

Diab-spot

Introduction Diab-spot

DIABETES DETECTION

Diabetes mellitus is now one of the most common diseases globally with an estimated 285 million affected persons worldwide and 344 million persons with pre-diabetes. Each year, another 7 million people develop diabetes^I and 3.8 million deaths worldwide are linked directly to diabetes related causes^{II}. The estimate is that at least one third of the patients with diabetes is undiagnosed^{III}.

Diabetes complications are very common. A large proportion of diabetics (50% or more in some studies) have at least one complication present at the time of diagnosis^{IV}. In order to reduce diabetes associated complications and mortality there is a great need for screening and monitoring methods to assess the risk of diabetes and diabetic complications. If (pre-)diabetes is detected early, with only lifestyle, or with pharmaceutical interventions the development of diabetes and its complications can be postponed or even prevented.



CURRENT SCREENING METHODS

The current methods for diabetes screening are inadequate. Questionnaires are easy to perform but score moderate as predictor of (pre-)diabetes and still need confirmation by blood testing as second step. Fasting and non-fasting plasma glucose, and also HbA1c are inconvenient for the patient, because they require a finger prick or blood draw. They also score moderate as predictors of (pre-)diabetes, and there is poor concordance between these different blood tests.

The gold standard for diagnosis of diabetes is an oral glucose tolerance test (OGTT). This OGTT is not feasible as a screening tool because it requires fasting, multiple blood samples and takes 2 hours per test. Currently there is no generally accepted alternative screening test, or stepwise procedure of tests, for early detection and diagnosis of diabetes.

AGES

Advanced glycation end-products (AGEs) play a key role in the development of diabetes and its complications. The level of AGEs in tissues with slow turnover (not in blood!) serves as a memory of glycometabolic stress and is a valuable predictor of (pre-)diabetes and cardiovascular complications.

Intermittent periods of (post-meal) hyperglycemia result in persistent increases in (tissue) AGE levels. This makes the measurement of tissue AGE levels a useful tool to detect IGT and diabetes in such periods of still intermittent hyperglycemia.

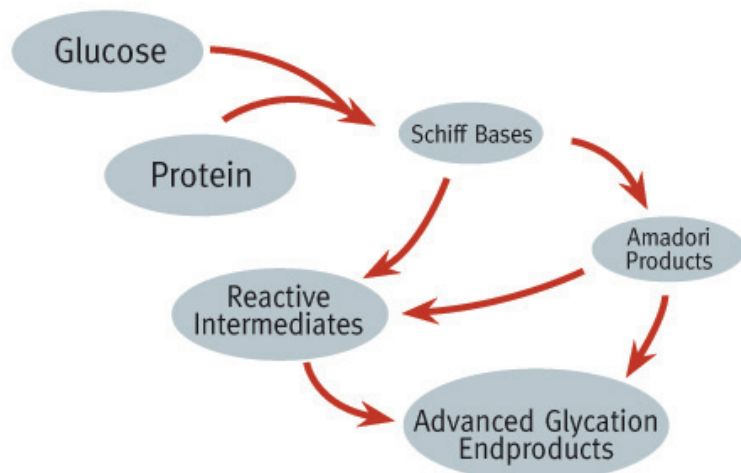


Figure 1: Formation of AGEs

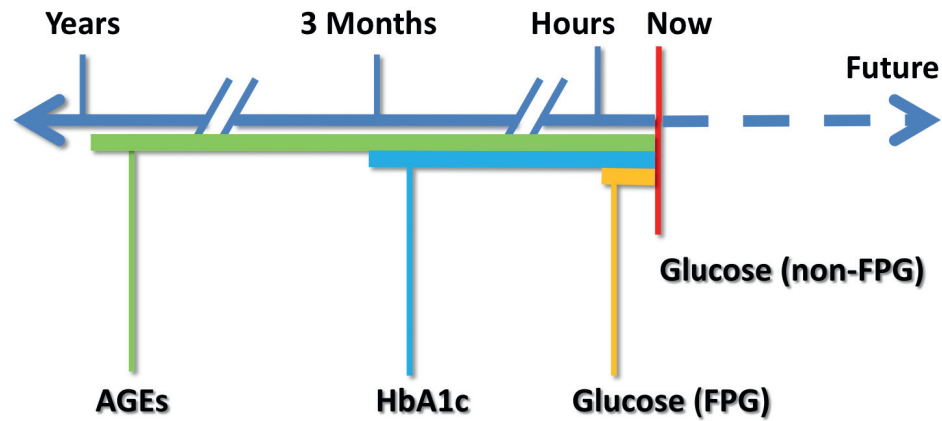


Figure 2: AGEs reflect a much longer time of glycometabolic memory than HbA1c and glucose.

