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26. High-Dose Adrenocorticotrophic Hormone or Prednisone for Infantile Spasms? A Prospective, Randomized, Blinded Study

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Standard therapy for infantile spasms (IS) consists of adreno-corticotrophic hormone (ACTH) or prednisone. ACTH, especially when used at high doses recommended by some (150 U/m²), results in severe, dose- and duration-dependent side effects. Retrospective or uncontrolled studies, however, claimed a higher efficacy of ACTH as compared to prednisone. Blinded prospective studies demonstrated equal response to prednisone and low-dose ACTH [1], and recently, to low- versus high-dose ACTH. Overall efficacy reported was low [2]. We report on a prospective, randomized, single-blinded comparison of ACTH (150 U/m²/day) or prednisone (2 mg/kg/day) given for 2 weeks. The patient population consisted of consecutive infants fulfilling entry criteria evaluated at Childrens Hospital Los Angeles and Kaiser Permanente. Of 36 eligible patients, 29 were enrolled. Excluded infants received ACTH (4), prednisone (1), and valproate (2). Diagnostic/inclusion criteria included the presence of clinical spasms, hypsarrhythmia (or variants) on a full-sleep-cycle videotelemetry, and no prior steroid or ACTH treatment. Response required both clinical cessation of spasms and elimination of hypsarrhythmia on follow-up electroencephalographic (EEG) scan read by an investigator "blinded" to treatment. Treatment of responders was tapered off over 12 days; those failing 1 hormone were crossed-over to the other. The median age of patients was 6 months. Twenty-three infants were "symptomatic," with known or suspected cause, and 6 were cryptogenic (2 normal, 4 abnormal). Of 15 infants randomized to ACTH, 13 responded by both EEG and clinical criteria (86.6%); another stopped having spasms, but EEG remained hypsarrhythmic (considered a failure). Four of 14 patients given prednisone responded (28.6%), significantly less than with ACTH: $p = 0.002$ (χ^2 test). Using a prospective, randomized approach, a short (2-week) course of high-dose ACTH is superior to prednisone for treatment of IS, as evident by both clinical and EEG criteria.

References

1. Hrachovy RA, Frost JD, Kellaway R, et al. J Pediatr 1983;103:641-645
2. Hrachovy RA, Frost JD, Glaze DG. J Pediatr 1994;124:803-806