A novel ultraviolet B home phototherapy system: Efficacy, tolerability, adherence, and satisfaction

Emily L Unrue[1] BS, Abigail Cline[1] MD PhD, Alexandra Collins[1] BS, Vu H Nguyen[2] MD PhD, Michelle T Pelle[3,4] MD, Patrick Blake[3,5] MD, Steven R Feldman[1,6,7] MD PhD

Affiliations: [1]Center for Dermatology Research, Department of Dermatology, Wake Forest School of Medicine, Winston-Salem, North Carolina, USA, [2]California Skin Institutes, [3]MedDerm Associates, [4]Scripps Mercy Hospital, [5]Western University [6]Department of Pathology, Wake Forest School of Medicine, Winston-Salem, North Carolina, USA, [7]Department of Social Sciences & Health Policy, Wake Forest School of Medicine, Winston-Salem, North Carolina, USA

Corresponding Author: Emily L. Unrue BS, Department of Dermatology, Wake Forest Baptist Health, 4168 Country Club Road, Winston-Salem, NC 27106, Tel: 336-716-1773, Fax: 336-716-7732, Email: eunrue@wakehealth.edu

Abstract

Background: Phototherapy is effective in treating psoriasis and other skin conditions. However, clinic-based phototherapy can be time-consuming, expensive, and inconvenient. Conventional home phototherapy addresses many hurdles, but has other limitations.

Objective: Assess the treatment efficacy, adherence, and satisfaction of a novel ultraviolet B home phototherapy system.

Methods: Eight patients with stable plaque psoriasis completed a multicenter, prospective, open label, interventional study using a home phototherapy device designed to improve treatment control and adherence. Matched control and study lesions were assessed on each subject. A dosing protocol based on American Academy of Dermatology guidelines for narrowband UVB phototherapy was managed by the phototherapy system. Responsiveness to the treatment was measured using the Psoriasis Severity Index (PSI) at 10 weeks versus control. Patient satisfaction was graded on a five-star Likert scale.

Results: At 10 weeks, all patients experienced improvement in the treated lesions, with a mean improvement of 57% in PSI ($P<0.0001$ compared to baseline and $P<0.0002$ compared to the control lesions). Patient treatment adherence was 96% and treatment satisfaction was 100% five-star rated. Control lesions did not significantly change in PSI over the 10-week period ($P=0.1411$).

Conclusions: The home phototherapy system provided a safe and effective means to manage plaque psoriasis.

Keywords: psoriasis, phototherapy

Introduction

Phototherapy is safe, effective, relatively low-cost, cost-effective, and compatible with other therapeutics for psoriasis. However, use of Ultraviolet B (UVB) phototherapy in the office setting can be challenging for patients. Office-administered UVB requires psoriasis patients to visit two- to-three times per week for 15 to 25 treatments, which can be a burden for patients [1-3]. In addition, patient co-pays, decreased physician compensation, and a variety of disincentives from payer coverage and reimbursement structures have contributed to underutilization of outpatient phototherapy [2, 4, 5].

Home UVB is as safe and effective as office-based UVB with improved adherence and convenience with no increase in acute adverse events [6, 7], Home UVB is significantly more cost-effective than outpatient phototherapy [2, 7-13]. Home UVB includes whole-body and portable, lightweight handheld units. Home phototherapy can help avoid the safety risk of systemic therapies and it can be used safely in pregnancy and while breastfeeding [2]. Handheld units can be used in the home and office, and may be more likely to limit unintended skin exposure to ultraviolet (UV) light [3, 14, 15]. Home phototherapy is preferred by patients, results in higher patient satisfaction and a lower treatment burden, and should be considered for patients eligible for phototherapy [2, 7, 16, 17].

Despite its advantages, there are mixed perceptions among physicians regarding home phototherapy [2, 18]. Concerns about safety, efficacy, and adherence,

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Figure 1. *Home phototherapy unit.*

stem from fears of misuse, inaccurate dosing, unsupervised administration, lack of in-person follow-up, phototoxicity, and legal issues, among others [1, 7]. Home narrowband ultraviolet B (NB-UVB) units have advanced to address safety and efficacy concerns [2]. Advances in light emitting diode (LED) technology have facilitated development of devices that emit targeted, precision UVB phototherapy without warm-up time, output degradation, or need for replacement bulbs [19]. Widespread adoption of smartphone technology provides the ability to facilitate schedule management, dose adjustment, and outcome measurement. This study aimed to determine treatment efficacy, safety, and satisfaction of psoriasis patients using a localized home phototherapy system.

