

RANDOX

ADIPONECTIN



A CLINICAL DIAGNOSTIC BIOMARKER FOR
METABOLIC RISK ASSESSMENT



ADIPONECTIN

Visceral Fat | T2DM | Metabolic Syndrome | Cardiac Risk | Cancer

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Benefits



A niche product from Randox

Meaning that Randox are one of the only manufacturers to offer the adiponectin test in an automated clinical chemistry format.



Stable to expiry date

When stored at +2 to +8°C.



CE marked

For diagnostic use.



Onboard stability of 28 days

When stored at +10°C.



Automated assay

Offering a more convenient and time efficient method for the measurement of adiponectin levels compared to traditional ELISA based testing.



Excellent correlation

Coefficient of $r=0.989$ when compared to commercially available methods.



Latex enhanced immunoturbidimetric method

Delivering high performance and producing results in as little as 10 minutes.



Dedicated adiponectin controls and 6-point calibrator available

Offering a complete testing package.



Extensive measuring range

Of 0.32 - 23.8µg/ml for the comfortable detection of clinically important results.



Excellent precision

Of 2.1% CV



Limited interferences

From haemoglobin, total bilirubin, conjugated bilirubin, triglycerides, intralipid®, ascorbic acid, and rheumatoid factor (RF).



Applications available

Detailing instrument-specific settings for the convenient use of the Randox adiponectin assay on a wide range of clinical chemistry analysers.



Liquid ready-to-use format

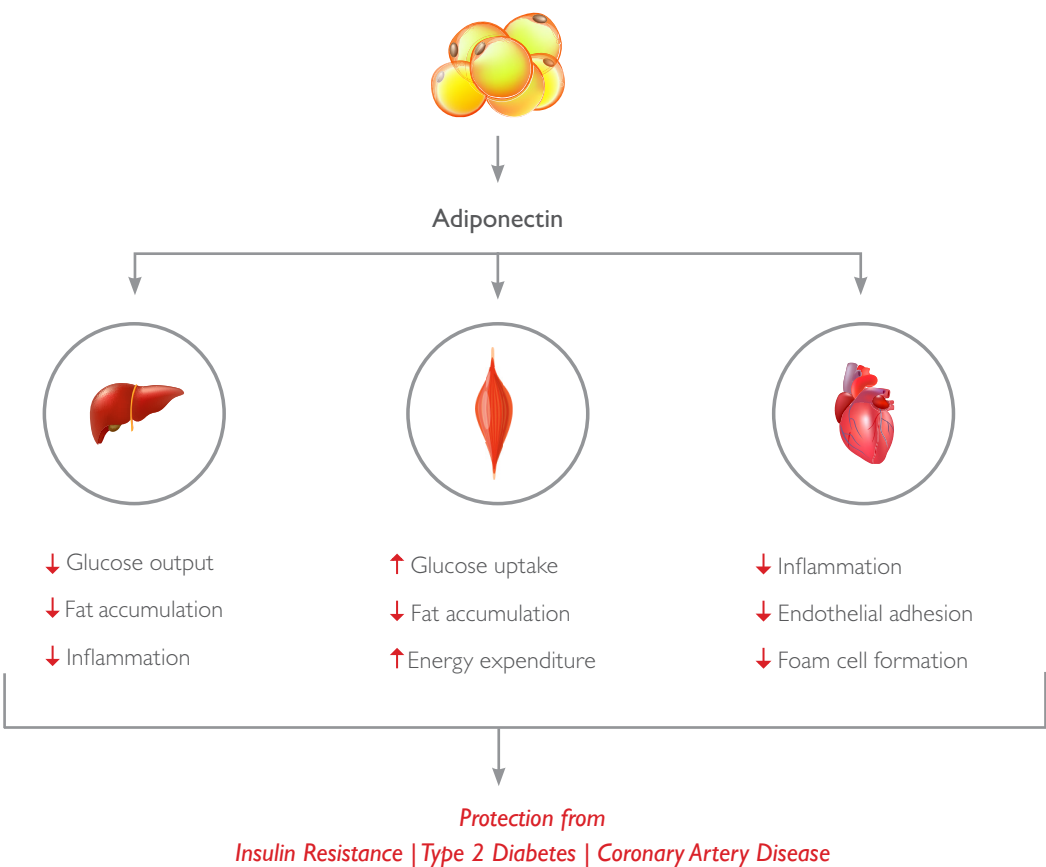
For convenience and ease-of-use.

Background

Adiponectin (adipocyte complement-related protein of 30 kDa (Acrp30)) is an adipokine (protein hormone) produced and secreted by the adipose tissue, an endocrine organ ¹. Adiponectin acts as a messenger in the communication of adipose tissue and metabolic organs. In doing so, adiponectin suppresses the production of glucose in the liver through inhibiting the genes involved in glucose production and enhances fatty acid oxidation in skeletal muscle. Consequently, adiponectin is a strong protector against several pathological events in various cells through inhibiting inflammation, suppressing cell death and enhancing cell survival ².

Adiponectin has been identified as having pleiotropic functions widely associated with anti-atherogenic, anti-diabetic, cardioprotective and anti-inflammatory effects. Adiponectin levels inversely correlate with insulin levels, BMI, triglyceride levels, insulin resistance (IR), glucose, and most importantly, visceral fat accumulation ³. Moreover, physiological functions of adiponectin have also been observed in inflammation and cardiovascular disease (CVD), especially in atherosclerosis ².

Fig. 1. Proposed salutary effects of adiponectin ¹



Visceral Fat: The Risk Factor

Obesity, a major health concern worldwide and burden on healthcare systems, is a major risk factor for type 2 diabetes mellitus (T2DM) and IR. Adiponectin has an inverse correlation with abdominal visceral fat (AVF). Low levels of adiponectin increases the risk of metabolic abnormalities. Furthermore, excess adipose tissue, especially visceral adipose tissue (VAT) is an important risk factor for IR, correlating with an increased risk of cardiovascular disease (CVD) ⁴.

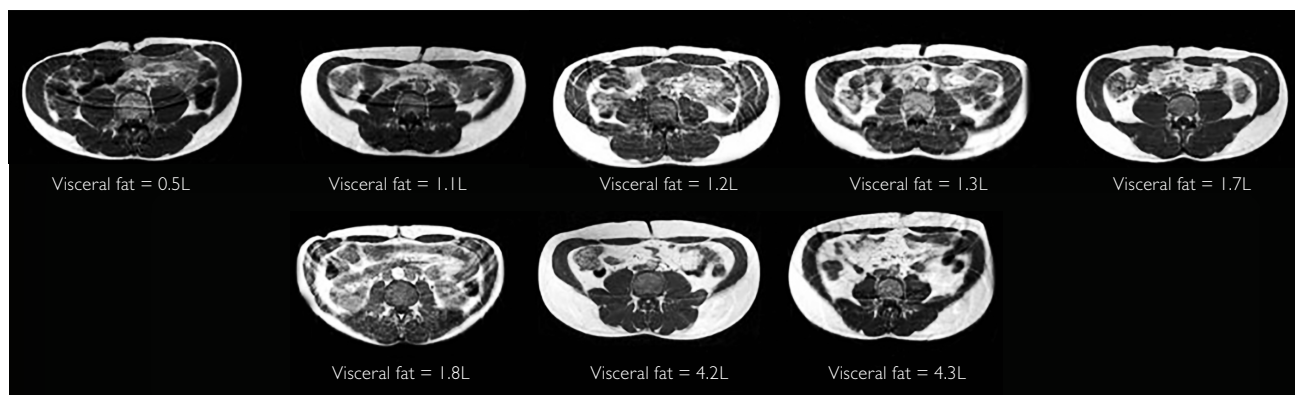
However, abdominal VAT is not the only risk factor associated with the development of T2DM. Other factors include: high blood pressure, ethnic background and age. It has also been recognised that a person is **two to six times more likely to develop T2DM if a parent, sibling or child have diabetes** ⁵.

