Chronic ingestion of flavan-3-ols and isoflavones reduces CVD risk biomarkers in medicated postmenopausal women with type 2 diabetes: a one year double-blind randomised controlled trial.

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Introduction Postmenopausal women with type 2 diabetes (T2DM) are at increased risk of cardiovascular disease (CVD), even following pharmacological treatment. There are no long-term trials examining the additional benefits of flavonoids to CVD risk in medicated postmenopausal women with T2DM.

Methods and materials A parallel-design placebo-controlled trial randomised 118 medicated postmenopausal women with T2DM to 27g /d flavonoid-enriched chocolate (850mg total flavan-3-ols (90mg epicatechin) and 100mg isoflavones (aglycone equivalents) /d) or matched placebo for 1 year. Intima-media thickness (IMT), arterial stiffness (pulse wave velocity, augmentation index), 2hr ambulatory blood pressure (BP) and biomarkers including CRP, lipids and insulin were measured at baseline and 1 year. A diabetes specific 10-year CVD risk calculation was made using the UKPDS algorithm.

Results 93 participants completed the 1-year intervention (aged 51-74 years, BMI 21.5 - 57.9kg/m^2) and compliance was high (flavonoid 91.3%, placebo 91%). Flavonoid intervention resulted in a significant reduction in insulin resistance (HOMA-IR -0.3±0.2, p=0.004) and improvement in insulin sensitivity (QUICKI +0.003±0.00, p=0.04) as a result of a decrease in insulin levels (-0.8±0.5 uU/L, p=0.02). Significant reductions in total-cholesterol (C):HDL-C (-0.2±0.1, p=0.01) and LDL-C -0.1±0.1mmol/L, p=0.04) were also observed following flavonoid intervention. Progression of 10-year total coronary heart disease (CHD) risk was attenuated (p=0.02). No effect on BP was observed in this medicated T2DM population and IMT and arterial stiffness data are currently being evaluated.

Conclusions

1-year intake of a combined intervention with flavan-3-ols and isoflavones improved biomarkers of CVD risk, highlighting the additional benefit of flavonoids to standard drug therapy in reducing risk of vascular disease in T2DM patients.