PED: chi-square p = 0.62

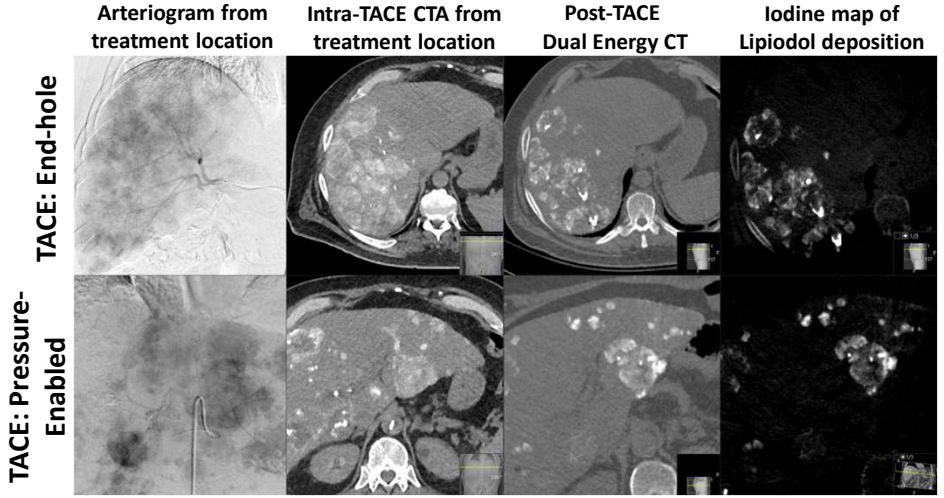


Lipiodol Deposition

N = 18 EH-treated tumors, N = 18 PED-treated tumors analyzed. Average tumor size 2.9 cm (SD = 1.3 cm)

	END-HOLE CATHETER				PRESSURE-ENABLED CATHETER				
Patient	Mean tumor density, mg/mL (SD)	Nontumor liver density, mg/mL	% Coverage (SD)	MRI ORR %	Mean density, mg/mL	Nontumor liver density, mg/mL	% Coverage	MR ORR %	Tumor Vascularity
1	**16.7** (19.5)	-10.6	**61.7** (N/A)	0	**35.0** (21.1)	33.6	**82.8** (21.1)	75	iso
2	**101.1** (50.0)	56.9	**99.0** (1.1)	33	**47.3** (19.0)	99.8	**97.2** (4.5)	100	hypo
4	**95.0** (29.1)	91.6	**99.8** (0.3)	100	**50.8** (34.5)	90.1	**94.6** (N/A)	100	hyper
5	**93.7** (53.9)	3.5	**96.6** (7.0)	100	**132.1** (67.6)	0.5	**98.8** (1.9)	100	hyper
6	**113.2** (39.0)	18.0	**98.8** (2.1)	Pending	**177.2** (67.9)	46.0	**100.0** (0.1)	Pending	hyper
Total Cohort	**96.4** (32.8)	**31.9**	**96.4** (9.4)		**104.4** (72.3)	**54**	**95.1** (11.4)		

No significant difference in density of lipiodol deposition/tumor, deposition in non-tumor liver, or % tumor coverage (p = 0.46, 0.42, 0.64).



DISCUSSION

- Pilot data show no difference in lipiodol deposition in TACE in NET liver metastases when treated with PED or EH catheter when assessed on a per-tumor basis.
- Iodine density, volume coverage of tumor, and non-tumor liver showed no difference between catheters.
- No significant difference in ORR was seen between catheters.
- Intrapatient analysis suggests a difference that may relate to underlying vascularity of metastases.
- Further assessment of lipiodol deposition on DECT may provide numeric thresholds to predict response on follow-up MRI