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Safety Evaluation of Ficus Deltoidea Administration in Atherosclerotic Rabbits

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Background/Synopsis: *Ficus deltoidea* (FD) is commercially available for human consumption; proposed to be used as a supplement for diabetes mellitus and wound healing. FD has been reported to exhibit anti-atherogenic properties. Acute toxicity study in rats revealed that FD var. *kunstleri* (FDK) extract did not exert any toxic effects even at the highest dose of 2000 mg/kg. However, there is scarce safety data on FD in rabbit atherosclerotic model.

Objectives/Purpose: To investigate the safety of FDK administration in high-cholesterol diet-induced atherosclerotic rabbits.

Methods/Results: Ethanolic aqueous leaves extract of FDK were used in this study. The dried leaves were soaked in 50% ethanol (50:50; ethanol:water (v/v)), sonicated for 30 minutes at 45°C in the water bath and freeze-dried. Twenty-five male New Zealand White rabbits weighing (2.0-3.0 kg) were divided into two groups and fed with 1% high cholesterol diet (HCD) for four and eight weeks to induce early and established atherosclerosis respectively. Subsequently, the rabbits in were given (i) FDK 700mg/kg (n=10) (ii) FDK 800mg/kg (n=5) and (ii) placebo (n=10). Treatment was given once daily by oral gavage for 8 weeks. Blood pressure and body weight were measured throughout the experiment. Blood and urine was collected at the start of the experiment, end of HCD inducement and end of the experiment and measured for liver and renal function tests. Various organs (heart, brain, liver, spleen, pancreas and kidney) were obtained after euthanasia. The organs were fixed in formalin, processed into paraffin-embedded tissue blocks, stained with Hematoxylin & Eosin and evaluated histologically for morphological abnormalities. There were no significant changes observed in the blood pressure and body weight of rabbits after the consumption of FD extract in both treatment arms. Oral administration of FDK at 700 and 800 mg/kg did not result in abnormality in serum alanine aminotransferase (ALT), alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), albumin (ALB) and total protein (TP) concentrations. Similarly, serum creatinine concentration showed no significant changes after two months of consumption compared to post-HCD levels in early and established atherosclerosis groups. No significant differences seen in morphology of the organs between treated and placebo groups.

Conclusion: Dietary administration of FDK extracts up to 800 mg/kg/day for two months may is safe in HCD-induced atherosclerotic rabbits.