The PRESERV Trial on Contrast-Induced Nephropathy: An Interview With Richard Heuser, MD

Interview by Jennifer Ford

The PRESERV (Prospective Randomized Evaluation to Study the Effects of Reduced Contrast Media on the Vitality of the Kidney) Pivotal Trial will enroll patients at 25 centers for a randomized trial of the CINCOR Contrast Removal System (Osprey Medical). The primary outcome measures include incidence of contrast-induced nephropathy, bleeding and transfusion events, and local events that require treatment or result in myocardial infarction or death.

Richard Heuser, MD, from the Phoenix Heart Center and St. Luke's Medical Center in Phoenix, Arizona, enrolled the first two patients in this trial in May 2013. Vascular Disease Management spoke with Dr. Heuser about the CINCOR system and the PRESERV trial.

Q: Could you describe your involvement in the PRESERV trial?

A: This is a multicenter trial. We just enrolled the first patients in the United States. Phoenix Heart Center will enroll about 10 to 15 patients. There will be 25 hospitals.

Certainly all of us have issues with patients with renal insufficiency and there's nothing magic that works out there. We've tried everything. We've tried the pharmacologic drugs. We've tried Mucomist. We've tried sodium bicarbonate.

We usually do a saline infusion, but we still encounter situations in which certain patients with elevated creatinine do get contrast-induced nephropathy, and it can be devastating. It does affect morbidity and mortality, so when I heard about the concept being studied for the PRESERV trial, I thought it made a lot of sense because they were addressing the problem from multiple angles and making a concerted effort to ensure that contrast that you inject actually goes into the coronary arteries; it's not flushed out into the root where all it's doing is affecting the kidneys, so that was really smart technology. It also drains the coronary sinus and removes the majority of that contrast so it's not in the system.

Q: What have you experienced so far in using the system?

A: It basically reduces the contrast utilized down the coronary. It's much more efficient rather than using 5 cc or 6 cc where 4 or 5 of those are wasted; only about 2 cc go actually in the coronaries and then all of the contrast in the left coronary system is filtered out through the coronary sinus and so we retrieve probably 80% to 90% of that by having a device in the coronary sinus. So, it limits the amount of dye that the patient gets systemically. In other words, we remove it through the coronary sinus before it goes into the kidneys.

Q: And that's a dramatic change from the standard.

A: Yes, because we know if we have a patient with elevated creatinine and we can do a procedure where the patient only gets 5 cc to 10 cc of contrast, it's unlikely that they're going to have any contrast-induced nephropathy. And basically that's what we're doing here. We are probably limiting contrast to less than 5 cc.

What's exciting about this system is that it can be safely utilized in patients with complex coronary disease, and the cases we did were fairly complicated lesions and it didn't cause any elevation in their creatinine.

Q: Can you explain how this could reduce costs?

A: The interesting thing about contrast-induced nephropathy is it in-

creases hospitalization because the patients usually have to be hydrated for 2 or 3 days, they usually have to been seen by nephrology, and sometimes they get dialyzed. Again, that portends mortality, but it also portends a prolonged hospitalization because you can't just expect the patient's going to be able to hydrate enough at home with oral administration. It usually requires intravenous hydration and in a small percentage of those patients they need to be dialyzed, which can go on sometimes for months.

Q: Do you see any potential limitations for using this system?

A: Yes. So far, today, it's really most effective in patients when you're working on the left coronary system, meaning the right coronary artery is not drained into the coronary sinus. So, although we can limit working in the right coronary by the contrast utilization in terms of the amount of contrast going down the coronary, we really can't remove the contrast going through the right coronary artery because it's not drained through the coronary sinus. So, right now we're not utilizing it with any patients that we are doing right coronary intervention.

Q: What's the projected timeline for the trial?

A: The original thought is to have about 25 sites in the United States and probably about 40 centers around the world. They may have to go with more centers. The problem you have is that patients have to have elevated creatinine and they have to have intervention in the left part of the heart so as we've seen a reduction in cardiovascular disease in terms of coronary disease and some centers in the United States, it might take a year and a half or so to enroll all the patients, but it's definitely worth it. And as we get sicker and sicker patients, I think we will find this is going to be utilized even more.

Q: Is there anything else that I might have missed that you wanted to add about the trial or the dye-removal system?

A: I think that we are going to see more and more of these techniques to reduce contrast utilization. Quite frankly, we've tried all different kinds of contrast. We've tried all the mixtures of different things. We've tried to put shunts in the renal arteries where they increase pharmacologic dilation of the renal arteries. That doesn't seem to work. Phentolamine was one of the drugs we used. We thought that worked, but it ended up in a trial that showed it was no better than placebo. And it was very expensive.

The technique takes a few cases to get comfortable with in the coronary sinus, but once you've mastered that, it's pretty straightforward and I think it's useful. So far, I think that if this proves helpful then this could be utilized in all patients that might have an elevated creatinine to start with. I don't think we would use it prophylactically, like in diabetic patients, but I think for patients with elevated creatinine, greater than two, this may be utilized worldwide if this trial has a positive effect.

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