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INTERVIEW

Results of the LAVA Study: An Interview With Dr. Mahmood K. Razavi

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At the 2023 Society of Interventional Radiologists (SIR) Annual Meeting in Phoenix, Arizona, Interventional Radiologist Mahmood K. Razavi, MD, FSIR, presented results from the Liquid Embolization of Arterial Hemorrhages in Peripheral Vasculature (LAVA) study. This prospective, single-arm, multicenter study was designed to evaluate the safety and effectiveness of the Lava liquid embolic system (LES) (BlackSwan Vascular), an injectable, nonadhesive liquid embolic agent. *Vascular Disease Management* spoke with Dr. Razavi to discuss the results of the study and what it means for embolization treatment.

Dr. Razavi, tell us about the LAVA study and why it's important.

In the United States, there are no currently approved liquid embolic agents for peripheral use outside the brain. Although liquid embolics have been available for a long time in the United States, no pivotal study has been done to look at their efficacy and safety outside the brain. The LAVA study is the first of its kind and given some of the advantages of liquid embolic agents in this space, it's very timely.

Lava LES is a liquid embolic agent that has been optimized for use in the peripheral circulation, based on viscosity and radiopacity, but also, most importantly, vial volume. When we use glue such as n-butyl cyanoacrylate (n-BCA, Johnson & Johnson) or Onyx LES (Medtronic) in the periphery, they come in 1-cc vials, requiring the use of multiple vials in some cases. The Lava vial size goes up to 6 mL, which is obviously more appropriate for peripheral use.

The LAVA study was a prospective, single-arm study done in 20 centers, and the target enrollment was 113 patients. That sample size was based on a review of the literature and the developed performance goals. During the review of the literature it was very clear (and of course we all knew it) that the data on bleeding and embolization are not robust. Most of the data comes from retrospective, single-center studies without adjudicated follow-up. So in addition to being a pivotal study, this was an opportunity to provide robust, prospective, core lab-adjudicated data in this space.

The study enrolled 113 patients at 20 sites. The distribution of patients included upper gastrointestinal (GI), lower GI, renal, trauma, and the usual suspects that you would see in peripheral bleeds and hemorrhagic conditions. Lava LES alone was successful in almost 71% of the patients without the need to use any other embolic agent. Adjunctive treatments like coils and gel foams were allowed at the discretion of the operators. An additional 21% or so used coils. So 92%, almost all the patients, had either Lava LES or Lava LES and coils. Gel foam was used in 4% of the patients.

Bleeding was successfully controlled in 133 of 141 lesions (94.3%) in 113 patients (primary endpoint of the study). No re-embolization or emergent surgeries were needed within 30 days. No other target lesion interventions were needed in 98.6% of these patients. The primary effectiveness endpoint was defined as absence of bleeding from the target lesion, without the need for emergency surgery, re-embolization, or other target interventions within 30 days. The primary safety endpoint was absence of ischemia or infarction of the target territory, of which none was seen. Other components of the primary safety endpoint included non-target embolization, allergic reaction, catheter breakage, and catheter entrapment; none of these were seen in this study. Catheter entrapment was one of the issues that the FDA was concerned about. It's really a legacy from the old glue days, but this is not an issue any more with the current generation of microcatheters and improved techniques. Nevertheless, that was part of the primary safety endpoint, and it was not seen in this study.

When we have an opportunity to do such a trial, it's always important to study other outcome measures (secondary endpoints) that have nothing to do with the approval of the device but that may be quite informative. Technical successes, which were defined as the angiographic evidence of immediate cessation of bleeding, absence of clinically significant ischemic infarction, all-cause mortality, occurrence of thromboembolic disease, procedural complications, etc, are examples of such and were among the secondary endpoints of this study.

While there were no safety signals in this study (primary safety endpoint), the all-cause mortality was 8.3% with bleeding-related mortality of just under 2%. These rates were actually lower than what we predicted we would see, based on the literature review.

What were the conclusions of the study?

Based on the data, the Lava LES appears to be safe and effective. The data are now before the FDA. There appears to be a statistically significant difference between the literature-based performance goals and what was seen here. Not speaking for the company, but I am optimistic that Lava LES will get approved for use in the United States.

Do you have plans for follow-up studies?

Well, these patients obviously need to be followed, and there is a requirement of following these patients as part of the protocol. Although this was the first pivotal study of its kind, liquid embolics are not new to us. My recommendation as the co-principal investigator would be to do a registry and follow a new set of patients so we learn more about the use of this product in real-world patients, outside the restraints of a clinical trial with a set of inclusion/exclusion criteria.

But the contribution to science and the literature of that type of study would not be as significant as this one.

What is the biggest takeaway that you wanted attendees at SIR 2023 to learn from your presentation?

That the data on the use of liquid embolics, although documented in the literature only in retrospective studies, are now available in a robust study that shows Lava LES is safe and highly effective. This study confirms what we've talked about for years, that there are clear advantages to liquid embolics in peripheral applications. Our objective was to get the FDA approval, and with approval, practitioners can be trained to use this highly effective form of embolization, to the benefit of patients. ■

Disclosure: Dr. Razavi is the co-principal investigator of the Liquid Embolization of Arterial Hemorrhages in Peripheral Vasculature (LAVA) study, sponsored by BlackSwan Vascular Inc. and Sirtex Medical.

