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New Data Challenge 130 mm Hg As Systolic BP Target in Diabetes

BY MITCHEL L. ZOLER

ATLANTA — The official U.S. guideline that patients with diabetes should receive treatment to a blood pressure target of less than 130/80 mm Hg became suspect following reports from a pair of large studies showing no benefit in these patients beyond a goal systolic pressure of less than 140 mm Hg.

In a controlled trial with more than 4,700 U.S. patients with type 2 diabetes randomized to an intensive antihypertensive regimen with a goal systolic pressure of less than 120 mm Hg or to a standard-therapy arm aiming for less than 140 mm Hg, “the results provided no conclusive evidence that the intensive blood pressure control strategy reduces the rate of a composite of major cardiovascular disease events,” Dr. William C. Cushman said at the annual meeting of the American College of Cardiology.

“We were surprised by the findings” from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) blood pressure trial, said Dr. Cushman, chief of the preventive medicine section at the VA Medical Center in Memphis. “The evi-



Intensive blood pressure control did not reduce the rate of major cardiovascular disease events in patients with diabetes, Dr. William C. Cushman reported.

dence supports less than 140 mm Hg. There generally was thinking that if you're dealing with [high cardiovascular risk], such as patients with diabetes, it makes sense that their goal pressure should be more intense.” The results

“clearly say that we can't think that way anymore” and should influence recommendations expected in about a year from the Eighth Report of the Joint National Committee on the Prevention, Detec-

See **Systolic BP** page 18

Physicians Consider Benefits, Challenges of Health Reform Law

BY MARY ELLEN SCHNEIDER

After more than a year of heated debate on the merits of health reform, policy makers and physicians are switching gears, assessing the impact of the new law and considering how to improve it in the future.

“This legislation improves the chance that our patients can see doctors,” said Dr. Frederick E. Turton, chair of the board of regents of the American College of Physicians. “When patients see their doctors, they live longer and live happier lives.”

Dr. Turton also lauded the law's provisions on preventive services, which will allow patients with Medicare, Medicaid, and private insurance to get many preventive services without incurring out-of-pocket costs. But the legislation does not go far enough in supporting primary care, he said. The 10% Medicare bonus payment to primary care physicians over 5 years is a positive feature of the new law, but much more is needed. “We're facing a crisis shortfall of primary care doctors, and 10% is not enough to make any difference whatsoever,” said Dr. Turton, a general internist in Sarasota, Fla.

The planned Independent Payment Advisory Board ‘could result in misguided payment cuts.’

President Obama signed most of the health reform provisions into law on March 23. On March 30, the president signed a smaller bill—known as the reconciliation bill—that Congress had passed to make adjustments to the original package, including the addition of more subsidies for purchasing insurance, and removal from the law of some of the more controversial political deals.

The new law clears the way for about 32 million previously uninsured Americans to have access to health insurance in the next few years. The law requires in-

See **Reform Law** page 6

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VITALS

Major Finding: Among diabetes patients at high cardiovascular risk, those treated to a mean systolic blood pressure of 119.3 mm Hg had a 1.87%/year rate of nonfatal MI, nonfatal stroke, or cardiovascular death over 4.7 years, compared with 2.09%/year in patients treated to a mean systolic blood pressure of 133.5 mm Hg. The difference was not statistically significant.

Data Source: ACCORD blood pressure trial, a randomized, controlled study of 4,733 patients with type 2 diabetes.

Disclosures: Dr. Cushman has received consultant fees and honoraria from Novartis, Sanofi-Aventis, Theravance, and Takeda, and served on data and safety monitoring boards of Novartis and Gilead. Dr. Bakris reported financial relationships with Abbott, GlaxoSmithKline, Novartis, Merck, Gilead, and other companies. Dr. Cooper-DeHoff and Dr. Simons-Morton had no disclosures.