Traditional methods utilised in the assessment of AVF

The most common and traditional methods utilised for the assessment of AVF include:

- **Waist circumference:** Studies have found that waist circumference measures total abdominal fat reliably, however, its association with visceral fat depends on visceral fat / subcutaneous fat (fat that sits beneath the skin) ratios that vary by gender and ethnicity as indicated in fig. 2 ⁶.

Fig. 2. Variation in visceral fat content in men with the same waist circumference ⁷



- **Body mass index (BMI)** (weight kg / height m²): BMI is supposed to provide an estimate of a person's body fat based on their weight and height. However, in recent years researchers have found that BMI has clinical limitations as it cannot distinguish between muscle and fat which classes those with high muscle and low fat mass as being overweight. Furthermore, BMI cannot distinguish between visceral fat and subcutaneous fat. Those with healthy BMIs can have high levels of AVF and so they could be at a high risk of developing health related problems such as T2DM ⁸.

Adiponectin levels are inversely correlated with AVF, proving to be a reliable indicator of at-risk patients.

Adiponectin in the Assessment of T2DM Risk

Traditional tests utilised in the assessment of T2DM risk

The traditional biomarkers utilised in the assessment of T2DM risk include: oral glucose tolerance test (OGTT), fasting plasma glucose (FPG) and HbA1c. However, each of these tests have their limitations.

OGTT: OGTT is treated as a "gold standard" for the diagnosis of diabetes. This is based on the 1979 National Diabetes Data Group (NDDG) decision to move away from six criteria to one. The NDDG evaluated three studies and came to the conclusion that the criterion for diabetes is a FPG level of $\geq 140\text{mg/dl}$ or a 2-hour value after 75g oral glucose of $\geq 200\text{mg/dl}$ to predict the development of diabetic retinopathy. The limitation of this "gold standard" method is the fact that only 77 subjects from a pool of 1,213 developed retinopathy, despite no further evaluation of the subjects glycaemic status in the years between the test and the diagnosis of diabetic retinopathy. Consequently, the OGTT test is known to produce false-positive results as this "gold standard" method rests on less than 100 subjects ⁹.

FPG: The FPG test measures the level of blood sugars which is used to diagnose and monitor diabetes based on insulin function. The main drawback of this test is that a hormone called glucagon, produced in the pancreas, is triggered during prolonged fasting, signalling the liver to release glucose into the bloodstream. In diabetic conditions, either the body is unable to generate enough insulin or cannot appropriately respond to insulin. Consequently, FPG levels remain high ¹⁰.

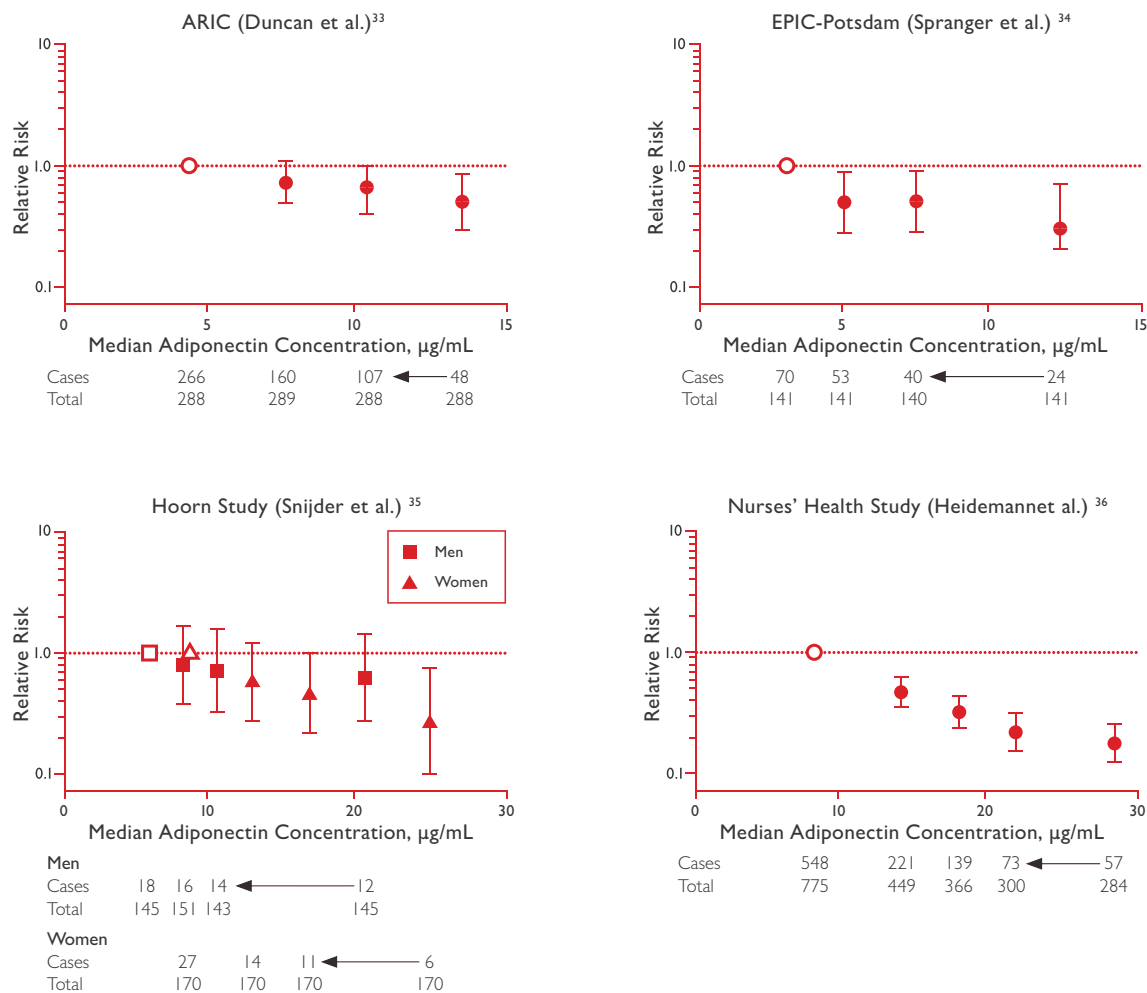
HbA1c: HbA1c testing has been utilised as an alternative test to glucose concentrations for the diagnosis of T2DM and in the identification of those at-risk of developing diabetes. However, any condition that reduces the survival rate of erythrocytes such as haemolytic anaemia will falsely lower the HbA1c test results regardless of the assay method utilised ¹¹.

I. JAMA (2009): Adiponectin levels and risk of type 2 diabetes: A systematic review and meta-analysis ¹²

Objective: A meta-analysis examined 13 prospective studies with a total of 14,598 participants and 2,623 cases of T2DM to review the association of plasma adiponectin levels and the risk of T2DM.

Findings:

Fig. 3: Risk of T2DM according to categories of total adiponectin levels for studies that provided results for quartiles or quintiles of adiponectin Levels ¹²



Open data markers indicate reference values for each plot; error bars, 95% confidence intervals.

ARIC = Atherosclerosis Risk in Communities; EPIC = European Prospective Investigation into Cancer and Nutrition.

