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Effect of herbal drug *Coccinia grandis* (*L.*) on antioxidant status and inflammatory markers and their association with glycemic status in newly diagnosed patients with Type 2 Diabetes Mellitus

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Background: Several studies have reported antioxidant and anti-inflammatory activities of the aqueous leaf extract of *Coccinia grandis* (Linn.) Voigt (Common name-"Kowakka").
Objective: To determine the effect of Herbal Drug *C. grandis* (HDC) on oxidative stress and inflammation in newly diagnosed patients with Type 2 Diabetes Mellitus (T2DM) in Galle, Sri Lanka via a randomized, double-blind, placebo controlled clinical trial.
Method: A total number of 158 patients (30-60 years) with newly diagnosed T2DM were recruited and equally randomized into two groups to consume either HDC (500 mg freeze dried powder of the hot water extract of *C. grandis* leaves) or the placebo drug (500 mg corn starch) once a day after the lunch for three months. Oxidative stress markers and anti-inflammatory markers were determined on the collected serum samples at the baseline and end of intervention. Correlations between baseline glycemic status and the changes of selected oxidative stress markers and anti-inflammatory markers upon the administration of HDC were determined.
Results: A total number of 145 patients (male=55/145) completed the intervention period. Mean±SD changes of variables from the baseline to the end of the intervention in the test and placebo groups were 0.2±7.3 and 0.5±7.6 U/mL for catalase ($p=0.40$), -3.3±3.9 and 1.4±4.8 U/L for glutathione reductase; GR ($p<0.001$), 12.8±33.4 and -1.5±41.9 nmol/dL for malonaldehyde ($p=0.025$), 0.1±1.8 and -0.1±1.2 pg/mL for tumor necrosis factor alpha ($p=0.225$), 5.9±11.5 and 0.5±13.1 pg/mL for interleukin-6 ($p=0.002$) respectively. The mean changes in malonaldehyde and interleukin-6 were significantly and positively correlated with the glycemic status measured by both FPG concentration and HbA_{1C}%. The change in GR was significantly and negatively correlated only with HbA_{1C}%.
Conclusion: Administration of HDC had favorable effects against oxidative stress and inflammation in patients with newly diagnosed T2DM and the effects were stronger in this cohort of patients who have high glycemic load than those with low glycemic load.

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