

INTERVIEW

STRIDE Study: When ALI Is Treated With Mechanical Aspiration Thrombectomy, Race, Not Sex, Is Associated With Adverse Outcomes

An Interview With Alex Powell, MD

[Alex Powell, MD](#)

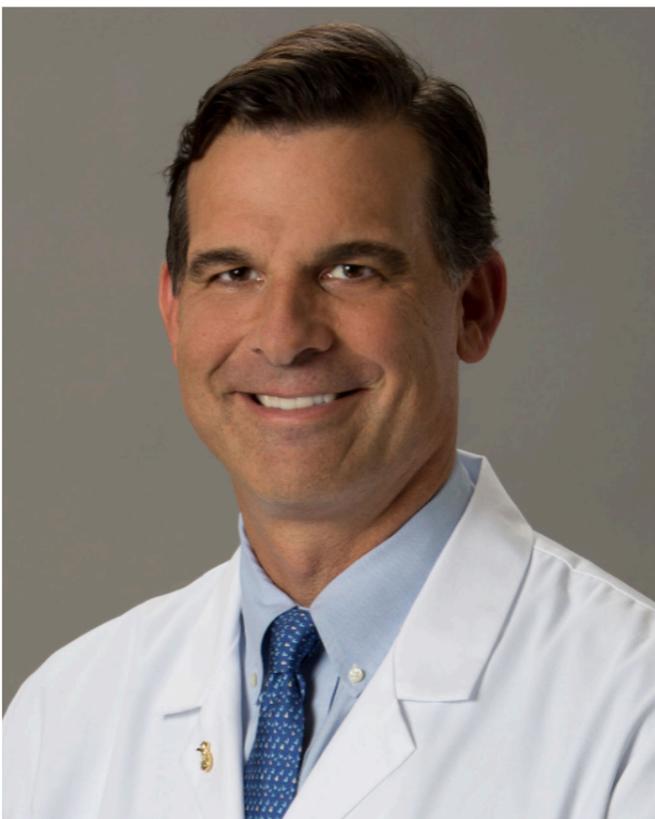
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A presentation entitled “STRIDE Study Suggests Race, Not Sex, Is Associated With Adverse Outcomes in Acute Limb Ischemia Treated With Mechanical Aspiration Thrombectomy” was given at ISET 2025 by Alex Powell, MD, interventional radiologist at the Miami Cardiac & Vascular Institute. *Vascular Disease Management* spoke with Dr Powell to discuss the surprising results from the STRIDE study, which looked at the use of the Indigo Aspiration System (Penumbra) for acute limb ischemia (ALI).

Can you provide a brief overview of the STRIDE study?

The STRIDE study was a formalized trial to identify and quantify what we have been seeing using aspiration catheters for patients who are presenting with ALI. If you go back 30 years, all these patients were treated with surgery. If you go back 20 years, these patients were treated with a combination of surgery or catheters where we would inject lytic medications, whether urokinase at one point or tissue plasminogen activator. They are fairly efficacious, although both of them have their significant downfalls; there is a morbidity and mortality associated with surgery, as is with all these procedures, but it is a little higher. The issue with giving lytic medications is that it requires careful overnight monitoring. There is an issue with bleeding in these patients, including intracranial hemorrhage, that obviously is a devastating complication.

So along comes this idea, that originally began in stroke, recognizing that patients were doing a lot better if we could go in and suck out the clot causing the stroke. We certainly know that happens in patients who present with acute arterial limb ischemia. If you just make everything bigger, the idea is that we can apply the same suction or vacuum to it and take the clot out. Ideally, you do it in a single setting and you can do it faster and safer. That was the basis of the STRIDE trial. Patients who presented with ALI were enrolled at multiple sites throughout the United States and Europe, and we studied the outcomes of how patients did at 30 days as well as 365 days. And the overall outcomes are excellent.

At 30 days, the target limb salvage, or the patient living with their limb, was 98% overall, which is excellent. Compared to surgery and catheter-directed lysis, those outcomes are superior. Then we looked at a number of safety measures such as bleeding and other adverse events. Results of the STRIDE study were published in the *Journal of Vascular Surgery* and it confirmed what we have been observing—that this is a superior way to treat patients with ALI. The results have gone out to 365 days now and the target limb salvage remains 88.5% in terms of all-comers.

What were the key findings of the STRIDE study regarding the impact of race vs sex on outcomes in patients treated for ALI with mechanical aspiration thrombectomy?

