SHORT REPORT: TREATMENT OF SNAKE ENVENOMATIONS BY A NEW POLYVALENT ANTIVENOM COMPOSED OF HIGHLY PURIFIED F(ab')2: RESULTS OF A CLINICAL TRIAL IN NORTHERN CAMEROON

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Abstract. A clinical trial was conducted in 2 health centers in northern Cameroon to assess the safety and efficacy of a new polyvalent antivenom composed of highly purified and pasteurized F(ab')2 (FAV-Africa). Forty-six patients with objective signs of envenomation, including 67% with hemorrhage, were included in the study. Each patient received at least 20 ml of FAV-Africa by direct, slow intravenous injection; 172 10-ml ampules were administered. All patients were clinically cured after treatment. Two patients (4.3%) showed minor immediate adverse events that may have been related to FAV-Africa (induction, light-headedness); no other treatment-related adverse event occurred. No patient had serum sickness. This trial confirms the safety of FAV-Africa administered by intravenous injection and its efficacy in the treatment of snake envenomations in sub-Saharan Africa.

Antivenom immunotherapy is the only effective treatment against envenomations. In Africa, however, due to the restricted availability of antivenoms, usage constraints, and the fear of adverse reactions, use of serum therapy has been limited.
to be possibly attributable to FAV-Africa (slight induration at the FAV-Africa injection site and moderate light-headedness). Four patients experienced at least 1 early event (pruritus at the venipuncture site, hematemeses, epistaxis, lower back pain, hematoma at the bite site, and an increase in edema). Seven patients presented a semi-delayed event (fever, necrosis at the bite site, meningeal hemorrhage, epistaxis, and hematuria). Of the 39 patients examined on day 26, 10 presented a delayed adverse event (diarrhea, headache, hematoma or pruritus at the venipuncture site, skin rash, vertigo, melena, Wolkmann’s syndrome, and necrosis at the bite site). No early, semi-delayed, or delayed events were considered to be related to FAV-Africa; in particular, no patient presented with serum sickness or serum-like sickness.

The efficacy of FAV-Africa can be inferred from data obtained before the antivenom trials, first in Garoua between 1988 and 1992 (200 cases, approximately 10–20% treated with antivenom, and 14 deaths) and then in Doukoula between 1989 and 1992 (296 cases, 80–90% treated with a low dose of antivenom administered intravenously, and 6 deaths).2

These results demonstrate the favorable safety profile of FAV-Africa compared with other less purified preparations. Under similar conditions, treatment with the antivenom IPSER-Africa, which is less purified than FAV-Africa, had a prevalence of adverse effects ranging from 7.6% to 12%.2,4 Nevertheless, during our study, we observed a significant relationship between the frequency of adverse effects and the volume of FAV-Africa injected (P < 0.001, by Mantel-Haenszel chi-square test). However, most reactions (hematoma at the venipuncture site, pruritus at the site of the bite site, diarrhea, lower back pain, agitation) did not appear to correspond clinically to signs and symptoms of horse protein intolerance, and other symptoms (fever, headache, hematemia) were explained by the presence of an intercurrent disease (malaria and schistosomiasis). Furthermore, there is an obvious confounding factor since the volume of protein injected was dependent on the severity of the envenomation.

This study confirmed the safety and efficacy of FAV-Africa administered by DIV for the treatment of snake envenomation. This antivenom could be used as a first-line treatment for confirmed envenomation, even in a peripheral health center. Moreover, its good safety profile enables it to be used broadly, even at early stages, or when the severity of envenomation has not yet been established. We attempted to define a simple therapeutic protocol that was both accessible to overburdened personnel and feasible in an under-equipped environment. The administration of 20 ml of FAV-Africa, with a repeat treatment 6 hr later in the absence of improvement of a hemorrhagic syndrome, or earlier in the case of deterioration, appears sufficient in the majority of cases. Clinical surveillance of bleeding should be completed by WBCT measurements that can predict a possible hemorrhagic syndrome and confirm its resolution.

Financial support: This work was supported by Pasteur Méieux Connaught (Lyon, France). No author has an undisclosed conflict of interest.

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