TriNav® INFUSION SYSTEM

CLINICAL SUMMARY

Clinical Summary: A Multi-Center Registry Study of the Safety, Feasibility, and Outcomes of Pressure-Enabled Drug Delivery in DEB-TACE for Patients with HCC

Kapoor, B. et al. 3:18 PM Abstract No. 133 Surefire Infusion System (SIS) hepatocellular carcinoma registry study interim results: a multi-center study of the safety, feasibility, and outcomes of the SIS expandable-tip microcatheter in DEB-TACE. *J. Vasc. Interv. Radiol.* 29, S60 (2018).

SUMMARY:

In a multi-center registry study, a total of 114 hepatocellular carcinoma (HCC) lesions in 72 patients treated with DEB-TACE delivered via the Pressure-Enabled Drug Delivery™ (PEDD™)* method of administration were reviewed.

Across 10 enrolling centers and a range of HCC tumor sizes, PEDD demonstrated an objective response rate (ORR) of 82.2% and a complete response (CR) rate of 64.3%, with no toxicities above grade 2.

This observational dataset confirms the safety and benefits of PEDD in DEB-TACE.

STUDY DETAILS:

In this multi-center retrospective and prospective real-world study of the PEDD method for DEB-TACE infusion in patients with HCC, demographic and clinical data **(Table 1)** and procedural details of patients enrolled from 2014 to 2017 were collected. Quadrasphere 30-60m (57.4%) and LC Beads 100-300m (37.6%) were the most commonly used bead types. All available 1-, 3-, and 6-month follow-up imaging (CT and/or MRI) was analyzed, and efficacy was assessed by treatment response via mRECIST criteria **(Figure 1)**. Safety was assessed according to CTCAE v4.0, and no toxicities above grade 2 were observed.

Table 1. Patient Demographics

VARIABLE		# (% OF 72)
Age (year)	Mean ± standard (n)	63.3 ± 9.7 (72)
	Range	36-89
Gender	Male	57 (79.2%)
	Female	15 (20.8%)
Liver Disease Etiology (multiple possible)	Hepatitis C (HCV)	40 (55.6%)
	Hepatitis B (HBV)	10 (13.9%)
	Nash	7 (9.7%)
	Alcohol	20 (27.8%)
	Autoimmune hepatitis	1 (1.4%)
	Unknown/Unclear	4 (5.6%)
	None	1 (1.4%)
Child-Pugh Class	A	48 (66.7%)
	B	21 (29.2%)
	C	2 (2.8%)
	Not reported	1 (1.4%)
ECOG Performance Status	0	34 (47.2%)
	1	37 (51.4%)
	Not reported	1 (1.4%)

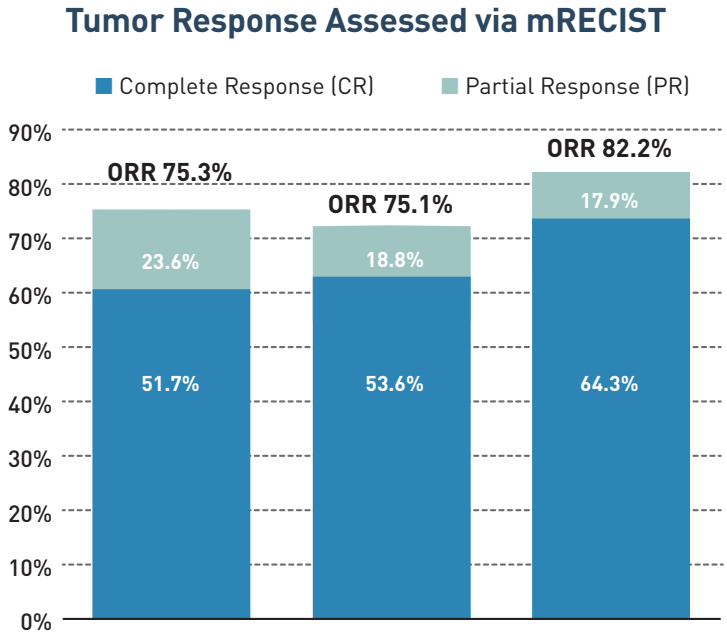

Figure 2. Tumor response assessed via mRECIST at follow-up [ORR = CR+PR]

*PEDD Device studied was the Surefire Infusion System.

1. Lammer J, Malagari K, Vogl T, et al. Prospective randomized study of doxorubicin-eluting-bead embolization in the treatment of hepatocellular carcinoma: results of the PRECISION V study. *Cardiovasc Intervent Radiol.* 2010;33(1):41-52. doi:10.1007/s00270-009-9711-7.