

Editorial

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SPRINT: Yes, it does need to be studied!

I recently attended the training meeting for a brand-new multicenter National Institutes of Health (NIH) study that is just about to start enrolling patients. I personally believe that it's a very important study. But I've been dismayed by some of the comments I've heard from colleagues when I tell them about the study and about what we hope to learn from it.

The study is called SPRINT, which is an acronym for the Systolic Blood Pressure Intervention Trial. As the name suggests, the primary focus of this study is to assess the value, or lack thereof, of aggressive efforts in the treatment of systolic blood pressure (BP). More specifically, we plan to enroll nearly 10,000 older, high-risk patients with systolic hypertension, and then randomly assign them to either a conventional BP goal of less than 140 mm Hg, or to a more aggressive systolic goal of less than 120 mm Hg. We're excluding patients with diabetes who have been extensively studied in a very similar protocol as part of the very large ACCORD (Action to Control Cardiovascular Risk in Diabetes) trial. We're also excluding patients who are post-cerebral vascular accident and also those with polycystic kidney disease, because both of these subsets of patients are also being studied in other trials. We will follow our older patients with systolic hypertension for between 4 and 6 years, depending upon when they enter the study, to compare the risks and the benefits of the 2 treatment goals.

I've been disappointed by the responses I have been getting when I describe the study to colleagues. A number of well-meaning providers who consider themselves fairly savvy

when it comes to hypertension look aghast and ask why the NIH would spend a ton of money on something that seems so pointless to them. Isn't it a total no-brainer that the lower systolic BP goal would be preferable in these high-risk patients? Isn't it foolish to ask if lower is better, when we know that a myriad of epidemiologic studies have clearly shown that risk increases progressively as systolic BP rises above 115 mm Hg, roughly doubling with each 20-mm Hg rise? Isn't it basically unethical to treat half of the patients in our study to a less-effective goal of less than 140 mm Hg, while the other half gets the undoubtedly sizable benefits of a more muscular and aggressive intervention (down to less than 120 mm Hg)?

pharmacologic information. Major differences may exist in the basic cardiovascular physiology of the 2 individuals—physiologic differences that cannot be eliminated simply by administering powerful antihypertensive medications. There's absolutely no free lunch when it comes to potent antihypertensive medications, with adverse effects on potency (no pun intended)—well, all right, partially intended), postural BP, glucose levels, lipid levels, and many other potential physiologic perturbations.

And let's keep in mind that nearly 50 years of clinical trials in the area of hypertension provide very scant evidence that driving systolic BP down to the seemingly low-risk range is really of benefit. We have to first real-

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Well, no. It turns out that we really don't know which systolic goal makes more sense as a public health recommendation. It's critical to remember that there is a huge difference between epidemiologic risk and the potential benefits or harm that are associated with intervention at varying levels of aggressiveness. There is a huge potential difference in the cardiovascular risk going forward in someone fortunate enough to have a very benign systolic BP naturally, as opposed to someone with the exact same systolic measurement whose BP matches only because of potent

ize that most of the intervention trials out there settled for systolic BP values in the more aggressively-treated wings of the studies well in excess of the default setting in our current study, which is a goal of less than 140 mm Hg. Those studies that did try to hone in on lower goals are basically few and far between. The recent one that was by far the best of the field was the ACCORD BP study—a study near and dear to my heart because of the 11 years of labor I put into it. In this study, we compared a systolic BP goal of less than 140 mm Hg with a more aggressive goal of less

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than 120 mm Hg. We were unable to demonstrate a statistically significant benefit in the primary end point from the lower systolic BP goal—although there was a sizeable percentage reduction in the number of strokes, but with small absolute numbers. Most hypertension experts concurred with our assessment that this was essentially a negative study, and that there was no need to change existing BP recommendations for patients with diabetes. (The patients in our control arm had a mean systolic BP of 133 mm Hg, not very different from

the current recommendation to aim for a systolic BP under 130/80 mm Hg in patients with diabetes.)

Will we find the same results in SPRINT? We truly don't know, and that is why it is critical that this important study move forward. We know less than we think, and well-designed, prospective, randomized studies are the best way to increase our knowledge and understanding. ●

Author disclosures

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