After the first set of results came the subgroup analysis. There is obviously a lot of interest in treating women and looking at outcomes in women. We just looked at a carotid stent trial, with all of that great data, then the caveat, well, none of this applies to women. So that was the first subgroup analysis: what are the outcomes in women? In the STRIDE study, 46% of all patients enrolled were women. That alone makes it somewhat unique in that there is near-equal enrollment between men and women. Basically, every outcome was comparing men to women, and there was no difference in safety outcomes and target limb salvage.

Target limb salvage was the primary endpoint, and there are a number of secondary safety endpoints, and we found no statistical difference in outcomes, which was an encouraging finding. That led to the next subgroup analysis looking at outcomes by race—and that is where we started to see a difference. Target limb salvage in the White population was 100% at 30 days and 91% in the African American population. That became a little more significant at 365 days when the overall outcome for all-comers in the trial was 88% and the subgroup of African Americans was 66%, which generates a hazard ratio of 13. It is really an astounding number. That is the hazard of losing your limb if you are an African American in this trial as compared to the overall population, particularly the White population.

It is important to note that the mortality was actually lower in the African American population. Limb loss, the primary endpoint, was higher, but further analyzing this, the mortality was lower than the overall population. That is important, and there are a number of factors that can go into mortality that we should probably really focus on, including the target limb salvage and why is it different. We did some comparisons of White directly to Black, but that excluded some Hispanic enrollees. When we did the direct comparison overall, that the White population is pretty representative and what were the differences, we looked at this in a number of ways. In terms of statistical significance, we could not find anything that said, “Ah, that was it,” but we did have some observations in that when patients present with ALI, we have a categorization. One is mild 2A, then 2B, and 2B is worse than 2A. There is a category 3, which means the limb is already dead, so those patients were not enrolled. But if we look at the 2Bs in the African American population compared to any other, it was higher. They were sicker at presentation, which leads to an obvious question: are they delaying care before coming in? We don't have that answer.

This wasn't statistically significant, but it was, if you use the term *signal*, that maybe there was a little signal there; one thing we know is that they trended toward being more severe on presentation, and we don't know why that is. There can be speculation around that but again, it is not statistically significant, but if you point out something and say, for instance, if you come in sicker it only stands to reason that you have a higher chance of losing your limb. That is something that we are going to need to study further. We don't have the answer, I wish we did, but we do know that if you look at a lot of population studies, African American patients compared to others typically present in a more delayed fashion.

To be enrolled in the trial, the symptoms had to occur less than 14 days, so it was not going on for a long period of time. What is unique about this trial is you are excluded with symptoms lasting longer than 14 days. But maybe there was something in between; these are not real numbers, but let's say presenting at 6 days vs 1 day for an average White person. Again, that is just speculation, but that is the only thing we noticed that was really significant. Of course, we looked at incidents of heart disease, diabetes, hypertension, age, all those other factors. While there are some slight differences, we did not find a big difference there other than what I already mentioned, a little higher percentage of 2Bs.

What did the data suggest about the effectiveness and safety of the Indigo Aspiration System in treating lower extremity ALI?

If you look at the STRIDE trial in general, Indigo was highly efficacious and exceeded our expectations, and that was compared to historical literature. If you compare both lysis as well as surgery, the outcomes in terms of limb salvage, morbidity, and mortality, those were all superior. So you can say that the effects of this STRIDE trial are a paradigm shift, basically, that a frontline treatment for ALI of the lower extremities should be done with aspiration thrombectomy. That should be frontline therapy for any patient who can undergo it. It does not mean that some of these patients do not go on to get lytic medications, because they do. We could continue to perfect our techniques, but some people still need lytic medications. Given the outcomes of this trial, aspiration thrombectomy should be the frontline therapy. And it really has become the frontline therapy for clinicians who are doing this.

Given the study's conclusions on racial disparities and treatment outcomes, what recommendations or future research directions do you propose to improve equality in managing ALI?

If the theory is right and there is still some delay in patients seeking help, although we were not able to show it in this trial, we need to increase community awareness and educate patients that when your leg starts being painful, things can be done in the hospital and you should seek care immediately. Unlike heart attacks—although there are still some people who delay coming to the hospital with a heart attack—they kind of know that this is a bad thing and they need to go to the hospital. For many people, however, their leg starts hurting, and it can hurt significantly, but they think it is going to go away, that it is going to get better. They notice the leg is cool, all those things, but somehow they don't come to the hospital. Increasing community awareness is important for them. ■