Targets in Diabetes

Systolic BP from page 1

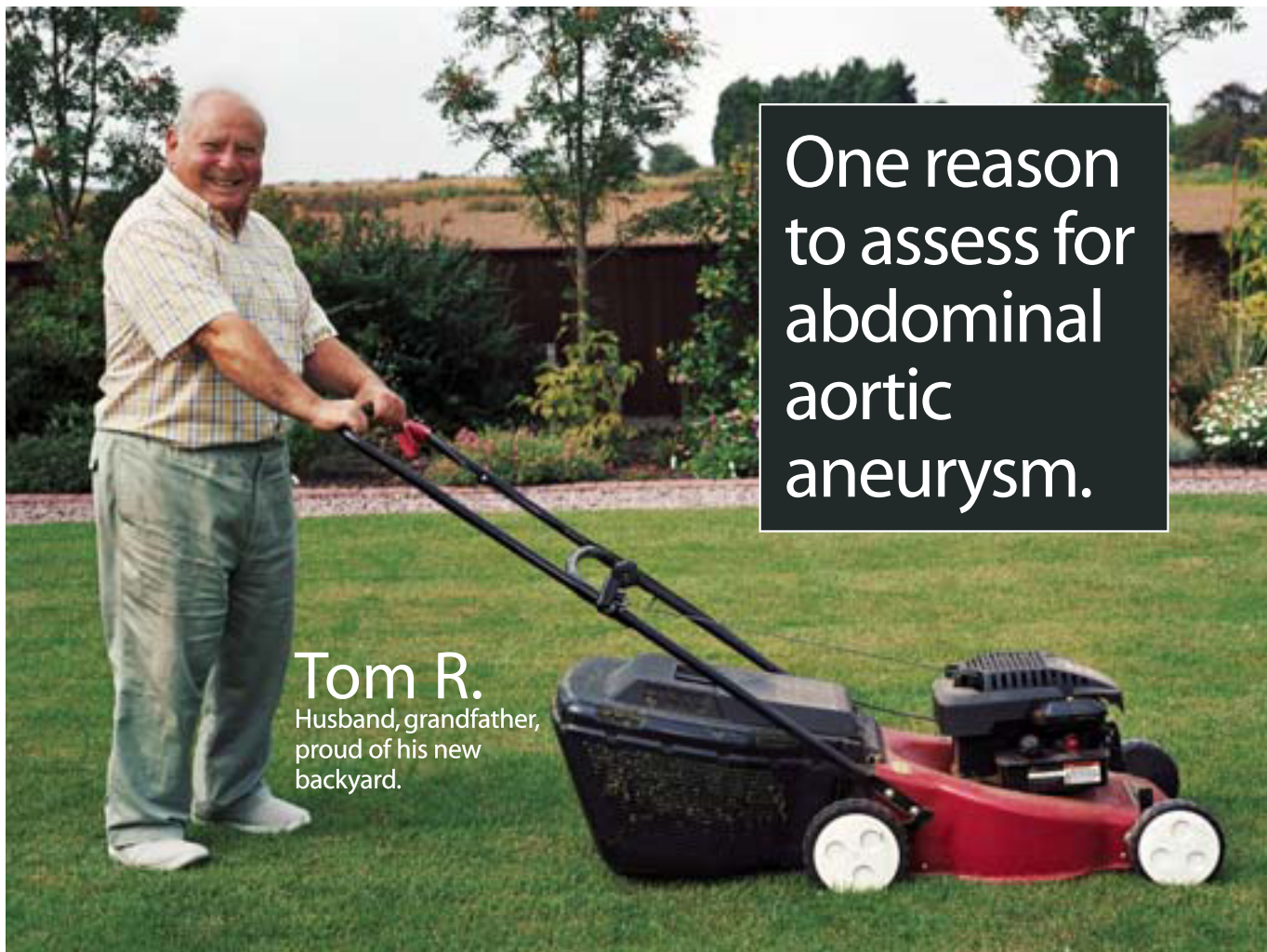
tion, Evaluation, and Treatment of High Blood Pressure (JNC 8), he said in an interview.

The existing hypertension treatment guidelines of the National Heart, Blood, and Lung Institute, JNC 7, have a blood pressure treatment target of less than 130/80 mm Hg for patients with diabetes (JAMA 2003;289:2560-71). Dr. Cushman was a member of the JNC 7 panel, and is a member of the group now working on JNC 8.

The JNC 7 blood pressure target for patients with diabetes “was an extrapolation based on observational data. The guidelines were beyond evidence from ran-

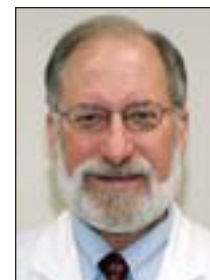
domized, controlled trials,” said Dr. Denise Simons-Morton, project director for ACCORD and director of the NHLBI division responsible for the JNC guidelines. The new ACCORD findings show that this extrapolation was a mistake, and that current evidence cannot support a goal systolic pressure that is more aggressive than the target of less than 140 mm Hg, she said in an interview.

Because of the way that JNC 8 is being prepared, the ACCORD results may be too late for inclusion in the new guidelines, said Dr. George Bakris, professor of medicine at the University of Chicago, who was a member of the JNC 7 writing committee but is not a member of the JNC 8 panel. But, he added in an interview, “all other guidelines” on treating hypertension in patients with diabetes, including those from the American Diabetes Association and various international societies, “will have to revise



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One reason
to assess for
abdominal
aortic
aneurysm.



If the indicated drugs bring a patient's pressure moderately below 130 mm Hg, 'I wouldn't back off.'

DR. CUSHMAN

their blood pressure goals” based on the ACCORD results. In an editorial last year, Dr. Bakris and an associate called the goal of a systolic pressure below 130 mm Hg in patients with chronic kidney disease “questionable” (J. Clin. Hypertension 2009;11:345-7).

