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 increased objective response rate (ORR) and complete response (CR) compared to historical controls[1] (ORR 82.2% vs 51.6%, CR 64.3% vs 26.9%), with no toxicities above grade 2.

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

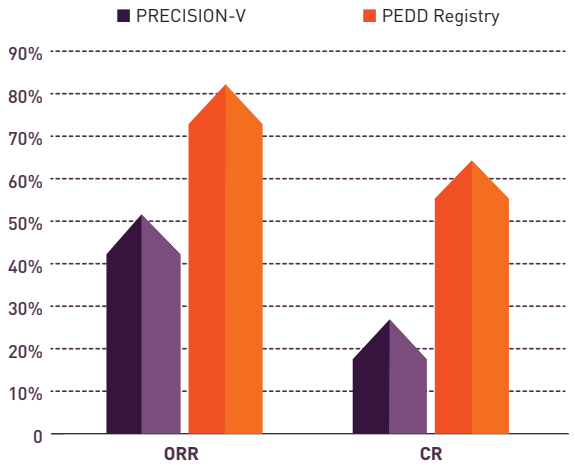

***Figure 1.** Tumor response assessed via mRECIST at 6-month follow-up, PEDD study vs PRECISION V study.*

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 2)**. 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%)

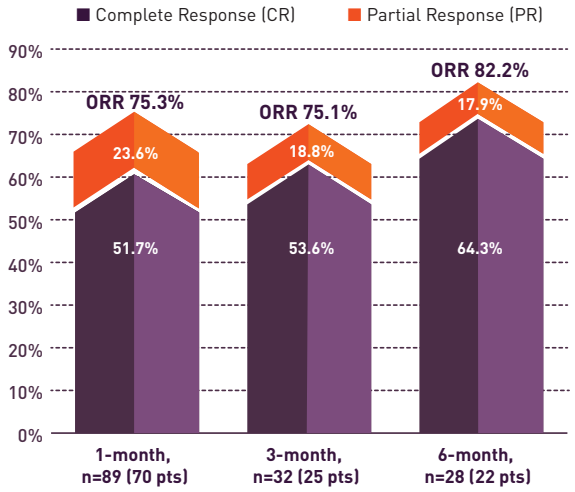

***Figure 2.** Tumor response assessed via mRECIST at follow-up [ORR = CR+PR]*

TAKEAWAY: The PEDD method improved the CR and ORR in DEB-TACE for patients with HCC compared to historical controls.

*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.

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.

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