Methods

Eligible patients were aged ≥18 years old with stable plaque-type psoriasis, who were previously unresponsive to topical therapies (**Figure 1**). Patients were screened to ensure that topical treatments were not used in the two-week period prior to enrollment and phototherapy or systemic treatments (drugs and biologics) were not used in the two-month period prior to enrollment. Written informed consents were collected from all study participants and the study was approved by Salus Institutional Review Board, protocol number CM-1001. Control and study lesions were identified on each subject. Six patients had one study lesion and one control lesion, one patient had one study lesion and two control lesions, and one patient had two study lesions and one control lesion. Control and study lesions on the same patient were of relatively the same score on the Psoriasis Severity Index (PSI). Once enrolled, patients were not permitted to use any other therapies that could affect the study or control lesions.

Study lesions were treated using a localized home phototherapy device (Clarify Home Light Therapy System), (**Figure 1**). Patients administered treatment at home using the scheduling, dosing, and guidance built into the system. The phototherapy system was also used to remotely monitor patient treatments and collect treatment records and adherence data. Treatments were completed three times per week for ten consecutive weeks or until clearance was achieved. Dosing was based on American Academy of Dermatology (AAD) psoriasis NB-UVB dosing guidelines [3]. The study and control lesions were assessed at 4, 6, 8 and 10 weeks using PSI scoring with the final efficacy evaluation at 10 weeks (**Figure 1**). Patient satisfaction was graded on a five-point Likert scale.

The phototherapy system managed the treatment schedule and dosing controls to help ensure home phototherapy was administered in accordance with a physician-prescribed protocol. The system is composed of four components: a handheld UVB phototherapy device, a custom smartphone application, a secure server with data storage, and a physician web portal. A physician or designee selects a phototherapy protocol to prescribe for the patient within the Physician Portal. The prescription is pushed to the patient's smartphone and the patient uses the smartphone application to manage the schedule and dosing of their prescribed treatment. On treatment days, the treatment plan is sent to the phototherapy device, which guides the patient through the treatment process to ensure that the proper dose is delivered to the right body location. After treatment completion, the treatment records,

Table 1. *Summary statistics for change in PSI score by treatment group.*

Treatment	N	Mean Baseline PSI	Mean Change in PSI	95% CI
Control	9	7.33	0.67 (9%)	-0.27 to 1.61 (-4% to 22%)
Study	9	7.78	4.44 (57%)	2.95 to 5.94 (38% to 76%)

Six patients had one study lesion and one control lesion, one patient had one study lesion and two control lesions, and one patient had two study lesions and one control lesion. Change in PSI was assessed 10 weeks after baseline

including body locations and doses, are sent for back up to the server where they are available for both the patient and the physician to view. The system will not allow the patient to administer UVB therapy without an active prescription in place and every prescription includes a treatment expiration date; after this time, treatment will be disabled to ensure that the patient returns to the clinic for follow-up appointments.

The battery-operated phototherapy device uses UVB LEDs and an optical filter to deliver precision light in a narrow band of UVB, predominately in the 300-320nm range. The treatment head is 4.5cm4.5cm (approximately 2″×2″) and is square in shape so that larger areas can be treated using a tiling method. A sunscreen stick is provided to mask healthy skin so that the treatment can target the affected areas. Patients are instructed to apply sunscreen around the affected areas to protect the unaffected skin. The device has safety features including a light shield that retains the light on the treatment area and a skin contact switch that only enables the device when it is placed on the skin. Once per week the patient is asked to complete a progress report using the smartphone application that assesses the status of the skin and records a photograph for each body location.

Results

Eight patients completed the 10-week study in two centers, with four patients at each center. Six patients dropped out of the study. Three were unable to adhere to the protocol study time commitment for in-office assessment in addition to home treatment. Two were dropped from the study owing to eligibility issues that were not discovered until after the start of treatment (one had psoriasis that was not stable and one was mis-diagnosed as psoriasis). One patient was dropped owing to use of medications that were prohibited by the study. None of the patients left the study for safety concerns.

At 10 weeks, all patients that completed the study experienced improvement in the treated lesions, with a mean improvement of 57% in PSI ($P<0.0001$ compared to baseline and $P<0.0002$ compared to the control lesions), (**Table 1**, **Figures 2**). Control lesions did not significantly change in PSI over the 10-week period ($P=0.1411$).

No adverse events were reported. No system functionality or durability issues were reported or identified. For those that completed the study, patient treatment adherence to the therapy was 96%. The phototherapy treatment system received five-star satisfaction scores from 100% of patients in this study.

Discussion

This study showed that a home phototherapy system is effective as a monotherapy, with all patients experiencing improvement in the ten-week study period. Although not a part of the study, patients were allowed to use phototherapy in combination with topical treatments as prescribed by their physician after the conclusion of the study. All patients reported clearance within three weeks once study restrictions on combination therapy were lifted. It is not known what contributions to improvement were made from the additional three weeks of phototherapy and what contributions were made from other topical treatments; however, this suggests that patients may experience results better than reported in this 10-week monotherapy study.

