## A prospective observational study evaluating hypothalamic-pituitary-adrenal axis alteration and efficacy of intramuscular triamcinolone acetonide for steroid-responsive dermatologic disease

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**Background:** The lack of recommendations regarding dosing and administration, an undetermined risk of hypothalamic-pituitary-adrenal axis alteration, and the unknown effectiveness of intramuscular (IM) corticosteroid injection to treat dermatologic disease may be deterrents to use.

**Objective:** We sought to evaluate presence and duration of iatrogenic Cushing syndrome and secondary adrenal insufficiency in patients receiving IM triamcinolone acetonide (TAC), and to assess physician- and patient-reported outcomes.

*Methods:* We conducted a prospective observational study of 14 patients given the diagnosis of steroid-responsive dermatologic disease who received either 1 or 2 doses 6 weeks apart of IM TAC. Baseline and follow-up cortisol, adrenocorticotropic hormone, Physician and Subject Global Assessments of Disease Activity Scale score, and the visual analog scale score of pruritus were evaluated at 6-week intervals.

**Results:** Although mean total cortisol was significantly decreased at 6 and 12 weeks compared with baseline, IM TAC did not result in iatrogenic Cushing syndrome or secondary adrenal insufficiency in any patient. Mean Physician and Subject Global Assessments of Disease Activity Scale scores were significantly improved at 6 and 12 weeks compared with baseline. Mean visual analog scale pruritus scores were significantly improved at 6 weeks compared with baseline.

*Limitations:* The study was limited by the cohort size and a lack of a comparator group.

*Conclusion:* IM TAC appears safe when administered as 2 injections at 6-week intervals. Significant improvement was noted across a number of steroid-responsive dermatoses. These results may provide a guide to dosing, frequency, and administration for dermatologists considering the use of IM TAC in the appropriate clinical contexts. (J Am Acad Dermatol 2013;69:226-31.)

Key words: adrenal insufficiency; cortisol; Cushing syndrome; intramuscular; steroid; triamcinolone.

he intramuscular (IM) corticosteroid injection is an important therapeutic option in the treatment of steroid-responsive dermatologic disease, especially when topical corticosteroid treatment is impractical when disease is widespread, or when it is ineffective. IM triamcinolone acetonide (TAC) has been used to treat various steroidresponsive dermatologic diseases including lichen planus, drug eruptions, contact dermatitis, atopic dermatitis, and other eczemas.<sup>1</sup> Concerns deterring the use of IM TAC may include the undetermined risk of hypothalamic-pituitary-adrenal (HPA) axis

0190-9622/\$36.00

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Funding sources: None.

Conflicts of interest: None declared.

Accepted for publication February 3, 2013.

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Published online April 1, 2013.

<sup>© 2013</sup> by the American Academy of Dermatology, Inc. http://dx.doi.org/10.1016/j.jaad.2013.02.005

alteration with resulting secondary adrenal insufficiency (SAI) caused by iatrogenic Cushing syndrome, a lack of recommendations regarding the corticosteroid type and dose, site of IM injection, and the frequency of administration in the treatment of inflammatory dermatologic diseases. As a result, although seemingly effective and safe, this form of

corticosteroid therapy may be underused.<sup>1,2</sup> This study evaluates the efficacy of an IM TAC protocol in improving disease status and pruritus for inflammatory dermatologic diseases, and it assesses the presence and duration of SAI in patients receiving IM TAC. Our interest in investigating this topic arises from the complication of SAI and iatrogenic Cushing syndrome we reported in a patient with a diffuse unremitting dermatitis who received a single dose of IM TAC while also on a potent cytochrome inhibitor.<sup>3</sup>

#### **METHODS**

The Boston University School of Medicine Institutional Review Board approved this observational study protocol. Fourteen patients from

the dermatology clinic with an existing or new diagnosis of a steroid-responsive dermatologic condition who opted to undergo treatment with IM TAC were enrolled prospectively. Those with concomitant use of systemic steroid, concomitant use of cytochrome P450 3A4 inhibiting medications, brittle diabetes, or baseline evidence of adrenal suppression were excluded from this study. Continuation of mid-potency topical steroids (ie, TAC 0.1% lotion, cream, or ointment) applied only to nonflexural areas of the body were permitted during the study period. None of the patients were using oral or topical antihistamines for itch, or any antiinflammatory or immunomodulating systemic therapies at the time of initiation or during the study period.

All patients received a single dose of IM TAC at baseline and were re-evaluated at the routine followup visit 6 weeks later. Patients requiring a second dose of IM TAC at 6 weeks as assessed by the evaluating physician were followed up an additional 6 weeks later, or 12 weeks after initiation. Patients with body mass index (BMI) less than 30 received a 30-mg dose, whereas patients with BMI of 30 or greater received 60 mg. All patients were injected with IM TAC in the deltoid muscle using a 27-gauge  $\times$  1.25-in needle.

Morning total cortisol (MTC) and adrenocortico-

### **CAPSULE SUMMARY**

- Scant information on the administration, effectiveness, and safety of intramuscular triamcinolone acetonide (IM TAC), an important therapeutic alternative when topical corticosteroid treatment is impractical or ineffective, is available.
- Thirty or 60 mg of IM TAC dosed 6 weeks apart on 2 occasions resulted in significant improvements in patient- and physician-reported clinical measures compared to baseline without causing iatrogenic Cushing syndrome or secondary adrenal insufficiency.
- This series offers preliminary evidence of the efficacy and safety of IM TAC for a number of steroid-responsive dermatoses and provides a guide to dosing, frequency, and administration for dermatologists considering the use of IM TAC.

#### tropic hormone (ACTH) levels were assessed at baseline, 6 weeks, and 12 weeks before administration of IM TAC. Disease severity and response to IM TAC was evaluated by the Subject Global Assessment of Disease Activity Scale (SGA) (0-100 mm), the visual analog scale (VAS) (0-100 mm) of pruritus, and the Physician Global Assessment of Disease Activity Scale (PGA) (0-100 mm), with lower scores reflecting improved status, at all 3 time points. PGA was completed by the same physician for all patients. Scale recordings were measured with a ruler and converted to numeric values. Any patient or physician reports of adverse effects were recorded at each clinical visit.

#### Statistical analysis

The Mann-Whitney test for nonparametric distributions was used to test the significance of differences in the means of MTC, ACTH, and SGA, VAS, and PGA scores among the baseline, 6-week, and 12-week time points. The 12-week MTC value for patient 3 was missing because of laboratory error and therefore was excluded from analyses. Pearson correlation coefficient was used to establish correlations between either MTC or ACTH with BMI and dose administered. An a priori statistical significance level of .05 was used for all analyses.

#### RESULTS

Men comprised 79% (11 of 14) of the cohort. Patients had the following diagnoses: lichen planus (n = 5), nummular eczema (n = 4), hand dermatitis (n = 3), dermatitis not otherwise specified (n = 1), and acute urticaria (n = 1). All 14 patients received at least 1 dose of IM TAC at baseline, whereas 6 of 14 (43%) patients received a second dose of IM TAC 6 weeks later. High-dose (60-mg) IM TAC was Download English Version:

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