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DOCTORS FAILING TO INTENSIFY NEEDED THERAPY IN PEOPLE WITH DIABETES

Clinical Inertia Means Hypertension and High Glucose Levels Inadequately Treated

Washington, DC (June 10, 2006) – Four independent studies showing that doctors are failing to intensify therapy in people with type 2 diabetes and high blood glucose levels or high blood pressure were reported here today at the American Diabetes Association's 66th Annual Scientific Sessions. Their findings suggest that clinical inertia – lack of physician action in the face of abnormal findings – may be an important barrier to effective diabetes management.

“Physicians do not appear to be aware of the American Diabetes Association guidelines or choose not to follow them because, in the population we studied, the antihypertensive regimen was intensified in only 26 percent of visits in which the individuals had elevated blood pressure,” said Alexander Turchin, MD, MS, Associate Physician, Division of Endocrinology, Brigham and Women’s Hospital, and Instructor in Medicine, Harvard Medical School, in a recent interview.

“Our study showed that failure to appropriately intensify antihypertensive treatment is a very common problem in diabetes care, because physicians intensified antihypertensive treatment in only 12 percent of visits in which we found sub-optimally controlled blood pressure,” said Shari Bolen, MD, Senior Clinical Fellow in Internal Medicine, The Johns Hopkins University School of Medicine, in a recent interview.

Other studies identified failure to intensify treatment to maintain blood glucose levels at the recommended A1C goal of less than 7%. A1C is a blood test that measures blood glucose levels over a period of two to three months. A U.S. study found that physicians delayed therapy intensification for those on oral anti-diabetic drugs on average until A1C was 8.5%. Another study indicated that up to 75 percent of people with type 2 who were using insulin alone in the UK and Germany may have levels exceeding 7%.

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Some 20.8 million adults and children in the United States have diabetes, a group of serious diseases characterized by high blood glucose levels that result from defects in the body's ability to produce and/or use insulin. Diabetes can lead to severely debilitating or fatal complications, such as heart disease, blindness, kidney disease, and amputations. It is the fifth leading cause of death by disease in the U.S. Type 2 diabetes involves insulin resistance – the body's inability to properly use its own insulin. It usually occurs in those who are over 45 and overweight, but it has increasingly been seen in obese children and teens in recent years.

Clinical Inertia in Hypertension – Brigham & Women's

The Brigham and Women's Hospital study reviewed nearly 11,000 outpatient records of 1,244 hypertensive people with diabetes followed by 166 physicians from 2000 to 2004. They analyzed the blood pressure results and evidence of antihypertensive therapy intensification and found that the regimens were intensified in only 26 percent of visits where elevated blood pressure was documented.

“The level of increase in the blood pressure significantly affected the likelihood that the treatment would be intensified,” explained Dr. Turchin, who was the lead author on the study. For every 10 mm of mercury of systolic pressure, the probability of an intensification of the antihypertensive regimen increased 40 percent; for every 10 mm of mercury of diastolic pressure, the probability increased 20 percent.

“It is not surprising that physicians would react more to systolic than diastolic pressure because elevated systolic pressure has a very strong correlation with cardiovascular complications,” he explained.

A physician's age also affected the likelihood of treatment of intensification. The younger the physician, the greater the probability that medication would be intensified. “It could be that the younger physician, having just completed a residency, is more aware of the current American Diabetes Association guidelines,” said Dr. Turchin.

If the individual belonged to a minority group, the physician was about 10 percent more likely to intensify the antihypertensive regimen, likely due to the fact that non-Caucasians have a higher rate of complications arising from hypertension.

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“While some reasons for not intensifying therapy at a given visit are valid – such as that the provider was not the individual’s regular physician or that the person has a history of stabilizing pressure by the next visit – the majority of people with diabetes with elevated blood pressure do not have treatment intensified appropriately at a given visit,” said Dr. Turchin. “Our analysis enables us to identify which doctors are not intensifying therapy so that we can provide professional education and feedback to them, which has been shown in other studies to decrease clinical inertia and improve outcomes.”

Clinical Inertia in Hypertension – Johns Hopkins

The Johns Hopkins study looked at 254 people with type 2 diabetes and hypertension in a managed care program of government employees and their dependents who were generally adherent and whose physicians were part of an academically affiliated outpatient center.

“Through a review of medical records and pharmacy and claims data from 1999 to 2001, we identified 1,374 visits with sub-optimally controlled blood pressure, during which physicians intensified antihypertensive treatment in only 12 percent of visits,” said Dr Bolen, who was lead author on the study.

In this study, elevations in diastolic and systolic blood pressure were about equally as likely to trigger intensification. For every 10 mm of mercury increase, the provider was 40 percent more likely to intensify. Also the reason for the visit was another factor. Physicians were twice as likely to intensify if it was a routine visit as compared to an urgent visit. Intensification was almost twice as likely if the person was seen by their regular doctor as opposed to a covering provider.

“Several factors were associated with a 40 to 50 percent lesser likelihood of intensification including a higher glucose level or a history of coronary heart disease, suggesting in both instances that the physician focused on other clinical concerns to the detriment of attention to the hypertension problem,” said Dr. Bolen. Co-management of the individual with a cardiologist yielded a similar lesser likelihood of intensification, suggesting that the physician was perhaps erroneously relying on the cardiologist to manage the blood pressure.

