ILK Index and Regrowth in Alopecia Areata

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There is insufficient data in the literature concerning optimal intralesional kenalog (ILK) dosing for the treatment of alopecia areata (AA). The purpose of this pilot study was to evaluate the utility of using the ratio of ILK received to initial Severity of Alopecia Tool (SALT) score to guide ILK dosing in patients with AA. Using photographic data from patients at baseline and 4-months follow-up, hair loss in 15 patients treated with AA was retrospectively graded using the SALT scores. The ILK received/initial SALT score (ILK index) was calculated for each patient, and the mean ILK index for patients who experienced significant ($\geq 50\%$) and suboptimal ($< 50\%$) hair regrowth at 4 months follow-up were compared. Patients who experienced suboptimal hair regrowth had a lower ILK index on average than patients who experienced significant improvement. Although the difference did not meet significance (< 0.1), the trend suggests that the ILK index, a novel calculation, may be a useful tool for guiding ILK dosing in the treatment of AA.

INTRODUCTION

Alopecia areata (AA) is an autoimmune skin disease characterized by episodes of patchy to total hair loss, most commonly on the scalp. The age of onset, extent of scalp involvement and time to recovery for discrete episodes varies greatly from patient to patient, which has complicated efforts to study the efficacy of treatments designed to modify the course of hair loss and recovery. Among the treatments currently used to treat this condition are intralesional kenalog (ILK) injections, which have long served as first-line therapy in the management of AA. However, despite the widespread use of ILK in the management of AA, research concerning the overall efficacy, the optimal concentration and quantity of dosing remains incomplete.

Research on the impact of ILK in AA has been challenged by inconsistent methodology and absence of a standard method of grading hair loss and regrowth. In 2004, (Olsen et al., 2004) offered a solution to one of the major challenges facing AA researchers with the creation of the Severity of Alopecia Tool (SALT), which provides a standardized method of quantifying hair loss and regrowth. In 2011, (Olsen, 2011) furthermore outlines an extensive list of factors shown to be associated with AA, which should be collected from each patient's past medical history when performing studies of treatment response. Currently, a gap in the literature pertains to optimal dosing of ILK for treatment of AA. This retrospective pilot study was performed to investigate the utility of the ILK index (ratio of ILK received/initial SALT score) in predicting hair regrowth after onset of a new episode of AA.

RESULTS

At 4 months follow-up, patients with a significant improvement in their SALT score ($\geq 50\%$) had a higher ILK index (mean 8.14, SD = 5.36) than patients with suboptimal improvement in SALT score (mean 3.96, SD = 3.08). Although the difference did not meet significance, the trend ($P < 0.1$) suggests that a larger study is warranted to evaluate the relationship between ILK index and ILK treatment outcomes in patients with AA. Notably, patients with significant improvement in hair regrowth had a shorter duration on average of hair loss than those who experienced significant regrowth. Although the difference did not meet significance, it is important to note that the group with significant improvement may have had a higher rate of spontaneous regrowth than the patients with suboptimal outcomes.

FUTURE DIRECTIONS

For the next phase, the study will be expanded to include more patients. Data from the larger sample will be analyzed to identify the ILK index at which % improvement is maximized, providing an opportunity to guide future recommendations for ILK dosing in patients affected by AA. Figure 1: patient who experienced significant improvement over 4-month treatment period. Age: 51, female. Duration of new lesion before treatment: 6 months. Initial SALT: 25.2%, final SALT: 2.4%.

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Abbreviations: AA, alopecia areata; ILK, intralesional kenalog; SALT, Severity of Alopecia Tool

Baseline | 4-months follow-up

Figure 1. **Patient who experienced significant improvement over 4-month treatment period.** Age: 51, female. Duration of new lesion before treatment: 6 months. Initial SALT: 25.2%, final SALT: 2.4%. Photos published with patient's permission.
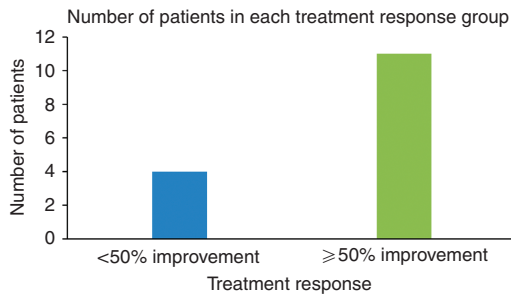

Figure 2. **Number of patients in each treatment response group.** .

