Diagnosing diabetes from a single blood sample

June 18 2018

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Diagnosing type 2 diabetes in clinical practice may require only a single
blood sample, according to a study led by researchers at Johns Hopkins Bloomberg School of Public Health.

The study, published June 19 in the journal *Annals of Internal Medicine*, found evidence that a positive result for two standard diabetes markers in a single blood sample is a highly accurate predictor of diabetes and of major diabetes complications such as kidney disease and heart disease.

About 25 million Americans have type 2 diabetes, which involves a failure of the body's normal regulation of sugar (glucose) levels in the blood. The resulting chronic elevation of blood glucose (hyperglycemia) increases the risk of other major illnesses including heart disease, eye disease, kidney disease, and stroke.

Current clinical guidelines recommend that an initial blood test result indicating elevated fasting levels of glucose or glycated hemoglobin (HbA1c) be confirmed at a second doctor's visit with another blood test—a time-consuming and relatively expensive practice that may lead to missed diagnoses.

"The results of our study suggest that the two tests from one blood sample can provide adequate confirmation of diabetes, potentially allowing a major simplification of current clinical practice guidelines," says study lead author Elizabeth Selvin, Ph.D., MPH, a professor in the Department of Epidemiology at the Bloomberg School.

Although diabetes is treatable, researchers estimate that roughly three million Americans who have it are undiagnosed. It also is thought that tens of millions of adults unknowingly have a borderline condition, "prediabetes," that similarly increases risks of heart disease and other complications, and can easily lead to full-blown diabetes if uncorrected.

Selvin and her colleagues hypothesized that positive results for both
glucose and HbA1c in one blood sample might be an acceptable alternative to the current two-sample standard.

"Doctors are already doing these tests together—if a patient is obese, for example, and has other risk factors for diabetes, the physician is likely to order tests for both glucose and HbA1c from a single blood sample," Selvin says. "It's just that the guidelines don't clearly let you use the tests from that one blood sample to make the initial diabetes diagnosis."

To determine how well the new approach would be likely to work, Selvin and colleagues examined data from a long-running Atherosclerosis Risk in Communities (ARIC) Study of the health of more than 13,000 Americans. The study, begun in the late 1980s, was designed to find risk factors for atherosclerosis, a major underlying feature of heart disease and stroke, but in tracking the overall health of participants for decades it has gathered data relevant to diabetes, including blood glucose and HbA1c test results.

The researchers identified 383 people who, at their second study checkup in the early 1990s, did not have a diabetes diagnosis but did have positive results for both blood glucose and HbA1c from a single blood sample. Almost all—90 percent—went on to be diagnosed with diabetes during the first 15 years of the study (99 percent by 20 years). These individuals also developed diabetes complications, such as heart disease, at much higher rates than individuals who did not have diabetes or who only had one elevated test result.

"The bottom line is that this combination of positive results from a single blood sample has a very high positive predictive value for a subsequent diagnosis of diabetes, and also indicates a high risk of typical diabetes complications," Selvin says.

Some people in the study who had positive results on only one test went
on to be diagnosed with diabetes. Thus, Selvin emphasizes that for people with a single positive test, a repeat test in accordance with current guidelines is still appropriate.

Even so, the study findings could lead to changes in the guidelines to make it possible for diabetes to be diagnosed more quickly based on the two positive results in one blood sample.

"I'm hoping that these results will lead to a change in the clinical guidelines when they are revised in early 2019, which could make identifying diabetes a lot more efficient in many cases," Selvin says.

"Prognostic Implications of Single-Sample Confirmatory Testing for Undiagnosed Diabetes: A Cohort Study" was written by Elizabeth Selvin, Dan Wang, Kunihiro Matsushita, Morgan E. Grams, and Josef Coresh.


Provided by Johns Hopkins University Bloomberg School of Public Health


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