“Improvements in continuity of care and care coordination are possible targets to help improve outcomes in hypertension management for people with diabetes,” said Dr. Bolen.

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Clinical Inertia in Oral Anti-Diabetes Agents

A study of clinical inertia in the prescribing of oral anti-diabetic drugs was based on a retrospective analysis of the pharmacy and lab claims of a commercial, preferred-provider organization model of a national managed care organization. Individuals covered by this plan are geographically diverse across the U.S. The health plan provides fully insured coverage for physician, pharmacy and hospital services, with 23 million participants dating back to 1994. To “create” a study group, they identified 9,416 people who had received a first prescription of an oral anti-diabetic drug – either metformin, a sulfonylurea, or a thiazolidinedione – between January 2001 and April 2004.

“At the time they started on these anti-diabetic drugs, the average A1C was 8.4% which included the 33 percent who were at or below the ADA goal of less than 7%,” reported Craig A. Plauschinat, PharmD, MPH, Outcomes Research Manager, Novartis Pharmaceuticals Corp., who was senior author of the study. “Unfortunately, this included 67 percent who were well above the goal at A1C levels of 9.5%.”

The average time to therapy intensification – when the physician added another oral anti-diabetic drug – was 240 days. By that time, the average A1C was 8.5%, but 67 percent of these individuals had A1C levels approaching 10%.

“Disturbingly, 50 percent of those who were intensified did not have an A1C in their charts prior to the addition of a second drug,” said Dr. Plauschinat. “It is unknown how the physician made the decision to add a second drug in the absence of A1C testing, although it is possible the decision was based on a finger stick glucose test in the office or patient reports of home blood glucose testing.” The study only looked at claims, not physician notes.

He observed that infrequent A1C monitoring may have contributed to delayed therapy intensification. On average, these patients only had one A1C test annually, in contrast to the twice a year testing recommend by the ADA when individuals are at the A1C goal and the four times a year recommended for those not at goal.

“Interventions assisting patients and physicians to recognize and overcome clinical inertia represent a specific opportunity to improve glycemic control in type 2 diabetes,” said Dr. Plauschinat.

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Failure of Insulin Therapy in Type 2 Diabetes

More complex problems were at work in a study of insulin therapy, which involves one or more insulin injections daily. Those on insulin therapy are typically expected to self-monitor their blood glucose levels daily with finger-stick blood testing, enabling them to modify their insulin, diet, and exercise levels, under their physician's guidance, to achieve recommended glycemic targets.

To assess the extent to which such targets are actually achieved, researchers obtained the last recorded A1C levels of adults with type 2 in Germany and the UK who were prescribed insulin. The data was obtained from Intercontinental Medical Statistics, a company that collects data for pharmaceutical firms. The data was sampled from 6 million records from 1,045 physicians in 983 practices in Germany, and from 3.6 million records from 630 physicians in 200 practices in the UK.

“Overall, the average A1C for 3,658 individuals was 8.4%,” said Stephen Gough, MD, Professor of Medicine at the Institute of Biomedical Research, the Medical School, University of Birmingham, and consultant physician at the University Hospital Birmingham, NHS Foundation Trust, UK. Dr. Gough was the lead author on the study. However, about one third had A1C levels $\geq 9\%$ and 18.2% had A1Cs $\geq 10\%$.

Similar proportions of patients were poorly controlled in both countries. The International Diabetes Federation, which establishes guidelines for physicians in Europe, like the American Diabetes Association, also recommends that treatment be instituted to keep blood glucose levels below 7%.

“If this sample is representative, which we believe it is, glycemic control may be suboptimal for up to three-quarters of the people using insulin alone to control type 2 diabetes,” said Dr. Gough. “Identifying and overcoming obstacles that prevent optimal insulin therapy, including adequate intensification when needed, is essential if the gap between recommended glycemic targets and control is to be closed.”

However, Dr. Gough was reluctant to blame the results entirely on clinical inertia because he believes the problem is more complex in patients on insulin. He noted that some physicians are fearful of causing hypoglycemia, especially in the elderly or in those with co-morbidities, where tight control can be a problem. Further, some patients simply refuse to take multiple injections every day.

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Nonetheless, he acknowledges that further physician education is needed with regard to achieving optimal glycemic control, such as how to mix different types of insulin properly and/or how to teach patients to use such insulins and new devices.

“Many physicians are still locked into once a day insulin injections, and you often cannot get good diabetes control with that approach,” said Dr. Gough. “Many patients need additional injections – so the physician has to deal with complexity and patient education – to help those with diabetes achieve appropriate control.”

The American Diabetes Association is the nation's leading voluntary health organization supporting diabetes research, information and advocacy. Founded in 1940, the Association has offices in every region of the country, providing services to hundreds of communities. For more information, please call the American Diabetes Association at 1-800-DIABETES (1-800-342-2383) or visit www.diabetes.org. Information from both these sources is available in English and Spanish.

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Abstract #12-OR (Turchin), #1140-P (Bolen), #552-P (Plauschinat), #477-P (Gough)

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