Clinical Summary: Innovation in Catheter Design for Intra-Arterial Liver Cancer Treatments Results in Favorable Particle-Fluid Dynamics

van den Hoven A F, Lam M, Jernigan S, van den Bosch M, Buckner G D. Innovation in catheter design for intra-arterial liver cancer treatments results in favorable particle-fluid dynamics. *J. Exp. Clin. Cancer Res*. 2015; 34:74.

SUMMARY:
Quantitative bench-top testing demonstrated how catheter design has a significant impact on microsphere administration. Using an in-vitro hepatic model, this study showed that a traditional microcatheter (TMC) and a Pressure-Enabled Drug Delivery™ (PEDD™) device with SmartValve™ technology differ substantially in cross-sectional catheter positioning (centering), particle outflow patterns, and downstream particle distribution between branches.

SmartValve technology was shown to consistently induce a turbulent flow pattern which promotes mixing of microspheres into the bloodstream. Combined with its self-centering property, this led to a **62% improvement in downstream microsphere administration via the SmartValve** (Figure 1). This is clinically important for ensuring adequate therapeutic coverage, and consistency over repeated administrations.

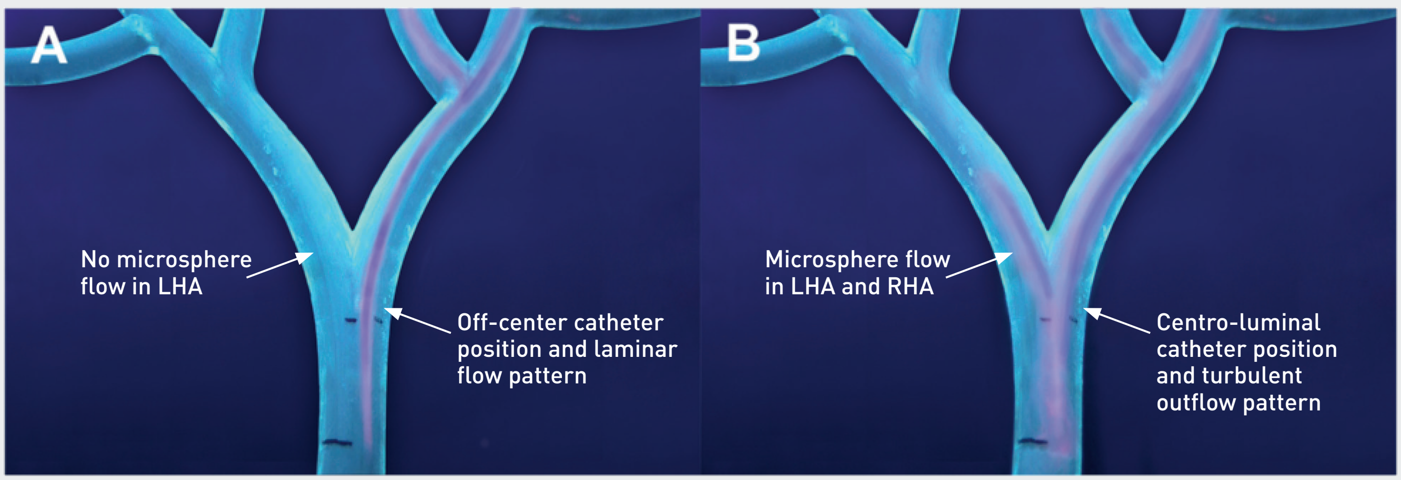

Figure 1. Composite image of microspheres showing catheter-related flow dynamics from a TMC (A) and a PEDD device (B).

BACKGROUND:
Laminar flow is the movement of fluid particles along well-defined parallel paths or streamlines. In contrast, **turbulent flow is the movement of fluid particles along an irregular or chaotic path.** (Figure 2)

Under normal conditions, arterial blood flow follows a laminar flow pattern, without lateral mixing.

In radioembolization treatment of liver tumors, microspheres are delivered via a catheter placed in the hepatic arterial vasculature. Catheter design, catheter placement, and particle fluid-dynamics also play an important role in microsphere distribution.

SmartValve technology centers the catheter tip within the vessel, prevents reflux and disrupts normally laminar blood flow. This bench-top study set out to quantify how these important design features may alter fluid-dynamics and change downstream microsphere distribution.

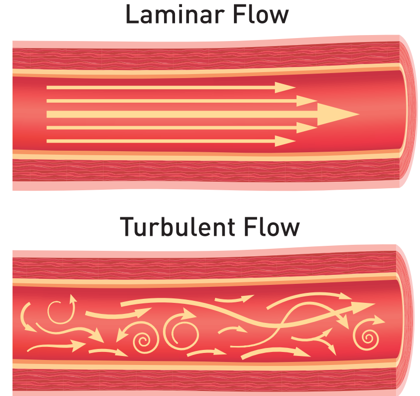

Figure 2. Laminar versus turbulent flow patterns.