AGEs normally accumulate over a person's lifetime, but this process occurs more rapidly in patients with (pre-)diabetes. Tissue AGEs correlate closely with and are predictors of early kidney, eye and nerve disease in patients with diabetes mellitus. Moreover they are valuable predictors of future cardiovascular morbidity and mortality^{VI}. AGEs are considered to be a major target in the treatment of diabetes and cardiovascular disease.

DIAB-SPOT

DiagnOptics was the first to introduce the technology to noninvasively measure the tissue accumulation of AGEs by means of fluorescence techniques^{VII}. Diab-spot features this AGE measurement and combines this with a small number of characteristics to calculate the Diab-spot test result. These simple characteristics include questions about the person's length, weight, age and family history of diabetes, which can be easily answered on the touch screen. Diab-spot yields an immediate screening result on the spot.

The detection of (pre-)diabetes patients by Diab-spot is superior to FPG and HbA1c. In a multi-center clinical study in the Netherlands, both sensitivity and specificity of Diab-spot were significantly better than FPG and HbA1c^{III}.

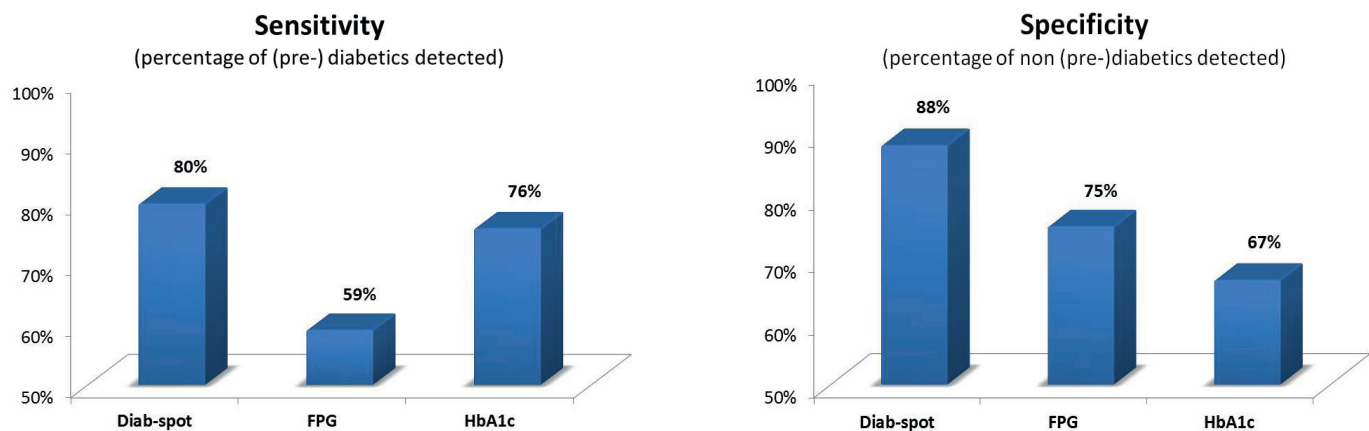


Figure 3: Sensitivity and specificity of Diab-spot are significantly better than FPG and HbA1c

The ease of use in any point of care setting, its non invasive character and the immediately available result qualify Diab-spot as an excellent tool for the detection of (pre-)diabetes.

REFERENCES

- I International Diabetes Federation. Diabetes Atlas, Fourth Edition. www.diabetesatlas.org.
- II http://www.worlddiabetesday.org/files/docs/Diabetes_facts.pdf
- III Smit A.J. et al. Oral presentation 4th International Congress on Prediabetes and the Metabolic Syndrome, Madrid; April 2011
- IV Milman S. et al. Med Clin North Am. 2011; 95(2): 309-25, vii
- V Bartnik M. Et al. Eur. Heart J. 2004; 25(21): 1880-90
- VI Lutgers H.L. et al. Diabetologia. 2009; 52(5): 789-797
- VII Meerwaldt R. et al. Diabetologia. 2004; 47: 1324-1330