

**Tofacitinib 2% ointment, a topical Janus kinase inhibitor, for the treatment of alopecia areata: A pilot study of 10 patients**



*To the Editor:* Alopecia areata (AA) is a common autoimmune disease. Although oral Janus kinase (JAK) inhibitors have emerged as promising targeted treatment for AA,<sup>1</sup> data regarding topical JAK inhibitors are lacking.<sup>2,3</sup>

Here, we describe the results of a 24-week, open-label, single-center pilot study of 10 patients with AA treated with tofacitinib 2% ointment applied twice daily. Inclusion criteria included  $\geq 18$  years of age, AA with  $\geq 2$  patches of scalp hair loss or complete scalp hair loss, stable or worsening disease for  $\geq 6$  months, and no treatment of AA for  $\geq 1$  month before study enrollment. All inclusion criteria are included in Supplemental Table 1 (available at <http://www.jaad.org>). Tofacitinib was applied to half of the involved scalp, and if and when evidence of hair regrowth was observed, tofacitinib was subsequently applied to the entire involved scalp. Endpoints included regrowth of scalp hair, assessed using the Severity of Alopecia Tool (SALT),<sup>4</sup> which estimates the percentage of scalp hair loss, and the time at which regrowth was first observed. Before treatment and at weeks 4 and 24 of treatment, all participants underwent laboratory evaluation, including complete blood count, comprehensive metabolic panel, and lipid panel. Follow-up visits were conducted every 4-8 weeks. This study was approved by the Yale Institutional Review Board and registered with [ClinicalTrials.gov](http://ClinicalTrials.gov) (NCT02812342).

The results are summarized in Table 1. The duration of the current episode of AA for patient 1 was  $< 6$  months (protocol deviation). One patient

withdrew after 20 weeks of treatment due to lack of efficacy, and data for this patient was included in the final analysis.

Three of 10 subjects experienced hair regrowth with topical tofacitinib with a mean SALT score decrease of 34.6% (standard deviation 23.2%). Patient 1 had an initial SALT score of 100 and experienced a 61% improvement in SALT score (Fig 1, A-C). Patient 2 had an initial SALT score of 17 and experienced an 18% improvement in SALT score. Patient 3 had an initial SALT score of 40 and experienced a 25% improvement in SALT score. Adverse events attributed to treatment included scalp skin irritation (40%) and folliculitis (10%), both of which resolved without treatment. There were no serious adverse events.

In summary, treatment with tofacitinib 2% ointment led to significant scalp hair regrowth in 1 patient and partial regrowth in 2 patients. In light of the short duration of the current episode of disease, it is possible that the response of patient 1 was spontaneous remission of AA, although this is unlikely given her progression to alopecia universalis over a period of 2 months and the preferential regrowth of hair on the side of the scalp of early tofacitinib application. Overall, the level of response to topical tofacitinib is less than that seen with oral tofacitinib<sup>1</sup> but is similar to that reported with clobetasol 0.05% ointment under occlusion.<sup>5</sup> Ointment might be a poor vehicle for the treatment of AA, or topical treatment might simply be inadequate. Further studies are necessary to better understand topical JAK inhibitor treatment of AA. The results of other trials of topical JAK inhibitors are forthcoming (NCT02553330, NCT02561585).

**Table 1.** Demographics of 10 patients with alopecia areata and their responses to treatment with tofacitinib 2% ointment

Characteristics	Value, N = 10				
Age, y, average (SD, range)	36.9 (14.2, 19-58)	Responders (N = 3)	1	2	3
Female, n (%)	4 (40)	SALT score at week 0	100	17	40
Male, n (%)	6 (60)	SALT score at week 24	39	14	30
Race, n (%)		SALT score percent change, %	-61	-18	-25
White	8 (80)	Week hair regrowth first observed	8	14	8
East Asian	1 (10)	Duration of disease	2 m	6 y	26 y
South Asian	1 (10)				
Initial SALT score, average (SD, range)	77.7 (32.3, 17-100)	Nonresponders (N = 7)			
Duration of disease, y, average (SD, range)	9.4 (8.7, 0.2-26)	SALT score % change, average (range)		0 (0-0)	
SALT score percent change, %, average (range)	10 (0-61)				

SALT, Severity of Alopecia Tool; SD, standard deviation.



**Fig 1.** Alopecia areata patient 1 before (A) and after 4 months (B) and 6 months (C) of treatment with tofacitinib 2% ointment. Ointment was applied only to the right half of the scalp for the first 2 months, at which time hair regrowth was evident only in the area of drug application. Subsequently, ointment was applied to the entire scalp. At month 4, there was more hair on the right scalp than on the left scalp. By month 6, hair growth was prominent on both sides.

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#### Epidemiology of staphylococcal scalded skin syndrome in the United States: A cross-sectional study, 2010-2014



**To the Editor:** Staphylococcal scalded skin syndrome (SSSS) is a potentially fatal, superficial blistering disorder caused by infection with exfoliative toxin-producing strains of *Staphylococcus aureus*. Previous research examining the epidemiology of SSSS has been limited by small sample sizes or confined to populations abroad.<sup>1-3</sup> To better characterize the epidemiology of SSSS in the United States, we generated national hospitalization estimates for SSSS using the 2010-2014 National Inpatient Samples, which are resources sponsored by the Healthcare Cost and Utilization Project of the Agency for Healthcare Research and Quality.<sup>4</sup>

**Supplemental Table I.** Inclusion and exclusion criteria

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Inclusion criteria

- 18 years of age or older
- At least 2 patches of alopecia areata or alopecia totalis or alopecia universalis
- Stable or worsening disease for 6 months or longer
- No treatment of disease for at least 1 month before enrollment
- No evidence of spontaneous hair regrowth

Exclusion criteria

- Received treatment known to affect alopecia areata within 1 month of enrollment
  - Current episode of alopecia totalis or alopecia universalis >5 years
  - History of malignancy
  - History of HIV, hepatitis B, or hepatitis C positivity
  - History of positive test for tuberculosis
  - History of leukopenia or anemia
  - History of renal or hepatic impairment
  - Currently taking immunosuppressive medications
  - Women who are pregnant or nursing
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