

Clinical assessment of the efficacy of an *Ardraka kanda* (AKI) drug for food hypersensitivity

Y. S.G. Wimalasiri,^{1,5} R. M. U. Ratnayake,^{2,5} T.D.N. Karunaratne,^{1,5} and K.K.D.S. Ranaweera^{3,4,5}

¹Department of Swasthavritta, Institute of Indigenous Medicine, University of Colombo

²Department of Biochemistry, Faculty of Medicine & Allied Sciences, Rajarata University of Sri Lanka, Saliyapura,

³Department of Food Science and Technology, University of Sri Jayewardenepura,

⁴Bandaranayake Memorial Ayurveda Research Institute, Nawinna

⁵Faculty of Graduate Studies, University of Colombo.

Food hypersensitivity is a common non communicable disease in the world which can be either caused by food allergy or non-allergic food intolerance. It has a wide range of symptoms from eczema to severe life-threatening anaphylaxis and has a clear impact on quality of life of an individual and the society. The objective of this study was to assess the efficacy of *Ardraka kanda* (AK1) formula as a suitable treatment on food related complications, allergy or intolerance for the sensitized individuals. AK1 was assessed in a clinical trial, testing total IgE, specific IgE, total leucocytes with its differential count and urine analysis as biochemical parameters and clinical symptoms evaluation using a scoring system through patient interview, consisting of four phases – pre treatment, post treatment, allergen/food induced stage 1 and 2. Volunteer patients with a convincing history, age 18 -75 years and mild to moderate symptoms were selected for the study conducted at the Ayurveda Teaching Hospital, Borella during the period from February 2014 to April 2015. Thirty four patients were tested with the AK 1 drug dose (6 g freshly prepared tablets before the breakfast for 14 days) during the trial with follow up for six months with patient maintained diaries. There were eleven recorded positive patients for food specific IgE levels; for beef, milk, wheat, grapes, prawn, pineapple or tomato. Thirty patients completed the study and 21 (70%) patients showed positive improvement after 6 weeks of the intervention study. There was a gradual significant IgE reduction in all participants after the treatment initiation with the test drug [p value 0.029], and 21 patients showed overall improvement [p value 0.026] from the disease. The p value for the difference in the Neutrophil count in initial stage and after the treatment of this group of 21 patients was a significant difference [p = 0.049]. In conclusion, the study reveals that the test drug *Ardraka kanda* (AK1) has a significant impact on reducing total blood IgE level with significant reduction of neutrophils observed among the improved food sensitized patients. There was no significant impact on urine and no observable adverse or side effects caused by the drug on individuals participated the study.