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INTERVIEW

New MAUDE Analysis Highlights Real-World Mechanical Thrombectomy Complications

An Interview With Chloe Issa, MD, and Sarah Montaquila, DO

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Key Summary

- Per an FDA MAUDE database analysis presented at SIR 2026, investigators reviewed 10 years of post-market adverse event reports for venous and pulmonary mechanical thrombectomy systems, reflecting real-world use but without denominators.
- They found that device malfunctions accounted for ~84% of reports but were less harmful, whereas access and bleeding complications made up ~1% yet carried a 7-fold higher injury risk (proportional reporting ratio 7.17; statistically and clinically significant).
- The findings suggest prioritizing prevention of rare, high-harm events (access and hemostasis) and optimizing procedural protocols (eg, ultrasound-guided access). However, because MAUDE lacks denominators, incidence rates and device comparisons cannot be determined, highlighting the need to link MAUDE surveillance data with clinical registries.

Chloe Issa, MD, *and* ***Sarah Montaquila, DO***

At the 2026 Society of Interventional Radiology Annual Scientific Meeting in Toronto, Chloe Issa, MD, and Sarah Montaquila, DO, transitional year residents at HCA Florida Westside/Northwest Hospital who will be continuing their training in interventional radiology at the University of South Florida and the University of California, Irvine, respectively, presented a decade-long analysis of FDA MAUDE data examining adverse events in venous and pulmonary mechanical thrombectomy systems. Their findings revealed a critical gap between how often complications occur and how much harm they cause. By spotlighting rare but high-risk events—particularly access and bleeding complications—their work underscores the need for procedural optimization, improved reporting, and a more nuanced approach to patient safety.

What motivated you to examine post-market adverse event patterns in venous and pulmonary mechanical thrombectomy systems, and why is this an important topic?

Dr Issa: Mechanical thrombectomy is one of the fastest-growing procedures in interventional radiology right now. More hospitals are doing it, indications are expanding, and utilization is rising. But most of the data we have on complications comes from clinical trials, and that doesn't always tell us what's happening in real-world practice across different centers and different operators. The FDA MAUDE Database is a large public repository of real-world adverse event reports. It captures malfunctions, injuries, and deaths, which allows us to perform signal detection. We decided to systematically review 10 years of data and try to give practicing interventionalists something clear and actionable to target.

I think this topic is important right now because as these devices diffuse across more centers and become more popular and utilized, understanding these failure patterns and getting ahead of complications is where we'll really make a difference in improving patient care and reducing patient harm.

Based on your FDA MAUDE analysis, what were the most notable trends or unexpected findings in adverse events associated with these devices?

Dr Issa: The most striking finding was the disconnect between frequency and risk. When we looked at the most common complications, device separation and other technical malfunctions were dominating with about 84% of our reports. These are things that the proceduralists tend to worry more about and that get more of their attention. But when we looked at what complications caused the most patient harm, a different pattern emerged. Access and bleeding complications were rare, only about 1% of our reports, but they had a 7 times higher injury risk than any other failure mode in our analysis. This corresponds to a proportional reporting ratio of 7.17, which is both statistically significant and clinically meaningful.

How should interventional radiologists interpret and apply your findings in their day-to-day clinical decision-making and device selection?

Dr Issa: I would frame it a little less toward device selection and more toward procedural protocol. MAUDE lacks denominators, so it doesn't allow us to compare device to device, but it does allow us to detect signals and focus quality improvement efforts there. There are a few things interventionalists and institutions can try to implement now. First, defaulting to ultrasound-guided access, which literature shows reduces complications. Second, having predefined bleeding algorithms—first compression, then reversal, then escalation—and that way, if something does go wrong in a case, the team already has a plan. And third, standardized anticoagulation and heparin dosing protocols. This can help reduce dosing errors and the, "Oh, I thought I was supposed to do this" type of issue that arises.

I also think we sometimes need to reframe our thinking: "frequency doesn't equal risk". In our study, access and bleeding complications were rare, only 1% of our reports, but they had a 7-fold higher injury risk. I think that's meaningful as we decide how to minimize this risk for patients. Rather than focusing on the high-frequency, low-harm complications, we should focus more on the rare complications that actually harm patients. Reframing that is what we hope clinicians would take away.

Now I am not trying to say to be afraid of these procedures or to avoid them, because they are important for patients with venous thrombosis or pulmonary embolism, and the literature shows that they do have good overall safety profiles. I think it's more about optimization rather than avoidance.

What else do you hope attendees of your presentation will leave with regarding the use of these systems?

Dr Issa: One of the main things we should try to do going forward is find a way to link MAUDE surveillance data with clinical registries. That would give us denominators, and we would be able to calculate true incidence rates rather than relying solely on signal detection. I think that's a gap that needs to be closed to strengthen what this kind of data can tell us. As I said, the main takeaway is focusing prevention efforts on access and hemostasis, because that's where the data shows the real risk is.

Dr Montaquila: Doing this project was interesting. I didn't even know that this MAUDE database existed, and I suspect many practicing clinicians may not be aware of it either. We were just talking earlier about how it would be interesting to incorporate more reporting, making it easier for all clinicians to report, because right now it's just self-reporting. If it was more standardized, I think we would have a lot more data and ways to address the different malfunctions and device issues. ■