Early risk assessment of Type 2 Diabetes Mellitus through the use of the biomarker adiponectin

The prevalence of T2DM has reached epidemic levels, affecting about 7% of the U.S. population, and is growing.

The Randox automated immunoturbidimetric adiponectin test offers an improved method for assessing T2DM risk, with a convenient format for routine clinical use. The Randox Adiponectin assay is available for use on most biochemistry analysers, including the RX series.

Background
The prevalence of type 2 diabetes mellitus (T2DM) has reached epidemic levels, affecting ~7% of the U.S. population, and current epidemiological trends indicate that the prevalence will continue to increase dramatically (Blonde, 2007). The global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014 (WHO, 2016). About 422 million people worldwide have diabetes (WHO, 2016). Furthermore, the prevalence of diabetes is growing most rapidly in low and middle-income countries (WHO, 2016).

Millions more people are also at risk. One in three adults have prediabetes, and 9 out of 10 of those with prediabetes don’t know they have it (CDC, 2016). Early risk assessment is vital for a number of reasons. Diabetes is one of the leading causes of death in the world – in 2012 it was the direct cause of 1.5 million deaths (WHO, 2016). 50% of people with diabetes die of CVD (WHO, 2016). Additionally, diabetes is the leading cause of newly diagnosed adult blindness for people between the ages of 20 and 74 (NIDDK, 2016).

Economically, diabetes and its complications bring about substantial economic loss to people with diabetes and their families, and to health systems and national economies through direct medical costs and loss of work and wages. While the major cost drivers are hospital and outpatient care, a contributing factor is the rise in cost for analogue insulins 1 which are increasingly prescribed despite little evidence that they provide significant advantages over cheaper human insulins (WHO, 2016).

Traditional methods for diabetes risk assessment
Non-biochemical methods for assessing a patient’s risk of developing T2DM traditionally take into account gender; age; family history of T2DM; BMI waist size; and high blood pressure to give a risk score. Other factors which health services may take into account include ethnicity (UK NHS); history of gestational diabetes (GDM) (American Diabetes Association (ADA)); physical activity (ADA and Finnish Diabetes Association (FDA)); blood glucose history (FDA) and diet (FDA). It is widely recognized that people who are overweight are at higher risk of developing T2DM. However, assessing those who are overweight can be challenging. Studies have shown that measuring waist circumference alone measures total abdominal fat reliably, but its association with visceral fat depends on visceral fat/subcutaneous fat ratios that vary by gender and ethnicity (Grundy et al, 2013). Body mass index (BMI) (weight kg / height m²) is another common method of determining which patients are classed as overweight or obese, however it has limitations in measuring athletes and varies in reliability based on age, sex, and race.

Furthermore, it has been found that risk prediction for T2DM and cardiovascular disease (CVD) remains suboptimal even after the introduction of global risk assessment by various scores. This has prompted the search for additional biomarkers (Herder et al, 2011). The most commonly used biochemical method of assessing risk of T2DM is measuring fasting plasma glucose (FPG); however, the specificity of this test is poor (Gennuth et al, 2003; Nichols et al, 2007). Although many individuals are identified as having impaired fasting glucose (IFG), their absolute risk of conversion to diabetes is only 5–10% per year (Gerstein et al, 2007). The oral glucose tolerance test (OGTT) is more accurate for risk assessment. However, it is rarely used in practice because it is unpleasant for the patient and requires 2 hours to perform. Another challenge is that by the time glucose regulation is abnormal, the underlying disease has been progressing for many years, and complications have already occurred in a significant number of individuals (Wong et al, 2008). Thus, the rationale of using one variable to assess risk is questionable, when the risk of harm actually varies based on a range of variables and would be better assessed using a multivariable individualized risk score (Mohamed and Evans, 2008).

Given the limitations of the OGTT, FPG, and indexes that the clinician must calculate, it is clear that an improved method for assessing T2DM risk, with a convenient
format for routine clinical use, would enable physicians to accurately evaluate more individuals (Kolberg et al, 2009).

**Clinical significance**
A number of recent, key publications have advocated the testing of adiponectin for T2DM risk assessment in clinical settings.

- Among healthy white and black adults with parental history of T2DM, adiponectin level is a powerful risk marker of incipient prediabetes (Jiang et al, 2016).
- Adiponectin levels in prediabetes patients is lower than that of healthy controls, indicating that the level of circulating adiponectin decreases before the onset of diabetes (Lai et al, 2015).
- Higher adiponectin levels are associated with a lower risk of T2DM across diverse populations (Li et al, 2009).
- Increasing plasma adiponectin is associated with decreased risk of T2DM and subsequently reduced risk of CV events (Lindberg et al, 2013).

**Implications for clinicians**
Adiponectin measurement is not yet a routinely run test in the majority of laboratories worldwide, and it is therefore not available for many clinicians to request. Yet the clinical implications of this becoming widely available could be extremely valuable.

When risk via adiponectin measurement is identified, lifestyle modification to reduce visceral fat should become a primary measure for the prevention of the development of cardiovascular diseases as well as its risks including T2DM in metabolic syndrome with visceral fat accumulation (metabolic syndrome in the narrow sense) through the improvement of adiponectin production (Matsuzawa, 2014).

**Randox automated adiponectin assay**
The Randox automated immunoturbidimetric adiponectin test offers an improved method for assessing T2DM risk, with a convenient format for routine clinical use, to enable physicians to accurately evaluate at-risk individuals. Randox is presently the only diagnostic manufacturer who has a globally available automated biochemistry test for adiponectin measurement to assess T2DM risk. The Randox Adiponectin assay is now available for use on most globally available clinical chemistry analysers, including the RX series.

The RX series combines robust hardware and intuitive software with the extensive RX series test menu, and the full range of routine and novel diabetes and cardiac risk tests, including the adiponectin assay. Renowned for quality and reliability, the RX series is suitable for clinical, research, education and pharmaceutical settings. This extensive dedicated test menu of high quality reagents guarantees excellence in results ensuring unrivalled precision and accuracy, reducing costly test re-runs or misdiagnosis and offering complete confidence in results. The series includes the RX misano, RX monaco, RX daytona+, RX imola and RX modena.

Contact us now for further information; for a quotation for the adiponectin kit on any third party clinical chemistry analyser; or to enquire about any analyser in the RX series range. Please contact marketing@randox.com

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