### Sunil V. Rao, MD

Dr. Rao discusses optimal medical therapy for avoiding post-PCI complications, the growing practice of same-day discharge, and seemingly minor changes that could make a big difference in your practice.



What do you believe is currently the best medical strategy for preventing ischemic complications in percutaneous coronary intervention (PCI) patients? Are there factors that might make some patients better candidates for certain drugs?

I think that's an important issue, and the number of choices for antithrombotic strategies during PCI is pretty dizzying. The fundamental approach to patients in the cath lab that are undergoing PCI is to recognize that they are not only at risk for ischemic complications, but they are also at risk for bleeding complications. We now have models to determine who is at higher risk for bleeding relative to others (ie, older patients, patients with renal failure, and women are at high risk for bleeding complications). But having said that, I think that at the end of the day, you have to approach each patient as if they are at risk for both ischemic and bleeding complications. So it's really in the patient's best interest to try and minimize both of those complications.

Now, how do you do that? Well, you start by recognizing that the players in these ischemic complications are very similar to the players that are involved in ischemic complications for acute coronary syndrome: platelets, thrombin, and the coagulation cascade. Then we start with early, somewhat aggressive antiplatelet therapy, particularly in patients that come to the cath lab with a history of acute coronary syndrome. We're believers in the early institution of oral antiplatelet therapy with aspirin and a thienopyridine; antithrombotic strategies such as unfractionated heparin or low-molecular-weight heparin; in the cath lab, I think bivalirudin provides an excellent alternative, because it's been proven in large randomized trials to not only maintain the anti-ischemic benefit of anticoagulation but at the same time minimize bleeding risk. So it is really a combination strategy with respect to pharmacological agents: aggressive antiplatelet therapy,

aggressive antithrombin therapy, and then the use of glycoprotein IIb/IIIa inhibitors as the bailout strategy for any patient who may develop ischemic complications during the procedure.

By combining those strategies, you can minimize the ischemic risk. Certainly, you have to pay attention to the patient's renal function to make sure you are providing an appropriate amount of drugs. If you are using a very potent agent such as prasugrel, make sure you follow the labeling for contraindications (eg, caution in patients over the age of 75 years, patients who have had previous stroke, or very low body weight patients).

Also, I think the use of transradial access is a very important aspect of a bleeding avoidance strategy. Radial access is the best way to minimize access site bleeding. Therefore, it is ultimately a two-pronged approach: a pharmacological approach and an access site approach to reduce bleeding.

Because anemia can play an important role in high residual platelet reactivity and the efficacy of clopidogrel, how can this be compensated for if it is known that the patient is anemic before the procedure?

That's a really important aspect that I think we oftentimes overlook. Anemic patients are at fairly high risk for bleeding complications and they are certainly at risk for adverse outcomes, not only after PCI but also in the setting of acute coronary syndrome. With anemic patients, the first thing to do is understand how acute the need is for PCI. If this issue is more on the elective side, and the patient can be managed medically, I think it's important to chase down the cause of the anemia and try to get that corrected because that may address the symptoms that they presented with, and the patient may not even need PCI. Even in the setting of STEMI or acute coronary syndromes, in which PCI is a bit more urgent, we still need to recognize the fact that these patients are going to be at a higher bleeding risk than an ischemic risk, so we need to take all of the precautions possible to mini-

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mize the bleeding risk while at the same time maintaining an anti-ischemic strategy.

For these patients, our approach to access has certainly been radial. We tend to shy away from more potent antithrombotic agents, such as glycoprotein IIb/IIIa inhibitors, or more potent thienopyridines, because they have the potential to increase the bleeding risk. We tend to go with a clopidogrel strategy with radial access and try to avoid any potent antithrombotic agents.

#### Can you talk a bit about Duke's Mobile Catheterization Program and its impact on the local community?

In the South, and especially in North Carolina, there are a lot of areas that don't have access to higher-end medical care. So, the mobile catheterization program was designed to assist patients who otherwise wouldn't have access to the cardiac procedures and catheterization. We don't perform PCI in the mobile atmosphere; it's really just for diagnostic catheterization.

Even if the patient doesn't have any significant coronary disease, knowing that is actually a huge service to them because they will not have travelled all the way to Duke to learn this, which is often difficult for these patients. Furthermore, any information gained from the mobile unit can then be passed along to their own local providers for future treatment decisions.

