

PRODUCTION AND MULTIPLE CLINICAL TRIAL COURSE TO DEFINE THE SAFETY AND EFFICACY OF NAJA KAOUTHIA ANTIVENOM

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Abstract

Objective: Naja kaouthia (NK) is one of the most dangerous land snakes in the World. There were 30,000 cases of snake bites per year in Vietnam. 30.3 % of them were envenomed by NK. Before 1990, the mortality of patients bitten by snakes in Choray hospital was 19,5 %, because there was not any antivenom available. For that, NK antivenom has been researched and produced by permission of Vietnam Ministry of Health. Since 2004, a multiple clinical trial course to define the safety and efficacy of NK antivenom was carried out in Poison Control Center, Bach Mai and Choray hospitals.

Method: Research and produce 03 lots of NK antivenom by F(ab')₂ purified pepsin enzyme technological process. Bioproduct has been passed National Institute for Control of Vaccine and Biologicals, MOH, Vietnam. A multiple clinical trial course of novel antivenom in 98 patients envenomed by NK was established and carried out in PCC, Bach Mai and Choray hospitals according to the unified protocol.

Results: 03 lots (900 vials) of NK antivenom was manufactured and passed National Institute for Control of Vaccine and Biologicals, MOH, Vietnam: Lot No(X), Code:0107-KQKD/ DTNC, January 4th, 2007, Lot No(XII), Code:00508/SP-NC, June 26th, 2008 and Lot No(XIII), Code:00110/SPDT-NC, January 20th, 2010.

98 patients envenomed by naja kaouthia and naja atra who fulfilled the inclusion criteria entered the study during 2005 - 2009. 79 patients (80.5%) were labour age (18-60 years old), men: 88 patients (98.6%), 62 patients (63.6%) were farmers.

Local symptoms: swelling: 98 (100%), pain: 90 patients (92.2%), fang marks: 88 patients (89.9%), necrosis: 65 patients (66.2%), General paralysis: Ptosis: 79 patients (81.0%), laryngeal paralysis: 70 patients (71.4%), acute respiratory failure: 19 patients (19.0%). After 24 hrs of NK AV therapy with dose (13.6 ± 4,2) vials in PCC and dose (7.8 ± 0.6) vials in Choray hospital, the local and general symptoms disappeared. The side effect reactions were (11.7%), less than the limit of WHO (<15%).

Conclusion: Patients envenomed by NK were young farmers mainly. Swelling, pain, fang marks, necrosis and general paralysis (ptosis, acute respiratory failure) were symbolic symptoms. NKAV was produced in PCC, Bach Mai hospital met safety and efficacy's Vietnam and WHO standards.