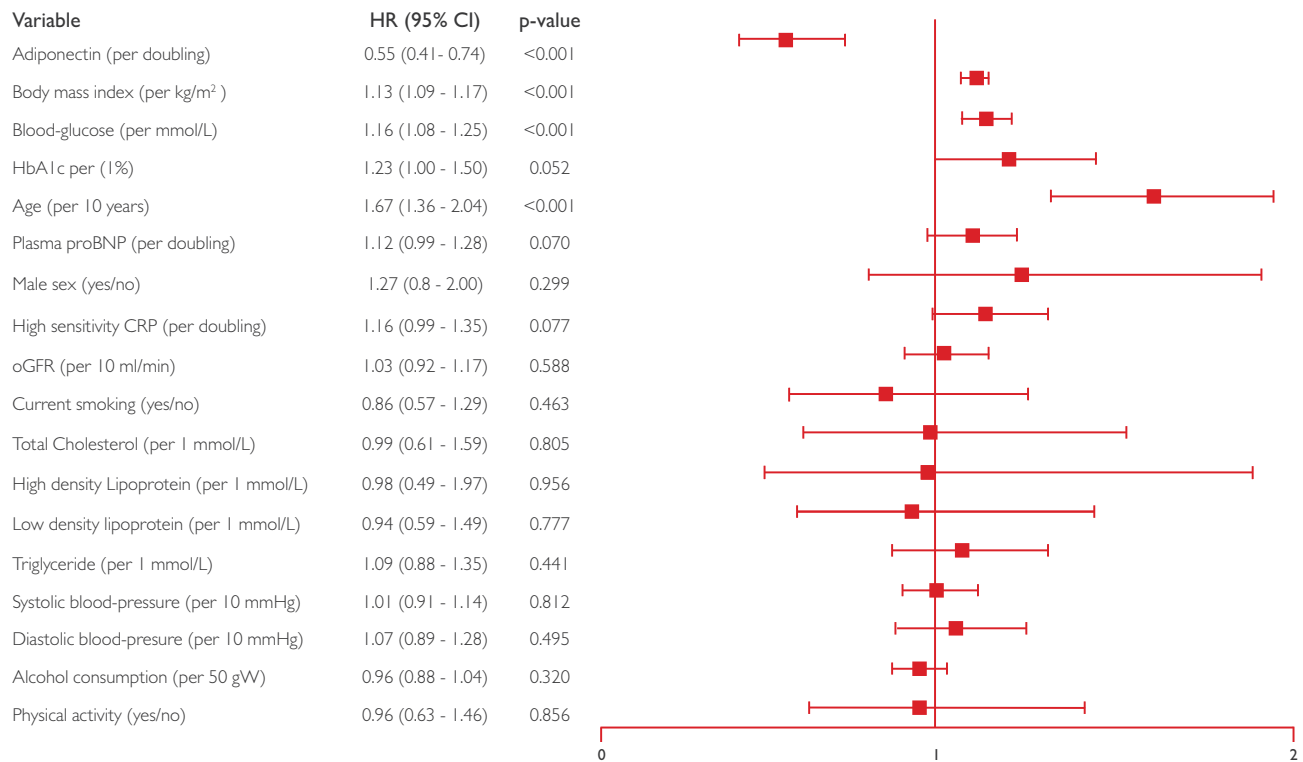
Conclusion: Higher adiponectin levels are associated with a lower risk of T2DM across diverse populations and is currently the strongest and most consistent biomarker of T2DM risk assessment.

2. European Journal of Preventive Cardiology (2015): Adiponectin, type 2 diabetes and cardiovascular risk ¹³

Objective: A Danish study prospectively evaluated 5,349 men and women who were randomly selected from the community, without T2DM or CVD to determine the relationship between adiponectin, incident T2DM and subsequent CVD events.

Findings:

Fig. 4: A multivariate competing risk Cox-regression proportional hazards model estimating risk of incident T2DM during 8.5 years of follow-up ¹³

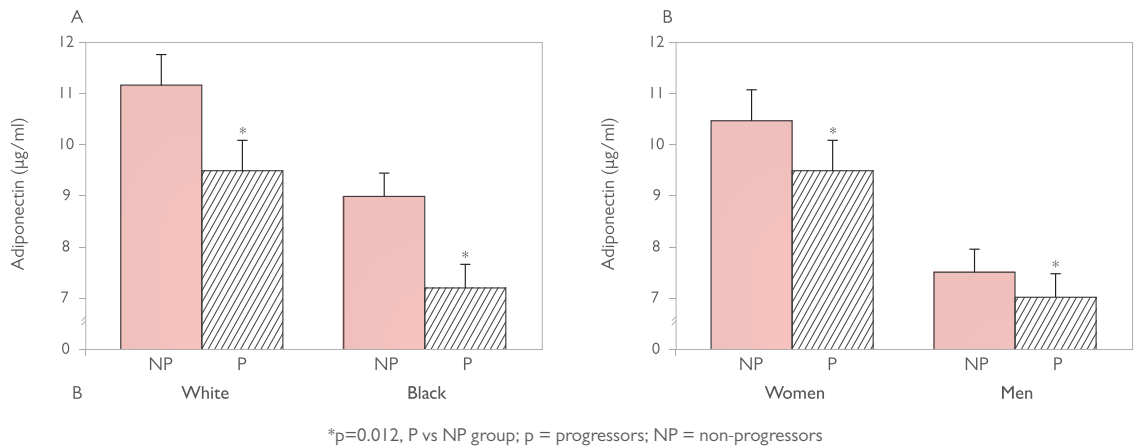


Conclusions: Increased levels of adiponectin is associated with a decreased risk of T2DM and subsequently a reduced risk CVD.

3. BMJ Open Diabetes Research & Care (2016): Adiponectin levels predict prediabetes risk: the pathobiology of prediabetes in a biracial cohort (POP-ABC) study ¹⁴

Objective: A US study prospectively evaluated 333 subjects from the Pathobiology of Prediabetes in A Biracial Cohort study which followed non-diabetic offspring of parents with T2DM to assess the occurrence of pre-diabetes over the course of 5.5 years.

Fig. 5: Plasma adiponectin levels by race/ethnicity (A) and gender (B) among study subjects who developed prediabetes/diabetes (P) in comparison to the incident free subjects (NP) ¹⁴



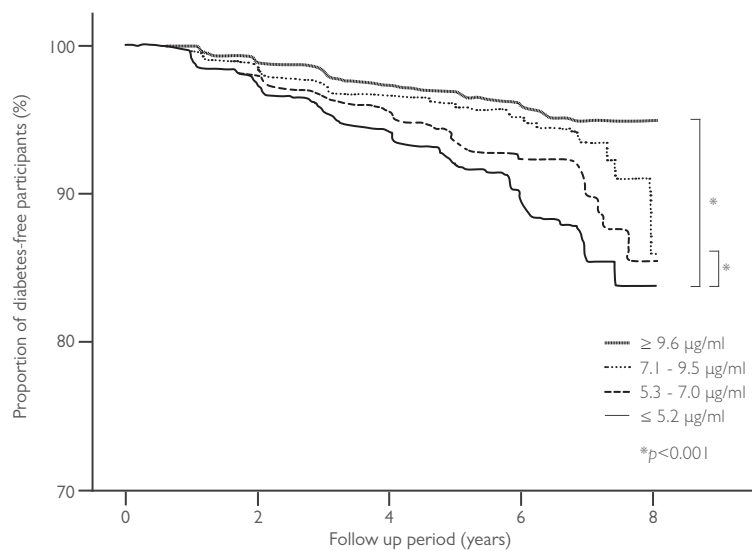
Conclusion: Baseline adiponectin levels were inversely related to the risk of pre-diabetes among the healthy African Americans and European Americans with a parental history of T2DM enrolled on the POP-ABC study. Despite gender and ethnic differences, this predictive relationship was evident.

