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INTERVIEW

Latest Advancements in Coronary Thrombus Removal

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Vascular Disease Management spoke with interventional cardiologist Sanjit Jolly, MD, from Hamilton Health Sciences, McMaster University in Hamilton, Ontario, Canada, about the use of thrombectomy devices in percutaneous coronary intervention (PCI), specifically the Indigo® System CAT™ RX (Penumbra) for the removal of emboli and thrombi from the coronary vasculature. Engineered with neuro-tracking technology, CAT RX is designed to navigate tortuous anatomy and track to distal coronary vasculature while maintaining sustained mechanical aspiration.

What are some of the challenges and risks associated with large thrombus burden in PCI?

Large thrombus burden in patients with acute myocardial infarction (MI) is associated with significantly worse outcomes, so patients have higher risks of cardiogenic shock, death, and stent thrombosis. It's an unmet clinical need, in terms of treatment. The risks, in terms of procedures, are predominantly issues around distal embolization of thrombus. There's no reflow phenomenon; the thrombus goes down and blocks the microvasculature, leading to outcomes such as cardiogenic shock.

Patients who have high thrombus burden may have a higher risk of other complications, including stroke, related to the procedure. This population is difficult to treat, and we need new therapies.

How do you assess a patient for large thrombus burden? Is it through imaging, or do you wait until you get into the vessel itself?

Typically, we'll do a diagnostic angiogram with our catheters at the time of the PCI, and we assess it both before and after wire crossing. Sometimes after wire crossing, the thrombus may just wash away or go downstream, so there's nothing to go after. Typically, the best time to assess it is after wire crossing, to decide if you're going to use any other technologies.

How are patients currently treated outside of mechanical aspiration? What's your typical first-line treatment?

In a patient with acute MI, we usually wire the vessel, use a small balloon, and establish some flow. If, on the other hand, there's a large amount of thrombus and reduced thrombolysis in myocardial infarction (TIMI) flow, we consider alternative options like manual aspiration thrombectomy. However, it has been demonstrated that manual aspiration suffers from diminished aspiration force as fluid fills in the syringe, potentially resulting in systemic embolization during catheter removal. Some centers use the AngioJet system (Boston Scientific) but this technology also has limitations. AngioJet utilizes saline

flush jets that flows forward as well as aspirates. There may be concerns about distal embolization with that technology and the data is mixed, some studies suggesting benefit, other studies suggesting harm.

Because of the limitations of these traditional technologies, having a solution like Penumbra's CAT RX is attractive. You don't have diminished aspiration or saline jets, potentially causing distal embolization. CAT RX provides continuous power aspiration and a large catheter lumen that creates a more effective form of aspiration.

What patient outcomes do you see when you revascularize quickly?

Mortality in acute MI has generally dropped over the last 20 years. We are seeing improved outcomes, and it's probably related to both pharmacotherapy and rapid reperfusion. Patients' symptom onset to reperfusion time is fairly short, just a couple of hours. Ambulances are activating in the field and bypassing their local ED and coming directly to PCI centers. I think that has led to an improvement in outcomes.

We still see a subset of patients who are in heart failure with large infarcts, proximal vessel occlusions, and lots of thrombus, and their outcomes are poor. We have a few patients in our coronary care unit who had large anterior MIs and are left with an ejection fraction (EF) of 20% and are in borderline cardiogenic shock; we don't have good options for them. They're not tolerating any goal-directed medical therapy because their blood pressure is so low. Some of them are in their 40s and 50s, and perhaps a heart transplant is down the line, but who knows? There is a subset of patients who have very poor outcomes. What is uncertain is whether a technology like CAT RX could help these patients in reducing infarct size. That's still to be seen; we need technologies to help improve the outcomes of this subset of patients.

What have historical studies shown around the use of thrombectomy in PCI? Has there been any new data that suggest thrombectomy could be beneficial, and how does that impact the field today?

