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Acute Adverse Events Associated With The Administration of FabAV Within The North American Snakebite Registry

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Background: Most data relative to hypersensitivity-related, acute adverse events (AE) associated with FabAV (BTG International Inc., West Conshohocken, PA; CroFab®) are retrospective. Prospective data are limited. The prevalence of treatment approaches to FabAV-related AEs is also poorly described. ACMT's North American Snakebite Registry (NASBR) is a prospective database established in 2013. One component collected by the NASBR are FabAV-related data on AE's.

Research Questions: The primary objective is to characterize the prevalence of hypersensitivity-related, acute AEs associated with FabAV administration. A secondary objective is to describe the treatment used for these AEs.

Methods: All cases prospectively reported to the NASBR between 1/2013 and 12/2015 were reviewed. Descriptive statistics were used.

Results: 368 patients received ≥ 1 vial of FabAV. Among these, 149 (40.2%) were children < 18 years of age. AEs occurred in five (2.3%) of the adults and in four (2.7%) of the children (2.4% total). The five different adults totaled 13 AEs and the four different children totaled eight AEs. The most common AEs for adults occurred at 0.9% each for three different AEs; rash, hypotension and bronchospasm. The most common AE for children was rash. Eight of nine with an AE received specific treatment consisting of various combinations of antihistamines (N=6), steroids (N=2), epinephrine (N=2), slowed infusion (N=2), or stopped infusion (N=1). Fifteen of 368 patients received prophylaxis medications prior to FabAV administration; none had an AE.

Discussion: Previously published AE-prevalence with FabAV has varied much. In three prospective studies, eight (14%) of 57 patients had AEs. In retrospective series; there are 480 adult patients of whom 22 (4.6%) had AEs, and there are 118 children patients of whom 7 (5.9%) had AEs (Combined-598 total patients with 29 AEs [4.8%]). Our 2.4% AE prevalence is lower than that reported in previous prospective or retrospective studies. Patients responded well to treatments of the AEs and only one patient had the FabAV infusion stopped completely. Serum sickness was excluded.

Conclusion: Our large prospective study indicates that acute hypersensitivity AEs occurred in only 2.4% of patients, which is less frequent than in prior studies.