4. Journal of Endocrine Society (2018): Increase in adiponectin level prevents the development of type 2 diabetes in Japanese men with low adiponectin levels ¹⁵

Objective: A study prospectively evaluated 7,052 healthy Japanese men who attended general check-ups more than twice between April 2007 and May 2015 to determine if changes in adiponectin in subjects with low baseline adiponectin levels can reduce the development rate of T2DM.

Findings:

Fig. 6: Kaplan-Meier curves of the proportion of diabetes-free participants stratified according to serum adiponectin levels at baseline ¹⁵



Conclusion: Increasing adiponectin levels in subjects with low baseline adiponectin levels can aid in reducing the risk of T2DM.

Adiponectin in the Assessment of Metabolic & Insulin Concerns

I. Nutrition and Diabetes (2011): Serum adiponectin level is not only decreased in metabolic syndrome but also in borderline metabolic abnormalities ¹⁶

Objective: A cross-sectional study involving 16,892 Japanese adults (10,008 men and 6,884 women) was conducted between April 2007 and November 2009 to assess the relationship between adiponectin levels and borderline metabolic / physiological abnormalities or metabolic syndrome (MetS) components.

Fig. 7a: The number of metabolic syndrome components and adiponectin ¹⁶

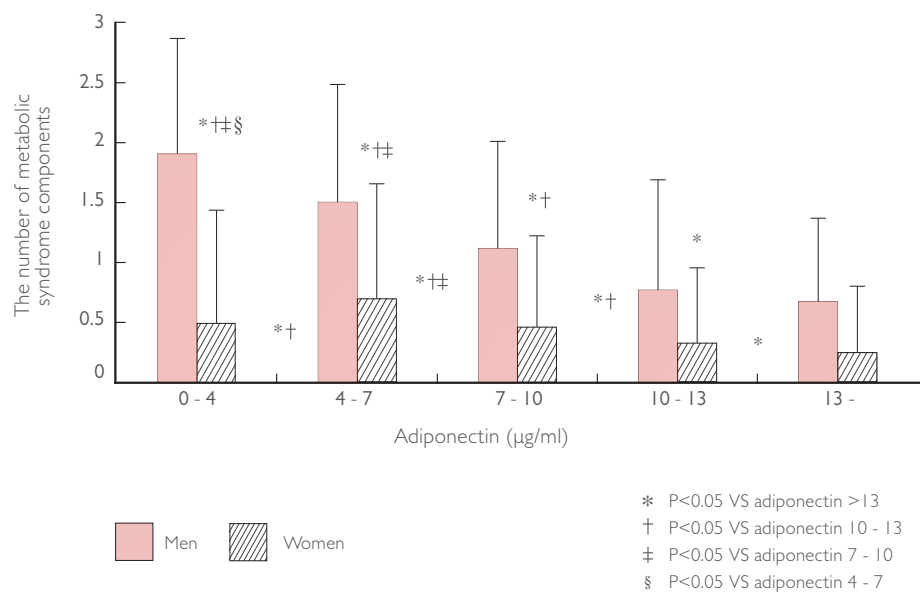
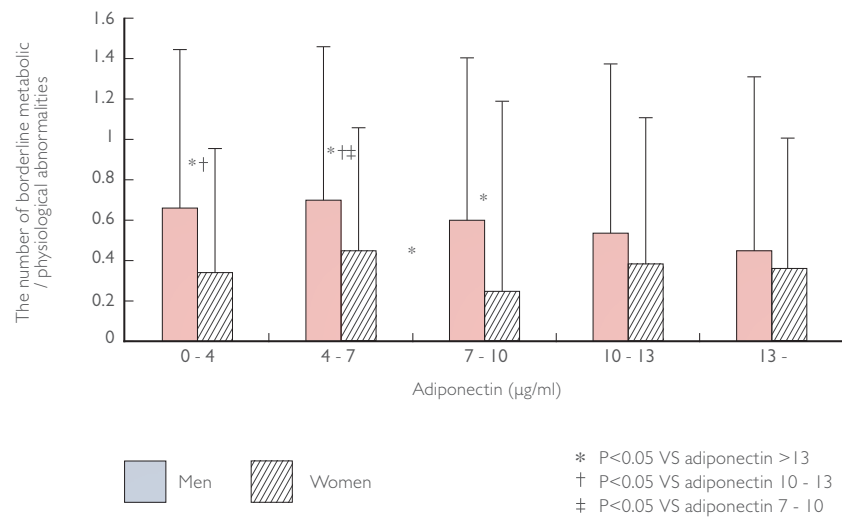


Fig. 7b: The number of borderline metabolic / physiological abnormalities and adiponectin ¹⁶



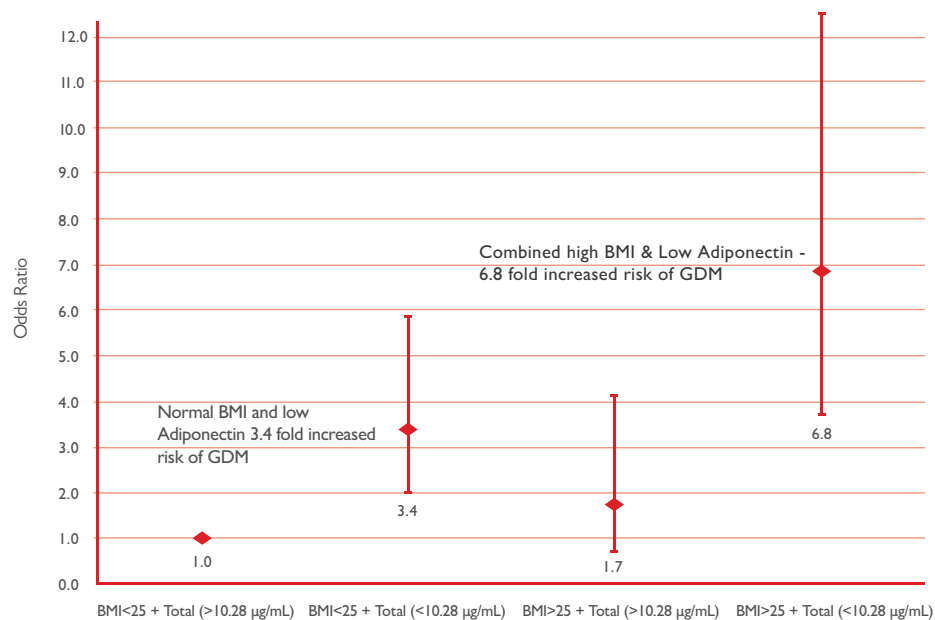
Conclusion: Decreasing adiponectin levels begins at an early stage before the onset of hypertension, diabetes, MetS or dyslipidaemia. Moreover, in those with metabolic / physiological abnormalities, adiponectin is an important biomarker for the risk of atherosclerosis both independently and as a reflection of the accumulation of AVE.

2. Diabetes Care (2013): Low pregnancy adiponectin concentrations are associated with a marked increase in risk for development of gestational diabetes mellitus ¹⁷

Objective: A US nested case-control study evaluated 256 eligible women who developed gestational diabetes mellitus (GDM) and participated in the Kaiser Permanente Northern California Multiphasic Health Check-up exam (1984-1996) and had a subsequent pregnancy (1984-2009). The aim of the study was to determine if circulating total and high-molecular weight adiponectin concentrations, measured before pregnancy, are associated with a subsequent risk of GDM.

