Phase I Clinical Study of Purified Honey Bee Venom(PHBV ; Apitoxin®) in Korean

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The phase I clinical study of purified honey bee venom(PHBV) was carried out to establish the dose-safety and tolerance of PHBV as therapeutic agent for the rheumatic disease in Korean population.

Study subjects were the healthy Korean volunteers and carried out from April 11th to July 9th 1994. PHBV were injected subcutaneously from the starting dose of 0.15mL, then with increment of 0.05mL final dosage of 0.7mL was reached at 12th injection. We injected the subjects at 2 to 3 days interval, and we saw to it that no one shot get more than 0.125mL. Blood and urine samples were collected the day before the 1st injection, and 24± 2 hrs after 1st, 6th, 12th injection. Serum cortisol levels were measured by radioimmunoassay ; serum ionized calcium level by direct ion selective electorde. Urinalysis, hematological and chemistry parameters were done with autoanalyzer. Pre-test results of above mentioned parameters were compared with those of post-test by paired t-test. And as the object of this study is to establish the safety of PHBV, the statistical values were reevaluated according to the clinical standards by authors.

No significant difference was found after the injection of PHBV at the dosage of this study in vital signs and above mentioned parameters. No significant physiologic change was demonstrated. After injection, relatively minor transient side effects, which subsided without any treatment, were reported. No major side effect or severe complication was observed.

Authors concluded that PHBV is safe therapeutic agent given to healthy Korean adults at our dosage level.