The 2,362 patients in the intensive-treatment arm of the ACCORD blood pressure trial reached a mean systolic pressure of 119.3 mm Hg after the first year while receiving an average of 3.4 antihypertensive drugs; those patients had a 1.87%/year rate of nonfatal myocardial infarction, nonfatal stroke, or cardiovascular death during an average follow-up of 4.7 years. The 2,371 patients in the standard-therapy arm reached a mean systolic pressure of 133.5 mm Hg after the first year and received an average of 2.1 drugs; they had a 2.09%/year rate for the combined end point. The difference in rates between the two groups was not statistically significant. Concurrently with Dr. Cushman's report at the meeting, the results were posted online (N. Engl. J. Med. 2010 March 14 [doi: 10.1056/NEJMoa1001286]).

“Less than 140 mm Hg is the message we need to put out, and less than 130 mm Hg is probably not necessary to

Continued on following page

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Reference: 1. Reardon RF, Cook T, Plummer D. Abdominal Aortic Aneurysm. In: Ma OJ, Mateer JR, Blaivas M, eds. Emergency Ultrasound. 2nd ed. New York, NY: McGraw-Hill; 2008: 149-168. AortaScan and Verathon are trademarks of Verathon Inc. © 2010 Verathon Inc. 1001IMN-Ad 0900-3025-00-86



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achieve benefit and may be harmful in certain populations," said Rhonda M. Cooper-DeHoff, Pharm.D., associate director of the cardiovascular clinical research program at the University of Florida, Gainesville.

Dr. DeHoff presented results from a second study that also called into question a systolic blood pressure goal of less than 130 mm Hg for patients with diabetes. Her study used long-term follow-up data from the 6,400 patients with diabetes who had participated in the International Verapamil SR-Trandolapril (INVEST) study, with an overall enrollment of more than 22,000 patients that compared two different antihypertensive regimens (JAMA 2003;290:2805-16).

Using data collected during the trial plus 5 years of follow-up, Dr. DeHoff and her associates showed that the 2,255 patients with diabetes maintained at a systolic blood pressure below 130 mm Hg had cardiovascular disease event rates similar to the 1,970 patients with diabetes maintained at a systolic blood pressure of 130-139 mm Hg; patients in both groups did significantly better than did a third group of 2,175 patients with diabetes whose systolic pressure consistently remained at 140 mm Hg or higher. Among the 5,077 U.S. patients with diabetes in INVEST, those kept at a systolic pressure of less than 130 mm Hg had a significant 15% increase in the rate of all-cause death, compared with the patients kept at a systolic pressure of 130-139 mm Hg.

"Based on the results from ACCORD and INVEST, is it time to rethink lower blood pressure goals in patients with diabetes and coronary artery disease?" Dr. DeHoff asked as she concluded her report at the meeting.

To apply the ACCORD results in practice, Dr. Cushman advises physicians to prescribe for patients with diabetes a "maximum" dosage of a renin-angiotensin-aldosterone system (RAAS) blocker drug, such as an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, plus a diuretic such as chlorthalidone. He also urges physicians to prescribe other drugs with antihypertensive effects, such as certain beta-blockers or calcium channel blockers, that patients with diabetes and a high risk for cardiovascular disease events might need for specific risk indications.

If a patient's systolic pressure remains above 140 mm Hg despite these treatments, then another agent should be added; if the indicated drugs bring the patient's systolic pressure below 140 mm Hg, then additional treatments should stop. However, if the indicated drugs bring the patient's pressure moderately below 130 mm Hg, "I wouldn't back off," and withdraw drugs that the patient might otherwise need, he said.

In this way, practice should not fully mimic the ACCORD trial design. In that trial, patients in the standard-therapy arm came off one or more of their medications if their systolic pressure fell below 130 mm Hg, noted Dr. Cushman, who also is professor of medicine at the University of Tennessee in Memphis. ■

Study Findings Diverge From Observational Data

MY TAKE

We would have predicted that the lower a patient's blood pressure the better the outcome, and we have therefore sought to get blood pressures lower.

Normal blood pressure is less than 120/80 mm Hg, but we had no data on treating patients to blood pressures that low. Nature says that high blood pressure is not good, and we try to simulate nature by using treatments

that lower blood pressure by lifestyle and drugs. There is no question that lower blood pressure benefits patients, but where is the floor? Is a pressure of 140 mm Hg good enough?

For patients with diabetes, chronic kidney disease, or dyslipidemia the guidelines set a lower target pressure. But in this large trial we did not see a difference from bringing the pressure lower. We need to look at the results

further to try to explain them.

ELIJAH SAUNDERS, M.D., is professor of medicine and head of the division of hypertension at the University of Maryland in Baltimore. He has been a consultant to, served on the speakers bureau for, and has received research support from Bristol-Myers Squibb, Forest, Novartis, Pfizer, and Sanofi-Aventis.

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