Sponsored by CeloNova BioSciences

Physicians Find Success in New Techniques With Embozene™ Microspheres

Combined procedures reduce length of hospital stay.

Embozene Microspheres from CeloNova BioSciences (Peachtree City, GA) is a versatile spherical embolic platform that provides a tightly calibrated sizing system designed for targeted embolization. Rather than offering a broad size range of particles in a single unit, Embozene Microspheres are provided in specific sizes of 40, 100, 250, 400, 500, 700, and 900 µm (75-, 1100-, and 1300-µm sizes are available outside of the United States) (Figure 1). The unique, highly calibrated particles have enabled physicians to pioneer new embolization techniques that are achieving exceptional results.

EMBOZENE MICROSPHERES FOR TUMOR CONTROL

Professor Franco Orsi, MD, Medical Director of the Unit of Interventional Radiology at the European Institute of Oncology, has studied the use of Embozene Microspheres for treating hepatocellular carcinoma (HCC) involving micro-bland embolization combined with radiofrequency ablation (RFA). Dr. Orsi was awarded the Symposium on Clinical Interventional Oncology 2010 Best Poster for his poster presentation titled "Micro-Bland Embolization Combined with Radiofrequency Ablation for Treating Complex Hepatic Tumors" (Figure 2).

In 18 patients affected by primary or metastatic lesions, the clinical team at the European Institute of Oncology combined RFA with micro-bland transhepatic arterial embolization (MBTAE) to demonstrate precise tumor control. During the procedure, 40- and 100-µm Embozene Microspheres were used to occlude the specific vascular network supplying blood to the tumors in the liver. Dr. Orsi's team performed RFA immediately after MBTAE, eliminating the need to schedule an additional procedure. Technical success was achieved in all patients with excellent results. Patient survival was markedly improved, and tumor volumes decreased within safe margins.

Micro-bland transarterial embolization has been carried out only with very small microspheres in order to induce a deep parenchymal ischemia in the tumor. This has been shown to enhance the thermal effect of RFA. Combined therapy in this series has been shown to improve local results, allowing for RFA of complex liver lesions. However, the series is limited, and further prospective studies are needed to fully validate the combined approach.

EMBOZENE MICROSPHERES DESIGN PLATFORM

Embozene Microspheres are built on a design platform that includes four distinct features: calibration, suspension, structural integrity, and biocompatibility.

Calibration

Dr. Orsi's team originally pioneered the micro-bland embolization technique using 40- and 100-µm particles. This technique is made possible due to the unique and precise calibration of Embozene Microspheres. Granulometry studies show that 40- and 100-µm Embozene Microspheres are calibrated to ±10 µm. This unique calibration enables physicians to specifically

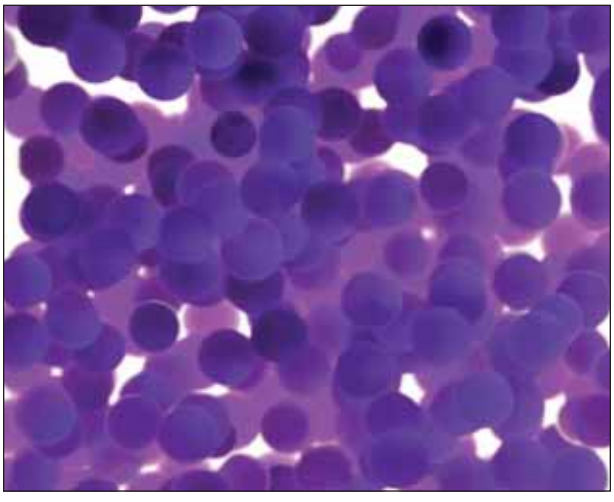

Figure 1. Embozene microspheres are color-coded to show size and suspension.