Findings:

Fig. 8: Adapted from odds ratio (ORs) for the association between joint effects of pregravid adiponectin and BMI and risk of GDM ¹⁷



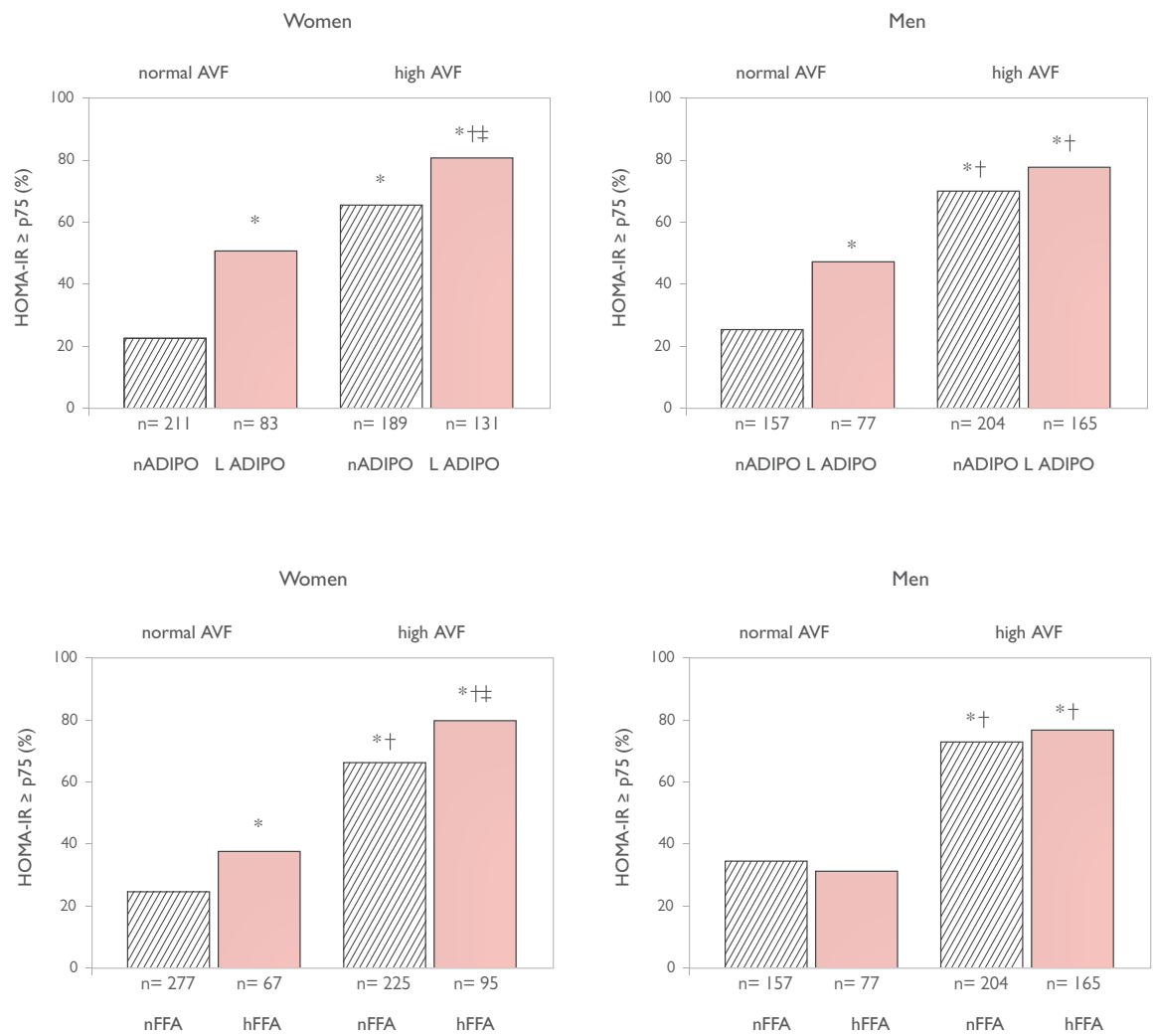
Conclusion: The study found that low adiponectin levels measured, on average, 6 years prior to pregnancy were associated with a **5-fold** increased risk of the development of GDM.

3. Cardiovascular Diabetology (2015): Role of adiponectin and free fatty acids on the association between abdominal visceral fat and insulin resistance ¹⁸

Objective: A cross-sectional analysis was undertaken to include 1,217 control participants to analyse the contribution of low adiponectin and high free fatty acids (FFAs) with IR in non-diabetic subjects.

Findings:

Fig. 9: Effect of adiponectin (ADIPO) and free fatty acids (FFA) levels on the prevalence of insulin resistance (HOMA-IR ≥ p75) ¹⁸



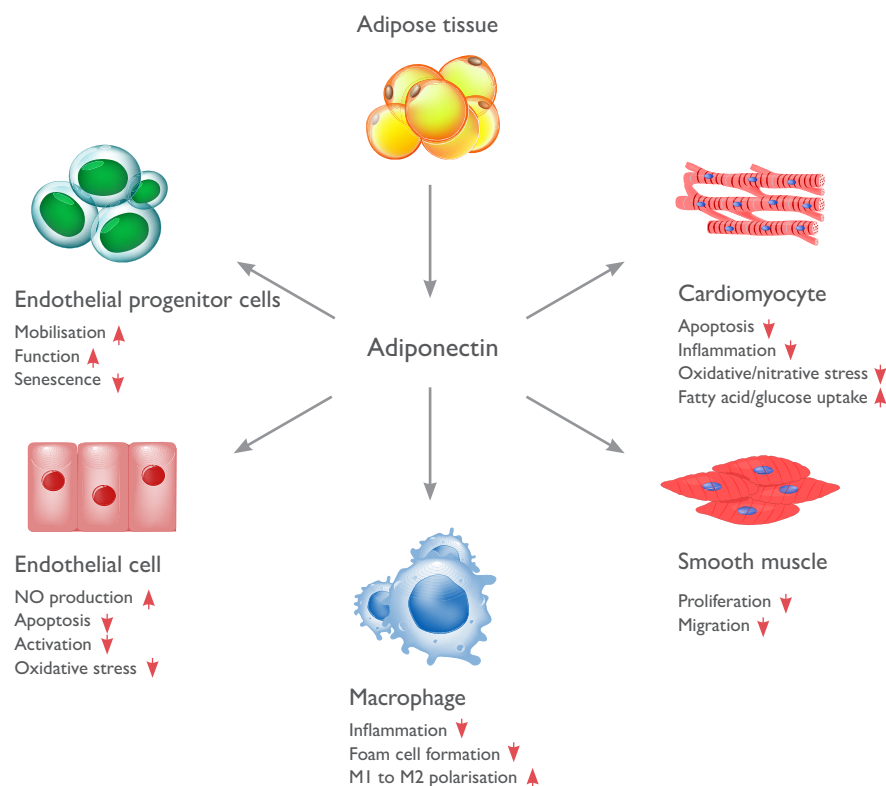
AVF = abdominal visceral fat; *p = <0.05 as compared to normal AVF/normal ADIPO; +p<0.05 as compared to normal AVF/low ADIPO; ++p<0.05 as compared to high AVF/normal ADIPO.

Conclusion: Subjects with high AVF or low adiponectin had a **three-fold increased risk of IR**. The combination of low adiponectin with high AVF doubled this probability.

Adiponectin in the Assessment of Cardiac Risk in Clinical Settings

It has been recognised that mRNA expression of the adiponectin gene and the secretion of high molecular weight (HMW) oligomeric adiponectin are impaired in adipose tissue of obese patients. Epidemiological studies undertaken in different ethnic groups established that low adiponectin levels, especially in HMW oligomer, is an independent risk factor for CVD. Fig. 10 illustrates the pleiotropic role of adiponectin in the cardiovascular system ¹⁹.