# Same-day hospital discharge is very similar to overnight observation in terms of death or rehospitalization rates. What do you think may account for the discrepancy between hospitals that discharge low-risk, uncomplicated PCI patients the same day as opposed to centers that choose to observe the patients overnight?

The vast majority of hospitals in the United States keep their patients overnight. It's important to distinguish between so-called in-patient and out-patient, which is a distinction that is really at the billing level and how the bill gets submitted to the payer. Same-day discharge and overnight stay can both be billed as out-patient care. There are certain criteria that the patient has to meet to be considered an in-patient; otherwise, all the patients are considered out-patients.

In terms of same-day discharge versus overnight care, I think that the main reason that patients are kept overnight is because physicians are genuinely concerned about their patients, and they want to make sure that they're in a monitored setting in case there is a problem. If there is any concern regarding acute stent thrombosis or bleeding risk, I think it's entirely appro-

priate to keep these patients overnight.

There is a lot of interest in same-day discharge, and we've done this for a couple of years. I think if you are interested in sending patients home the same day you perform PCI, it has to be part of an organized program. One of they key parts of a same-day discharge program is to make sure that patients have a number to call, a safety net if they have questions or concerns.

## Do you use a checklist system in your cath lab? If so, have you found this to be helpful in producing better outcomes or is it more time-consuming than it's worth?

We absolutely have a checklist. The checklist we use confirms that the right patient is in the room, whether the patient has allergies (eg, an allergy to contrast), and the exact procedure that is to take place. Another aspect that we found to be very helpful to include in the checklist, and is specific to interventional cardiology, is knowing the issues surrounding the patient's ability to adhere to antiplatelet therapy after stenting. Does this person have a major surgery coming up in the next year? Is he or she anemic? Does the patient have a history of medical noncompliance? Do they have an major dental work scheduled for the near future?

With those factors addressed before we even see the patient, we know all of the information we need to make the right decisions about drug-eluting stents versus non-drug-eluting stents and what types of medications we should be avoiding.

### Do you think that the BARC bleeding criteria will become widely used in tandem with TIMI and REPLACE-2 criteria?

The BARC criteria are the culmination of several years of research. We were among the first groups here at the Duke Clinical Research Institute to point out that the safety data, as they pertain to antithrombotic therapies, can be subject to gaming depending on the definition that's used (ie, defining bleeding in a way that assists in confirming the researchers' original hypothesis). We realized that there is a possibility that the clinical community is being done a disservice by not having the same definition of bleeding across all of these studies, the same way we have a standardized definition for myocardial infarction. However, it was difficult to convince people that this was a problem.

With the BARC criteria, we've gotten away from using qualitative terms like major and minor because one person's minor bleed may be another person's major bleed. Instead, we're using types 1 through 5 to define bleeding.

I'm happy to say that there have been published findings that show a relationship between these types of bleeding events and subsequent mortality, and several ongoing randomized trials are now also using these criteria.

It was shown that African Americans with STEMI are at a higher risk of bleeding complications than whites. Is there a theory as to which factors may explain this increased risk? Have studies been proposed to examine this phenomenon in other racial/ethnic groups?

I think we're just scratching the surface of this. I mean we know that there are differences across patient groups, even within the patient groups from patient to patient. Unfortunately, we don't have a lot of clarity on what the biological reasons are for this finding. It could be because African Americans have a higher incidence of renal failure, and we adjusted for that, but I'm not sure just how well we can adjust away those differences. It is also an important consideration in terms of the way that drugs are being developed, and I think we're going to see a lot more study in that regard.

You are a co-chair of the Transradial Interventional Program (TRIP) series, which is taking place in Houston, Texas in December, as well as Program Director of the 2nd Annual Duke Transradial Masters Course in October. Are there many differences between these meetings, and whom are they aimed toward?

These programs are meant to serve two different audiences. The SCAI TRIP program is mainly for physicians who are very early in their learning curve or are thinking about starting a transradial program. It will have some advanced content, but predominantly, it will be based on transradial techniques.

The Duke Transradial Masters Course is for those who have gotten over that initial learning curve and are looking to expand their radial skills to take on more complex cases and more complex patient subsets. They also have two different formats. The Duke Transradial Course is much more case-based, and the TRIP program offers more lectures and simulations.

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