

Conclusions: GC related AE reporting in AAV studies can be improved and follow published guidelines (EULAR Ann Rheum Dis 2010; 69: 1913-19). Serious AEs such as mortality and infection remain a major clinical problem. Metabolic and musculoskeletal events are also a patient burden. New therapeutic options for AAV should aim to reduce this AE profile.

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	Serious AE	AE
Patients exposed to GCs in studies reporting GC-related events (n)	3543	23278
Events (n)	1102	4284
Most common events reported	Mortality 33%	Metabolic 37%
	Infection 20%	Infection 15%
	Musculoskeletal 17%	Neuropsychiatric 8%
	Renal 15%	Musculoskeletal 8%

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Adverse Events Due to Glucocorticoids in ANCA-Associated Vasculitis Are Frequent but Reporting Should Improve

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Background: High dose glucocorticoids (GCs) are an integral part of therapy in ANCA-associated vasculitis (AAV). The adverse event (AE) profile of GC is well known and can lead to acute and chronic toxicity, resulting in an unmet need in clinical practice to reduce GC exposure in AAV. This systematic literature review aimed to examine AEs related to GC use in AAV clinical studies.

Methods: A systematic literature review was performed of studies published between 1 Jan 2007 and 30 January 2018. Data on GC-related AEs (any untoward/medical occurrence) and serious AEs (defined in European Medicines Agency CPMP/ICH/377/95) which threaten life or function were extracted from studies.

Results: Thirty-three studies were identified in which GC-related AEs were published. Of the 25,745 patients enrolled in the 33 studies, 24,566 were exposed to GCs. Seventeen studies reported AEs only, with 23 reporting serious AEs. Overall AE rate in AAV studies appears low possibly due to under-reporting, as GC effects are so well known. The most common serious AEs were infection and mortality. Infection was the leading cause of mortality, occurring more frequently in the first 6 months of treatment. Generally, infections are commonly reported but site and microbiological cause of infection were presented rarely. Metabolic and infection are the most common AEs, and 83% of metabolic events are due to diabetes mellitus. Musculoskeletal AEs and serious AEs are also relatively common.

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