Fig. 10: The pleiotropic role of adiponectin in the cardiovascular system ¹⁹

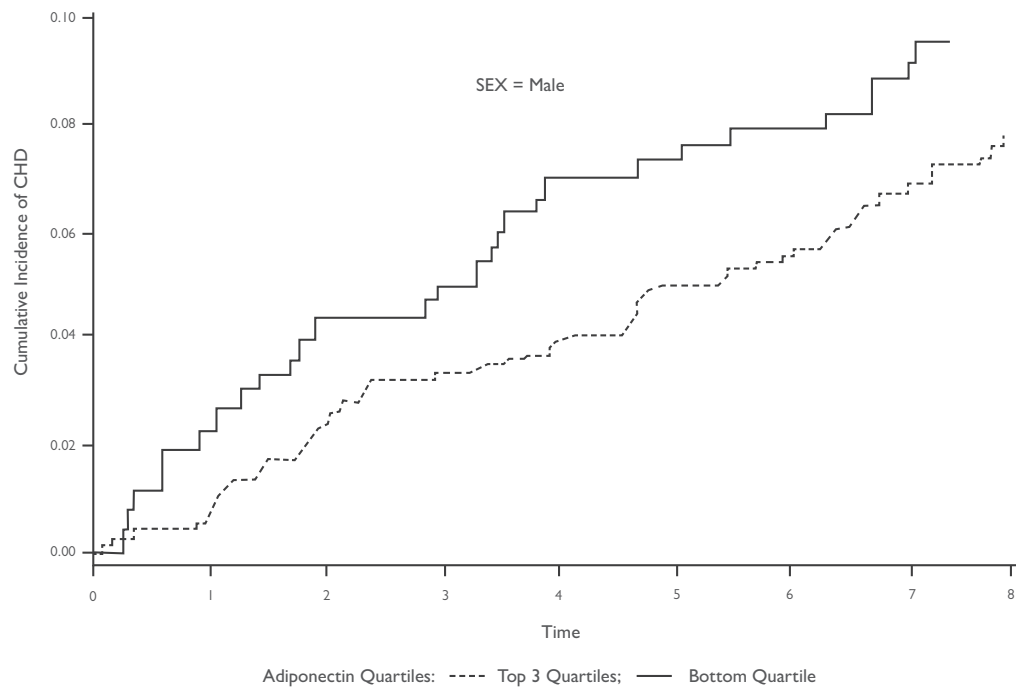


I. Atherosclerosis (2011): Adiponectin: An independent risk factor for coronary heart disease in men in the Framingham offspring study ²⁰

Objective: A US study prospectively evaluated 3,188 male and female participants from cycle 6 of the Framingham Offspring Study to determine if adiponectin is an independent predictor of coronary heart disease (CHD) risk. Participants were evaluated for a mean of 7.5 years.

Findings:

Fig. 11: Kaplan-Meier curves of incident CHD according to quartiles of baseline adiponectin levels in men, after adjustment for age ²⁰



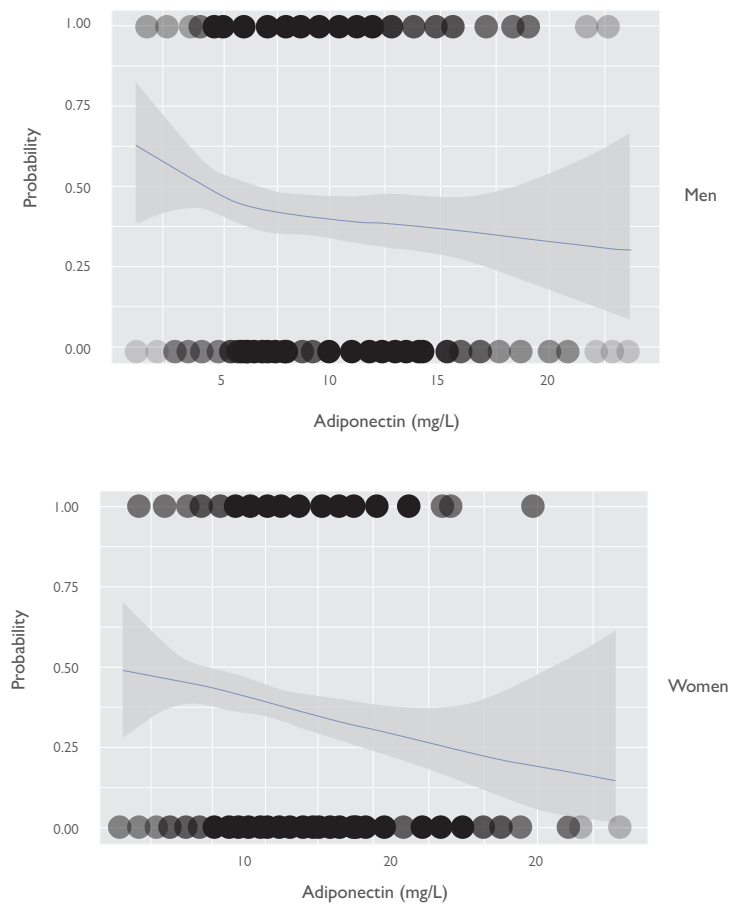
Conclusion: Elevated adiponectin levels is a significant independent risk factor of future CHD events in men, initially free of CHD. A similar trend was observed in women, but was no longer significant following multivariate adjustments.

2. PLoS ONE (2013): Adiponectin provides additional information to conventional cardiovascular risk factors for assessing the risk of atherosclerosis in both genders ²¹

Objective: A study prospectively evaluated 1,033 participants (454 men and 579 women) from the Korean Genomic Rural Cohort study to assess if adiponectin offers clinical utility in the diagnosis of atherosclerosis in both genders.

Findings:

Fig. 12: Logistic regression plot for risk of subclinical atherosclerosis (CIMT>0.9mm) according to adiponectin levels ²¹



The dot lines indicate the median level of adiponectin in each tertile levels (4.71 in 1st tertile, 7.85 in 2nd tertile, 12.52 in 3rd tertile in men; 7.36 in 1st tertile, 11.53 in 2nd tertile, 16.72 in 3rd tertile in women, unit = mg/L).

Conclusion: The risk of carotid intima media thickness (CIMT) inversely correlates with adiponectin levels in both genders. Adiponectin testing is a significant marker of atherosclerosis and can provide additional information in the assessment of atherosclerotic risk in both genders, independent of conventional cardiovascular risk factors.

3. Diabetes Research and Clinical Practice (2014): Relative contribution of obesity and serum adiponectin to the development of hypertension ²²

Objective: A South Korean study prospectively evaluated 1,553 participants (584 men and 969 women) without hypertension, aged between 40 and 70 years to investigate the association between adiponectin levels and new-onset hypertension. This cohort study retrieved baseline results between 2005 and 2008 and followed up between 2008 and 2011.

Findings:

Table 1a: Odds ratios (ORs) for new-onset hypertension in men and women according to baseline body mass index and serum adiponectin level ²²

	Odds ratios ^a (95% confidence interval)	
	Men	Women
Non-obese/high adiponectin	1.00	1.00
Non-obese/low adiponectin	1.48 (0.75 - 2.93)	0.73 (0.40 - 1.34)
Obese ^b /high adiponectin ^c	1.04 (0.32 - 3.41)	1.58 (0.75 - 3.32)
Obese/low adiponectin	2.80 (1.35 - 5.81)	1.77 (0.96 - 3.25)

^a Adjusted for age, baseline systolic blood pressure, diastolic blood pressure, fasting serum glucose, triglyceride, hs-CRP, smoking, regular exercise.