MATERIALS AND METHODS

Approval to conduct this clinical investigation was granted by the Cleveland Clinic's Internal Review Board. All patients considered for the study signed a written consent form permitting photographs taken during treatment to be used for research and educational purposes. Fifteen patients met the inclusion criteria, which included: new episode of AA (duration <2 years) with no treatment received for the episode before the baseline photos. Baseline and 4-month follow-up photos for each patient had to be available, and the patient needed to be treated with a known amount and concentration of ILK during the time between baseline and 4-month follow-up photos (Figure 1).

The patient sample was 13.3% male, 33.3% African American, 60% Caucasian, 6.7% Hispanic, average age of 51.9 years, average duration of current alopecia episode was 29.9 weeks before presentation. Eleven patients experienced significant improvement in their SALT score over the 4 month treatment period; four patients experienced suboptimal improvement. (Figure 2) Factors associated with AA outcomes, including duration of hair loss episode and number of previous episodes of alopecia, were compared between patients in the significant and suboptimal treatment response groups. (Table 1) Additional factors considered were number of ILK

Table 1. Table of inter-group demographic and treatment comparisons

	<50% improvement	≥50% improvement	P-value
No. of autoimmune conditions	0.75	0.73	<0.95
No. of previous AA episodes	1.33	0.89	<0.68
Duration current AA episode	48 (weeks)	11 (weeks)	<0.33
No. of ILK admin sessions	4.25	4.36	<0.91
Frequency ILK admin	41.5 days	31.2 days	<0.34
Age	58.5 years	44.8 years	<0.25
Initial SALT score	11.5%	7.6%	<0.32
ILK index	3.96	8.14	<0.1

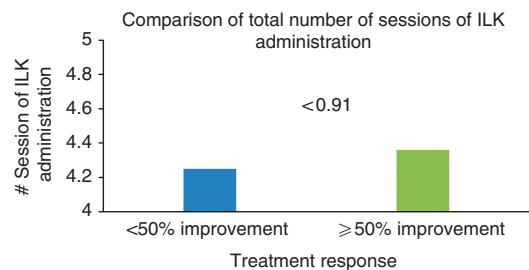Abbreviations: AA, alopecia areata; ILK, intralesional kenalog; SALT, Severity of Alopecia Tool.

Figure 3. **Inter-group comparison of the average number of ILK administration sessions received over the 4-month treatment period.** .
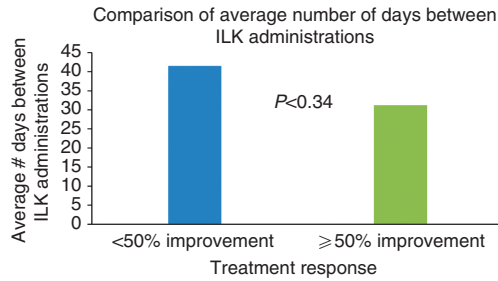
Comparison of average number of days between ILK administrations

Figure 4. Inter-group comparison of the average number of days between ILK administration sessions. .
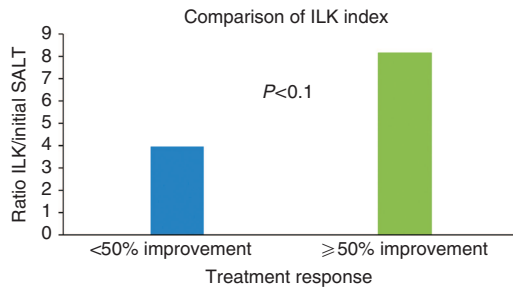
Comparison of ILK index

Figure 5. Inter-group comparison of the ILK index. .

administration sessions (Figure 3) and frequency of ILK administration. (Figure 4) There were no significant differences between the two groups in these areas.

SALT scores were generated by consensus of four board-certified Dermatologists through grading of photos from baseline and 4-month follow-up. The ILK index was calculated by totaling the milligrams of ILK received over the treatment period (ILK concentration multiplied by the number of milliliters injected, totaled over the 4-month treatment period), divided by the patient's baseline SALT score. ''Significant improvement'' in SALT score was defined as $\geq 50\%$ improvement; suboptimal improvement in SALT score was defined as $<50\%$ improvement. The mean ILK index for each group was compared using Welch's test, with a P-value of 0.05 to meet significance (Figure 5).

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