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Efficacy of Topical Herbal Anti-inflammatory Treatment (HAT1) for Treating Psoriasis: An Investigator-Initiated Open Label Study

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INTRODUCTION

A topical botanical complex from a novel combination of phytochemicals, denoted as herbal anti-inflammatory treatment 1 (HAT1), was developed for topical treatment of psoriasis. HAT1 is a US Food and Drug Administration compliant over-the-counter product that contain extracts of the following: *Achillea millefolium, Aesculus hippocastanum, Althaea officinalis, Avena sativa, Berberis vulgaris, Conium maculatum, Cochlearia officinalis, Ervum lens, Hamamelis virginiana, Hydrastis canadensis, Malva sylvestris, Matricaria chamomilla, Nasturtium officinale, Phytolacca decandra, Pimpinella saxifrage, Populus alba, Populus tremuloides, Rhus toxicodendron, Sanguinaria Canadensis, Sambucus nigra, Scophularia nodosa, Smilax medica, Tussilago farfara, Veronica officinalis,* and *Vincetoxicum officinale.* Mechanism of HAT1 is under investigation, but preliminary in vitro data of primary human keratinocytes demonstrated downregulation of IL-17A/TNF-α–induced IL-8 release.[1] Previous studies demonstrated superior efficacy of HAT1 compared to calcipotriol in achieving PASI (Psoriasis Area and Severity Index) 75 and reducing the Physician's Global Assessment (PGA) score to a clear or minimal response.[2]

An investigator-initiated, open-label study was conducted to evaluate efficacy and tolerability of topical HAT1 in adult patients with mild plaque psoriasis. The institutional review board approved the study and written informed consent was obtained. Eleven patients (4 males, mean age = 55.7) with body surface area (BSA) of 3 to 10% were enrolled (mean PASI = 4.5). Five patients were on a stable dose of systemic therapy, including apremilast (2), secukinumab (2), and ustekinumab (1). Patients applied HAT1 twice daily to active lesions and assessed every 4 weeks from baseline (week 0) to week 12.

The primary endpoint was the mean percent improvement from baseline in the product of the static PGA (sPGA) and BSA (sPGAxBSA) at week 12. sPGA>SPGA was used as it is a sensitive measurement of psoriasis severity compared to PASI in patients with mild disease.[3] Modified Intention-to-treat analysis (ITT) was used to include subjects who received at least 1 application of HAT1 and at least 1 post-baseline assessment. Last observation carried forward method was used for any missing data. Secondary endpoint was the percentage improvement in the Dermatology Life Quality Index (DLQI). Other parameters include percentage improvement of the Numerical Rating Scale for Itch (NRS), BSA, and PASI. One patient was excluded for the DLQI analysis due to a protocol deviation at baseline.

Nine patients completed the study. One patient was lost to

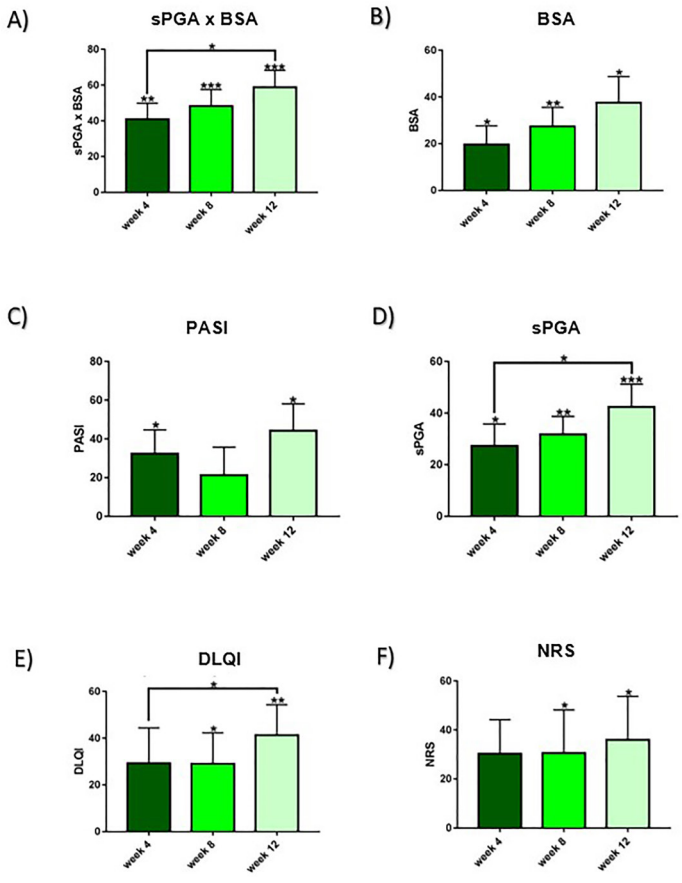
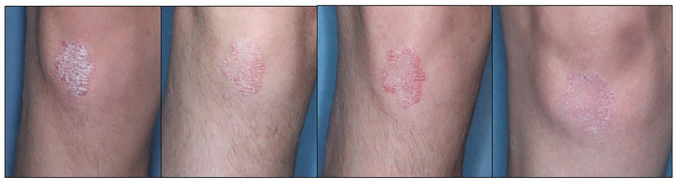


FIGURE 1. (A-F) Percentage improvement of sPGAxBSA, BSA, PASI, sPGA, DLQI, and NRS, respectively. Analyzed with paired two-tailed t-test. Statistically significant differences denoted as $^{*}p<0.05$, $^{**}p<0.01$, $^{***}p<0.001$).

FIGURE 2. Psoriasis on knee at baseline to treatment at week 4, week 8, and week 12.



follow-up and one withdrew due to perceived lack of efficacy. HAT1 was well tolerated and patients reported no treatment-related adverse events. There were no statistically significant differences in all examined parameters between groups treated with HAT1 monotherapy versus with concomitant systemic therapy. Therefore, the data was pooled between these two groups. Modified ITT analysis showed a significant reduction of sPGAxBSA by 58.7% (95% confidence interval (CI) [40.1, 77.4]) by week 12 (Figure 1A). Significant mean percentage improvement of sPGAxBSA was also noted as early as week 4 by 40.9% (95% CI [23.2, 58.6]). Percentage improvement from baseline for DLQI was 41.3% (95% CI [17.0, 65.6]) (Figure 1E). Furthermore, significant percent improvement at week 12 from baseline were observed for BSA, PASI, sPGA, and NRS (Figure 1B, 1C, 1D, and 1F).

This study is limited by the absence of a vehicle-controlled arm and its small number of patients. The addition of patients on systemic medications may also confound the results of the study. The results would benefit from a larger cohort and longer study duration to assess for long term efficacy and adverse effects.

Topical application of HAT1 for 12 weeks showed significant reduction in disease burden and symptom relief in mild psoriasis as evidenced by improvements in sPGAxBSA as well as the DLQI and NRS. This well-tolerated herbal formulation can provide an alternative over-the-counter regimen, especially in those seeking botanical products.

DISCLOSURES

Boni Elewski, MD is an investigator for AbbVie, Anaptys-Bio, Boehringer Ingelheim, Bristol Myers Squibb, Amgen (previously Celgene), Incyte, Leo, Eli Lilly, Merck, Novartis, Pfizer, Regeneron, Sun, Valeant (Ortho dermatology), and Vanda. Boni Elewski is a consultant for Boehringer Ingelheim, BMS, Amgen (previously Celgene), Leo, Lilly, Menlo, Novartis, Valeant (Ortho dermatology), and Verrica. Other authors do not have conflicts to declare.

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