^b The obese group was defined as a body mass index ≥ 25 kg/m².

^c The high adiponectin group was defined as the highest tertile of adiponectin in the study population ($\geq 9.31 \mu\text{g/ml}$ in men and $\geq 13.62 \mu\text{g/ml}$ in women)

Table 1b: Odds ratios (ORs) for new-onset hypertension in women according to baseline serum adiponectin and menopausal status ²²

	Hazard ratio ^a (95% confidence interval)	
	Pre-menopausal women (n = 350)	Post-menopausal women (n = 350)
Non-obese/high adiponectin	1.00	1.00
Non-obese/low adiponectin	0.43 (0.09 - 2.05)	0.81 (0.40 - 1.64)
Obese ^b /high adiponectin ^c	5.25 (0.86 - 32.04)	1.32 (0.56 - 3.11)
Obese/low adiponectin	0.99 (0.22 - 4.58)	2.41 (1.16 - 5.04)

^a Adjusted for age, baseline systolic blood pressure, baseline diastolic pressure, LDL cholesterol, HDL cholesterol fasting blood glucose, smoking, regular exercise.

^b The obese group was defined as a body mass index ≥ 25 kg/m².

^c The high adiponectin group was defined as the highest tertile of adiponectin in the study population ($\geq 13.62 \mu\text{g/ml}$ in men and $\geq 13.62 \mu\text{g/ml}$ in women)

Conclusion: Low adiponectin levels were associated with an increased risk of new-onset hypertension in men and post-menopausal women.

4. European Journal of Preventive Cardiology (2015): Adiponectin, type 2 diabetes and cardiovascular risk ¹³

Objective: A Danish study prospectively investigated 5,349 randomly selected men and women from the community without T2DM or CVD to determine the relationship between adiponectin, T2DM and CVD. Adiponectin levels were assessed on study entry and the median follow-up time was 8.5 years.

Table 2: A competing risk Cox-regression proportional hazards model predicting risk of incident major cardiovascular adverse events after development of incident T2DM ¹³

Variable	HR (95% CI)	p-value
Adiponectin (per doubling)	0.34 (0.16 - 0.72)	0.005
Age at diagnosis of T2DM (per 1-year increase)	1.10 (1.03 - 1.17)	0.005

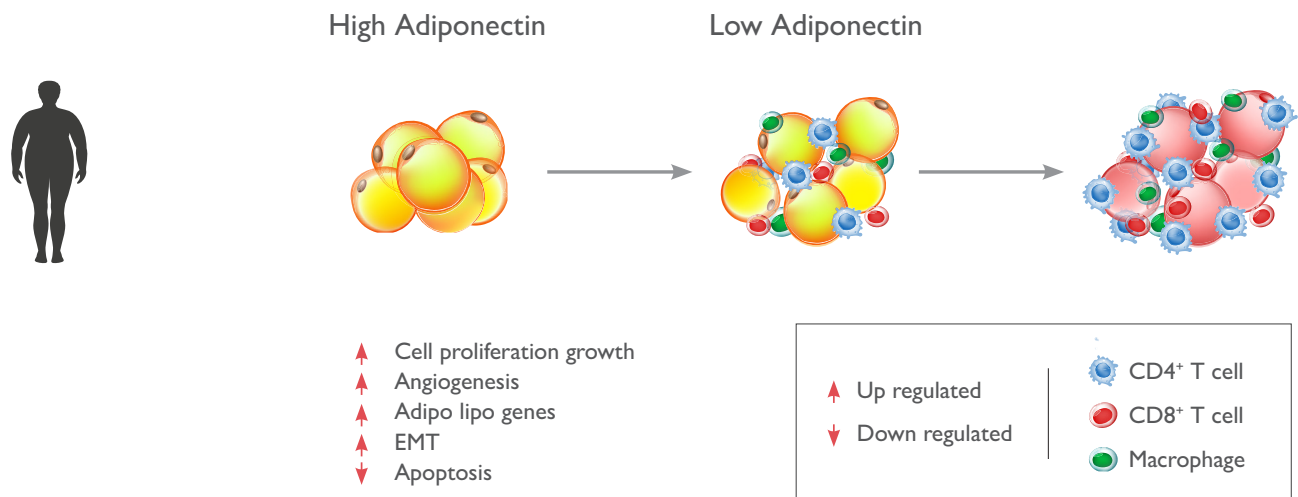
Nonsignificant result (p > 0.1) were obtained for the variables gender, smoking, plasma proBNP, hsCRP, HbA1c, blood glucose, eGRF, total cholesterol, HDL, LDL, triglycerides, hypertension, systolic and diastolic blood pressure, alcohol consumption, physical activity and BMI.

Conclusion: Increasing adiponectin levels in plasma is associated with a decreased risk of T2DM and subsequently, a reduced risk of CVD.

Adiponectin in the Assessment of Cancer

Excess body fat is not only associated with T2DM and CVD, but also with various types of malignancies. Many cancer cell lines express adiponectin receptors, and adiponectin *in vitro* limits cell proliferation and induces apoptosis. Evidence exists supporting adiponectin as a novel risk marker in the diagnosis and prognosis of cancer ²³

Fig. 13: The association between obesity, low adiponectin levels and cancer progression ²⁴



1. Indian Journal of Cancer (2015): Adiponectin correlates with obesity: A study of 159 childhood acute leukaemia survivors from India ²⁵

Objective: A cross-sectional study evaluated 159 acute leukaemia patients from the paediatric oncology outpatient of the cancer centre at the All India Institute of Medical Sciences between January 2010 and September 2012 to assess adiponectin, leptin and resistin levels in acute leukaemia survivors.

Findings:

Table 4: Mean of biomarkers in the "obese" leukaemia survivor group and the "non-obese" leukaemia survivor group ²⁵

Biomarkers	Obese (n)	Mean±SD	Nonobese (n)	Mean±SD	p
All survivors (n= 159)					
Leptin (n= 127)	24	3.70 ± 2.27	103	2.85 ± 1.91	0.06
Resistin (n= 152)	40	8.01 ± 6.75	112	9.33 ± 8.21	0.36
Adiponectin (n= 143)	36	7.75 ± 4.59	107	11.55 ± 8.79	0.01
ALL survivors (n= 126)					
Leptin (n= 99)	17	3.31 ± 1.96	82	2.99 ± 2.03	0.55
Resistin (n= 120)	32	8.58±7.28	88	8.98 ± 7.19	0.81
Adiponectin (n= 113)	28	6.67±3.88	85	11.76 ± 9.51	0.007
AML survivors (n= 33)					
Leptin (n= 28)	7	3.81 ± 2.86	21	3.01 ± 2.19	0.44
Resistin (n= 32)	8	5.75 ± 3.48	24	10.63 ± 7.21	0.08
Adiponectin (n= 30)	8	7.81 ± 3.12	22	11.51 ± 4.12	0.05

Conclusion: Resistin and leptin levels were similar between the overweight / obese and non-obese subjects. However, low levels of adiponectin were observed in overweight / obese acute leukaemia survivors compared to the non-obese survivors.

2. Medicine (2018): Serum adiponectin in breast cancer: A meta-analysis ²⁶

Objective: A meta-analysis reviewing 31 eligible studies containing 15,879 subjects, following a systematic search on Embase, PubMed, the Chinese National Knowledge Infrastructure and the USU Web of Science databases to determine the involvement of adiponectin in breast cancer (BC).

