An Evaluation of the Safety and Efficacy of Aminolevulinic Acid Hydrochloride Topical Gel, 10% with Red Light in the Treatment of Facial Cutaneous Squamous Cell Carcinoma in situ

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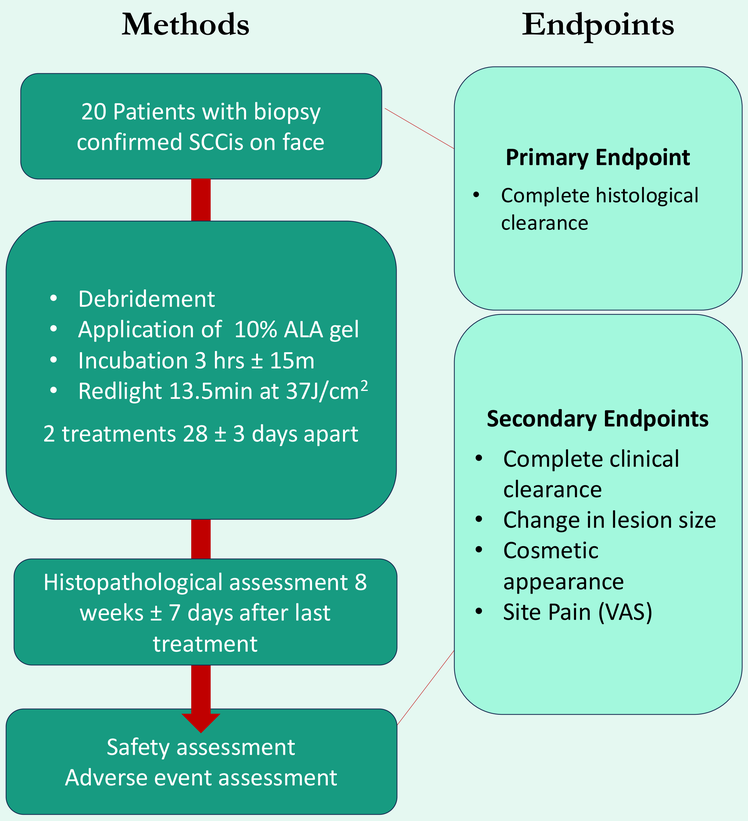
Background

Cutaneous squamous cell carcinoma in situ (SCCis) is a common skin cancer associated with chronic sun exposure and frequently arises on the face. While surgical excision remains the standard of care, there is growing interest in less invasive options. This study evaluates the safety, tolerability, and efficacy of red-light photodynamic therapy (PDT) with 10% aminolevulinic acid (ALA) topical gel for the treatment of facial SCCis.

Methods

Twenty patients were enrolled, with a median age of 72 years (range 56-86). Most had Fitzpatrick skin type II or III. The cohort included 13 males (65%) and 7 females (35%). Twenty patients with biopsy-confirmed facial SCCis were enrolled. Eligible lesions measured 0.4–1.1 cm in diameter. Lesions were debrided with gauze and acetone, and 10% ALA gel was applied to the lesion and surrounding skin for 3 hours ± 15 minutes, followed by illumination with red light (RhodoLED® XL, 13.5 mins, 635 nm, 37 J/cm2). Patients received two PDT treatments, 28 ± 3 days apart. At 8 weeks ± 7 days following the second PDT treatment, the lesion area was surgically excised for histopathological evaluation. The primary endpoint was complete histological clearance. Secondary endpoints included complete clinical clearance (CCC), lesion size change, cosmetic outcomes, and safety assessments. Adverse events (AEs) and local skin reactions (LSRs: erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation, and erosion/ulceration) and site pain (11-point numeric rating scale) were evaluated.