STUDY DESIGN:

Across a series of seven experiments using a bench-top vascular model that simulated hemodynamics, fluorescent and holmium microspheres were administered by a PEDD device and a traditional microcatheter, with both devices in the same position. Particle flow-dynamics were qualitatively analyzed using video technology. To quantitatively compare downstream distribution, the deviation from a perfect homogenous distribution (50:50%), abbreviated as DHD, was calculated in percentage points (e.g., a 10:90% distribution results in a DHD of 40%). To evaluate the impact of injection rates on particle flow dynamics, a range of injection forces (or rates) were tested with each device.

RESULTS:

	Traditional Microcatheter	PEDD Device with SmartValve Technology
Flow Pattern	Laminar flow	Tturbulent flow
Downstream Particle Distribution	**Heterogeneous particle distribution** Mean DHD: 41%	**Homogenous particle distribution** Mean DHD: 16%
Cross-sectional Catheter Position	**29% centro-luminal** positioning	**100% fixed centro-luminal** positioning
Injection Rate	Particle distribution not significantly impacted by injection rate	Homogeneous particle distribution increased with injection rate

The results demonstrate that arterial flow patterns and downstream branch targeting are catheter dependent. There was a significantly more homogeneous downstream particle distribution with the PEDD device; the mean DHD was 40.85% (IQR 22.76%) for the TMC and 15.54% (IQR 6.46%) with the PEDD device ($p = 0.047$).

The SmartValve ensured fixed centro-luminal positioning in 100% of the experiments, vs 29% when the TMC was used. Furthermore, homogeneous particle distribution was seen to increase with injection rate with the PEDD device, but this relationship was not observed with the TMC. (Figure 3)

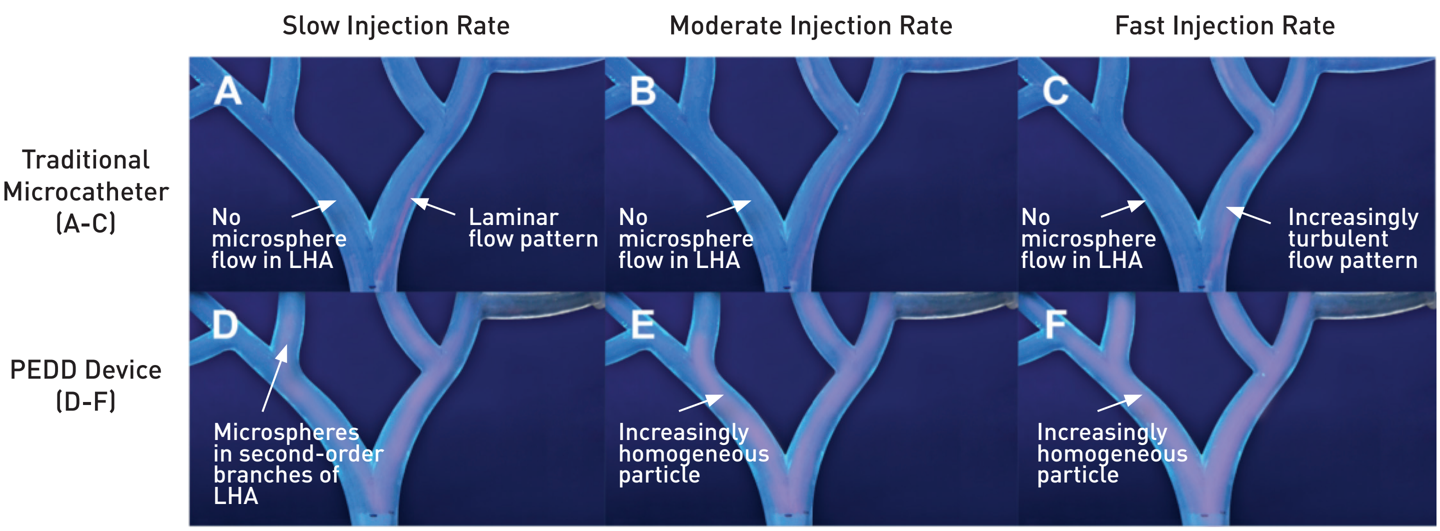

Figure 3. The impact of injection rate on downstream branch targeting. Even with increasing injection forces, the TMC was not able to target the LHA (A-C), although an increasingly turbulent flow pattern was observed in the RHA with a fast injection rate (C). At slow injection rates with the PEDD device there was preferential targeting of the RHA; however, microspheres are still visible in the second order branches of the LHA (D). Homogeneous particle distribution increased with injection rate when the PEDD device was used (D-F).

CONCLUSION:

In experiments using an in-vitro hepatic arterial model, **microsphere administration using SmartValve technology was associated with a favourable turbulent outflow pattern, a fixed centro-luminal catheter position, and 62% more homogeneous downstream branch targeting.** These effects have important implications for intra-arterial liver cancer treatments. Achieving a homogeneous distribution over first-order branches is crucial to ensure adequate therapeutic coverage, and consistency over repeated administrations.

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