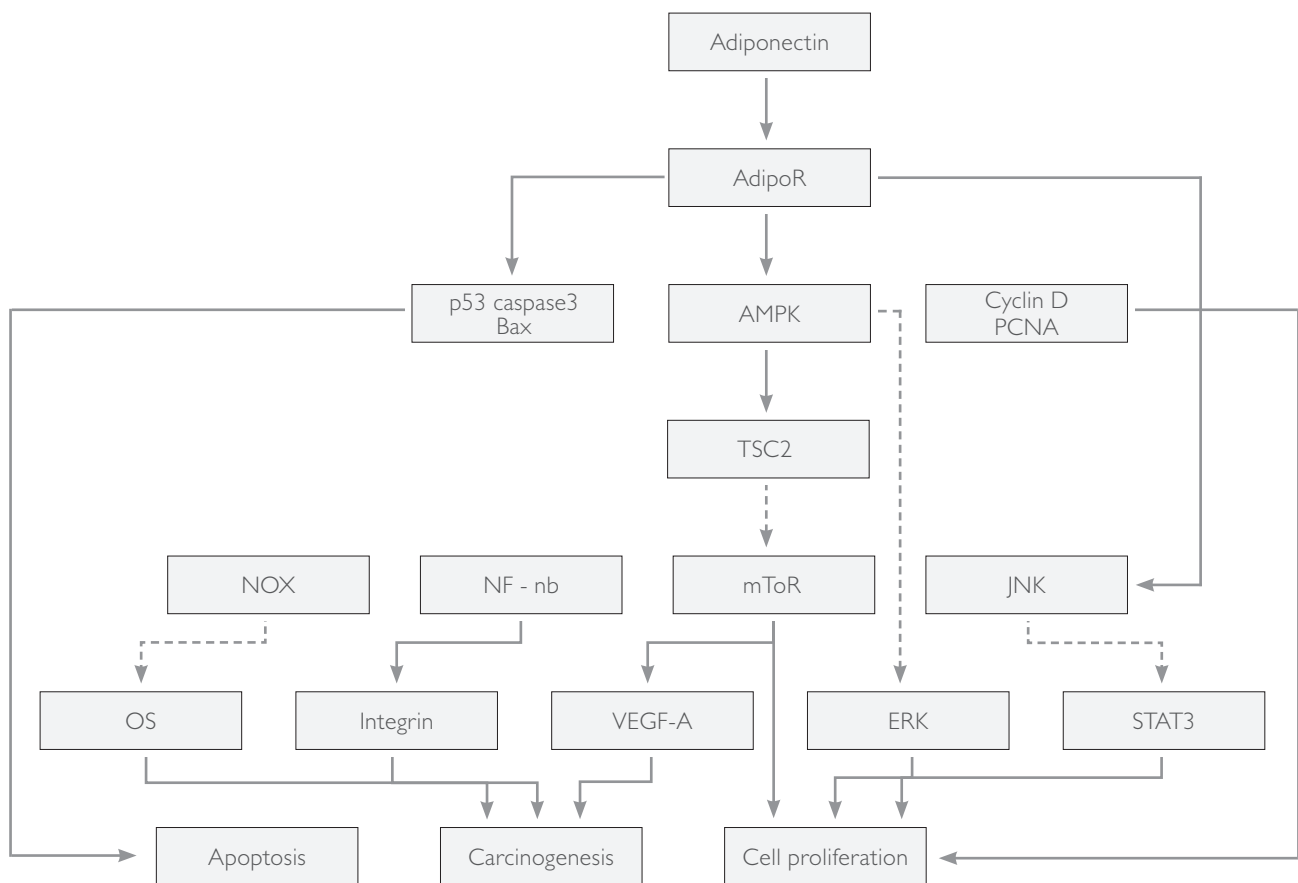
Conclusion: The meta-analysis indicates an intriguing association between low levels of adiponectin and an increased risk of BC. Furthermore, adiponectin has the potential to serve as a biomarker of BC risk and aid in the identification of those at a high-risk of developing BC.

3. International Brazilian Journal of Urology (2019): Role of adiponectin in prostate cancer ²⁷

Objective: A review of current literature to determine the potential role of adiponectin and the underlying mechanism of adiponectin in the development and progression of prostate cancer (PC).

Findings: Oxidative stress has been identified as a key event in the initiation, development and progression of PC. Adiponectin increased cellular anti-oxidative defence mechanisms and inhibited oxidative stress through increasing the NADPH oxidase NOX2 and NOX4 expressions in human 22Rv1 and DU-145 PC cell lines.

Fig. 14: Signalling pathways of adiponectin in prostate cancer cells ²⁷



JNK = c Jun N-terminal kinase; Stat3 = signal transducer and activator of transcription; AMPK = AMP - activated protein kinase; TSC2 = tuberous sclerosis complex 2; mTOR = mammalian target of rapamycin; NF-KB nuclear factor KB; NOX = NADPH oxidase; OS = oxidative stress ↓ indicates stimulation ↓ indicates inhibition.

Conclusions: Numerous studies analysed in this review support adiponectin as a protective and safe factor to prevent the progression of PC.

Ordering Information

Description	Cat. No.	Size
Adiponectin Kit	AO8154	R1 1 x 8.7ml R2 1 x 8.7ml
Adiponectin Kit	AO8162	R1 2 x 20ml R2 2 x 20ml
Adiponectin Control Level 2	AO2815	3 x 1ml
Adiponectin Control Level 3	AO2816	3 x 1ml
Adiponectin Calibrator	AO8156	6 x 1ml

Randox Diabetes Testing Panel

Obesity is a major risk factor for the development of IR, T2DM and CVD. Diabetes mellitus affects more than 180 million people worldwide, which is expected to reach 300 million by 2025. Obesity-associated T2DM accounts for 90-95% of all adult diagnosis. Early risk assessment is vital in those who are at a greater risk of diabetes ^{28, 29}.

Randox offers a comprehensive diabetes portfolio, incorporating niche and superior performance assays for the detection of conventional risk factors together with emerging biomarkers associated with future risk.

Risk Assessment

Adiponectin

Diagnosis and Monitoring

Fructosamine (Enzymatic) | Glucose | HbA1c

Complications Monitoring

Albumin | B₂Microglobulin | Creatinine (Enzymatic & JAFFE) | Cystatin C | D-3-Hydroxybutyrate (Ranbut) | Microalbumin | Non-Esterified Fatty Acids (NEFA)

Randox Cardiology & Lipid Testing Panel

The early diagnosis of CVD aids in the identification of cardiovascular risk, both in primary and secondary risk categories, enabling appropriate treatment plans to be implemented to improve patient outcomes. Early risk assessment is particularly important in those who are at a greater risk of CVD. This is evaluated through the identification of one or more risk factors including: hypertension, diabetes or hyperlipidaemia^{30, 31}.

Randox offers a comprehensive cardiology and lipid testing portfolio incorporating niche and superior performance assays for the detection of conventional risk factors together with emerging biomarkers associated with future risk.

Risk Assessment

Adiponectin | Apolipoprotein A-I | Apolipoprotein A-II | Apolipoprotein B | Apolipoprotein C-II | Apolipoprotein C-III | Apolipoprotein E | HDL Cholesterol | HDL2/3 Cholesterol | Homocysteine | hsCRP | LDL Cholesterol | Lipoprotein (a) | sdLDL Cholesterol | sPLA₂-IIA | Total Cholesterol | Triglycerides

Diagnosis of MI

CK-MB | H-FABP | Myoglobin

Therapy Monitoring

Digoxin | TxBCardio™

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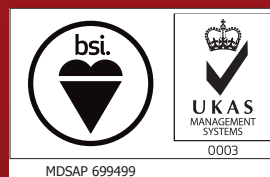
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