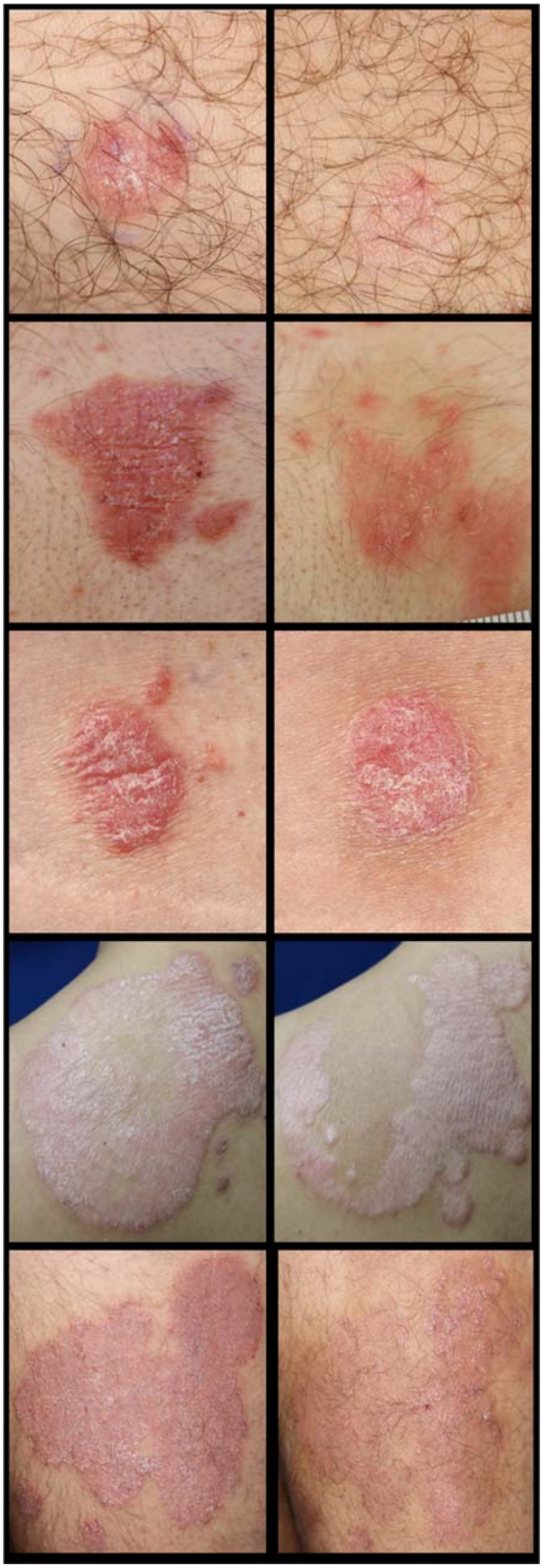

Figure 2. *Resolution of psoriatic lesions following home phototherapy. Images on the left were taken prior to initiation of phototherapy at week 0. Images on the right were taken after 10-weeks of home UVB phototherapy.*

The home phototherapy system managed the schedule of the patients, providing treatment day reminders, which may have contributed to the high study treatment adherence rate. The integrated protocol and dose management features obviated the need for charts and calculators, thereby allowing patients to focus on phototherapy administration. Phototherapy administration was guided by the smartphone application, which may have contributed to the positive experience. A home phototherapy system is a good option for convenient UVB treatment of localized dermatological conditions because it is safe and effective.

Conclusion

Home phototherapy systems provide a safe and effective means to manage plaque psoriasis.

Potential conflicts of interest

Dr. Feldman has received research, speaking and/or consulting support from a variety of companies including Galderma, GSK/Stiefel, Almirall, Leo Pharma, Baxter, Boeringer Ingelheim, Mylan, Celgene, Pfizer, Valeant, Taro, Abbvie, Cosmederm, Anacor, Astellas, Janssen, Lilly, Merck, Merz, Novartis, Regeneron, Sanofi, Novan, Parion, Qurient, National Biological Corporation, Caremark, Advance Medical, Sun Pharma, Suncare Research, Informa, UpToDate and National Psoriasis Foundation. He is founder and majority owner of www.DrScore.com and founder and part owner of Causa Research, a company dedicated to enhancing patients' adherence to treatment. Emily Unrue, Abigail Cline, Alexandria Collins have no conflicts of interest to disclose. Dr. Nguyen, Dr. Pelle, and Dr. Blake were clinical investigators for this Clarify Medical sponsored study and were compensated for their work.

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