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Clinical Utility and Safety of *Coccinia grandis* Extract in Patients with Newly Diagnosed Type 2 Diabetes Mellitus: A double Blind, Placebo Controlled, Randomized Clinical Trial

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Preclinical studies (*in vitro* and *in vivo*) have demonstrated the antidiabetic effect of the aqueous leaf extract of *Coccinia granids* (Linn.) Voigt (Cucurbitaceae). This study determined the clinical utility and safety of the herbal capsule of *C. grandis* (HCC), which consisted freeze dried powder of the hot water extract of *C. grandis* leaves, in patients with newly diagnosed type 2 diabetes mellitus (DM). Newly diagnosed type 2 DM patients (n=158), belonging to age group of 30-60 years, were recruited for three months long double blind, randomized, placebo controlled clinical trial. Patients with known hyperlipidemia, hypertension, renal, liver, cardiac, respiratory, thyroid, psychiatric and any other chronic or acute diseases, and pregnant women were excluded. Recruited patients were randomized into two groups (1:1 ratio) either to receive HCC (500 mg/day) or placebo capsules of corn starch (500 mg/day). Percentage of glycated hemoglobin (HbA_{1C} %), fasting plasma glucose (FPG) concentration, insulin and homeostatic model assessment for insulin resistance (HOMA-IR), serum concentration of fructosamine and safety parameters were estimated at the base line and at the end of the intervention. Intention-to-treat analysis, the "gold standard" for analyzing data of clinical trials, was performed. The mean (SD) changes between the groups were assessed using unpaired sample t-test and Mann–Whitney U test for normally and non-normally distributed data respectively. Mean (SD) changes of variables from the baseline to the end of the intervention in the test and the placebo groups were 0.66 (0.52) and 0.06 (0.64) for HbA_{1C} % ($p<0.001$), 1.91 (2.95) and -1.28 (9.32) for insulin ($p<0.001$), 0.02 (0.03) and -0.01 (0.03) for fructosamine ($p<0.001$), 1.43 (0.55) and 0.04 (0.48) for FPG ($p<0.001$), 1.73 (1.31) and -0.37 (3.22) for HOMA-IR ($p<0.001$) respectively. Hematological parameters, renal and liver safety parameters and blood pressure were within the normal physiological reference ranges at the base line and at the end of the intervention. In patients with newly diagnosed type 2 DM, administration of HCC (500 mg/day) for three months was well tolerated and significantly improved glycemic control.

Keywords: Clinical trial, Coccinia grandis, Diabetes mellitus, Herbal drug, Safety