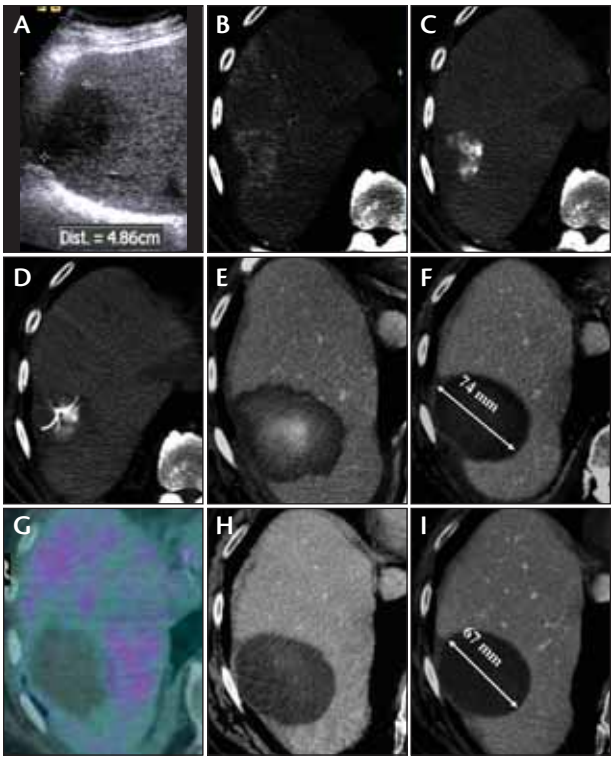

Figure 2. Pretreatment computed tomographic (CT) scans (A, B). CT after transhepatic arterial embolization (C) and 4-cm RFA (D). CT scans at 1 day (E) and 1-month (F) follow-up. PET scan at 1-month follow-up (G). CT scans at 3- (H) and 7-month (I) follow-up.

and selectively embolize target vessels. As demonstrated by Dr. Orsi's results, this mechanism of action may provide better tumor response and improve patient outcomes.

Suspension

The ability to control the rate of injection and resulting optimal endpoint is essential to achieving success in embolizing the vascular network surrounding the HCC. The durable suspension of Embozene Microspheres provides the physician with excellent control over the rate of injection.

However, suspension of particles is sometimes worth sacrificing for more efficacious tumor control. Dr. James Caridi of the University of Florida has found that overdiluting the particles permits more distal and thorough embolization. Slow, deliberate, diluted administration with a 1-mL syringe is performed with a delay between injections. When diluted, the particle has less chance for aggregation and is packed peripherally with contrast. Typically the larger, higher-flow tumor vessels sump the initial particles and are embolized. If there is limited volume of embolic, the smaller, slower-flow vessels may not be embolized. This opens the door for postembolization parasitization.

Using the dilute method, the larger vessels are occluded initially, and the embolic is subsequently redistributed and packed into the smaller vessels. Adding a slight time delay between injections allows these smaller vessels to open up and accept the embolic material. The result is more peripheral and complete embolization. Additionally, this method can be useful in localizing tumors. It results in trapping contrast within the lesion, making it radiopaque for at least 24 hours.

Structural Integrity

In bench tests, Embozene Microspheres have been shown to resist fragmentation and deformation in the solution during injection or after settling in the target vessel. This allows a high correlation between the diameter of the sphere used and the size of the target vessel being embolized.

Biocompatibility

Embozene Microspheres are composed of a hydrogel core and an exterior shell of Polyzene®-F, CeloNova's proprietary polymer that is clinically proven to be anti-inflammatory. In a 2009 study published in the *Journal of Vascular and Interventional Radiology*, Stampfl et al[1] demonstrated in a porcine model that pronounced immunomarker expression was seen 4 weeks after embolization with small tris-acryl gelatin microspheres, whereas Embozene presented low inflammatory results.

THE PLATFORM FOR THE FUTURE

The outcome of these combined features is a platform that has succeeded in optimizing every parameter relevant to the embolization procedure. Embozene Microspheres offer the added benefit of particles color-coded by size for instant visual confirmation of size and suspension, along with increased procedural safety. ■

Embozene Microspheres are cleared by the US Food and Drug Administration for the embolization of hypervascular tumors and arteriovenous malformations. Embozene Microspheres are not approved or marketed at the present time in the United States for HCC. Available outside the United States with CE Mark approval for the embolization of uterine fibroids, HCC, and other hypervascular tumors and arteriovenous malformations located inside and outside of the neurovascular and central circulatory systems, Embozene Microspheres have been available in Europe since 2006. For more information, visit www.celonova.com.

1. Stampfl S, Stampfl U, Bellemann N, et al. Immunohistochemical characterization of specific inflammatory tissue reactions following embolization with four different spherical agents in the minipig kidney model. J Vasc Interv Radiol. 2009;20:936-945.