Going back more than a decade, a trial called TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) of about 1000 patients suggested that manual aspiration thrombectomy may be beneficial, in terms of myocardial blush grade, which is a measure of microvascular perfusion on the angiogram. There was a reduction in mortality, but this was based on a relatively small number of events.

Larger follow-up studies, such as the TASTE (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia) trial and the TOTAL (Thrombectomy With PCI vs PCI Alone in Patients With STEMI) trial, of which I was the principal investigator, failed to demonstrate a reduction in mortality. TOTAL, but not TASTE, showed an increased risk of stroke associated with routine manual aspiration thrombectomy.

Following the result of those trials, manual aspiration use declined. Subsequently, a follow-up meta-analysis[1] looking at the individual patient data of nearly 20,000 patients, suggested this interesting finding: In patients with high thrombus burden, there appeared to be a cardiovascular mortality reduction at 30 days, but also an increased risk of stroke. And that's the paradox with manual aspiration thrombectomy observed in patients with STEMI.

The recommendation was that we need further data with improved technology, so the most recent data is the CHEETAH study, which is performed with the CAT RX[2] aspiration system. CHEETAH was a single-arm, multi-center, prospective study that demonstrated very good angiographic outcomes, improved myocardial blush grade, low risk of stroke, and very low rates of mortality. However, future randomized studies are needed with this new technology.

The CHEETAH study results came out about a year and a half ago. Can you go into some of the details of what that study showed?

In a group of 400 patients with high thrombus burden, CAT RX demonstrated high rates of TIMI-3 flow, along with very high rates of myocardial blush (grade 3), close to 99%, low rates of mortality, and low rates of stroke. The CHEETAH study demonstrated high safety and performance outcomes and the results are promising. But the next step should be to evaluate this technology in a randomized controlled trial.

How does power aspiration with the CAT RX differ from some of the traditional treatment options for coronary thrombus management?

Traditional manual aspiration is simply a syringe-based mechanism. Very quickly, you lose suction during the procedure. And often, when you're withdrawing the catheter, you would have minimal to no suction with the potential for losing thrombus and increasing the risk of stroke. CAT RX provides continuous aspiration for the duration of the procedure which may limit the risk of distal embolization and stroke.

In your recent experience, how has CAT RX impacted your practice?

In our experience, CAT RX has been much more effective at removing thrombus than manual aspiration thrombectomy. We've had cases where we've tried manual aspiration and it was unsuccessful, and the CAT RX has worked to remove thrombus and allow us to proceed with the procedure.

Looking forward, where do you see the future of coronary aspiration?

Our individual patient meta-analysis shows that there is a subset of patients that can benefit the most, which are patients with high thrombus burden. The TOTAL and TASTE trials looked at everybody, but we really need to focus on patients with TIMI thrombus grade 4 or greater.

And the single benefit from the individual patient meta-analysis suggests that this hypothesis is important to continue to pursue. There is an upcoming randomized trial called the CHEETAH-ACS trial, which will randomize patients with high thrombus burden to upfront CAT RX with PCI vs PCI alone. That's really exciting, because for the first time we will have a randomized trial with this new technology, and this has the potential to be very important for patients and for clinical outcomes.

If the CHEETAH-ACS trial goes well, how do you think mechanical thrombectomy will impact patient care? Do you think more people would adopt aspiration thrombectomy vs traditional standard of care?

If the CHEETAH-ACS trial is positive, and it shows improvement in the primary outcome, that will certainly be a step in the right direction and adoption of this technology in PCI will likely grow. ■

Interview sponsored by Penumbra, Inc. Dr. Sanjit Jolly is a consultant for Penumbra, Inc.

[1]Jolly, Sanjit et al. Thrombus Aspiration in ST-Segment-Elevation Myocardial Infarction. *Circulation* 2016 Dec, 9;135:143-152.

[2]The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) has not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.

Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment. The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors.

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