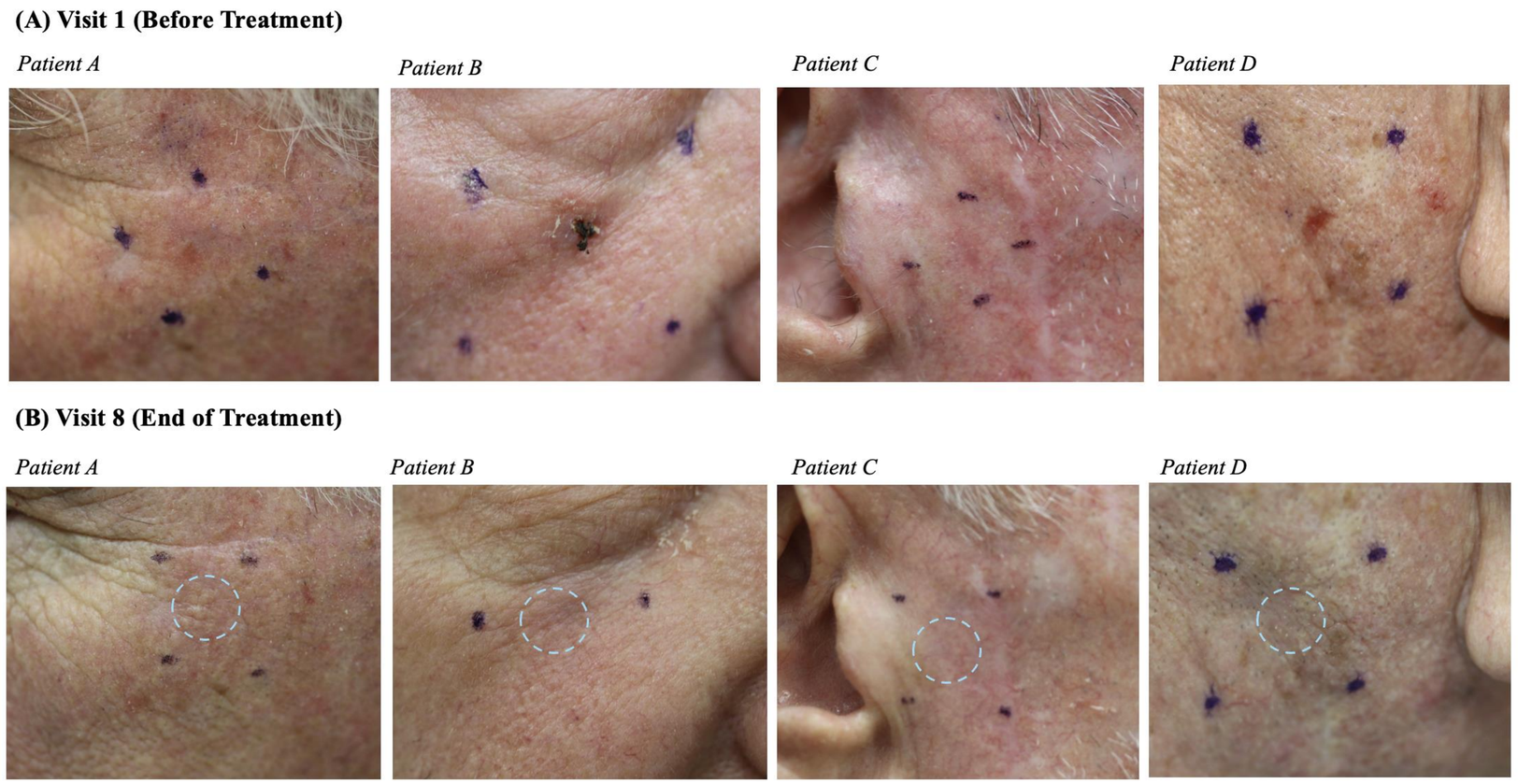
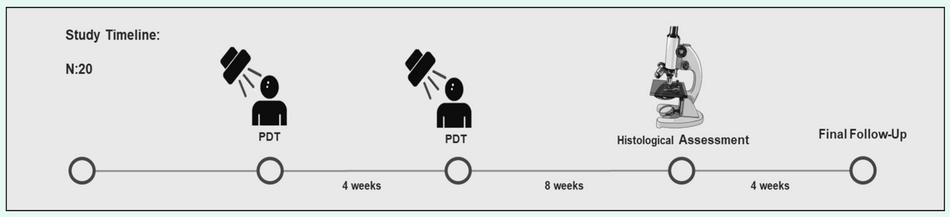


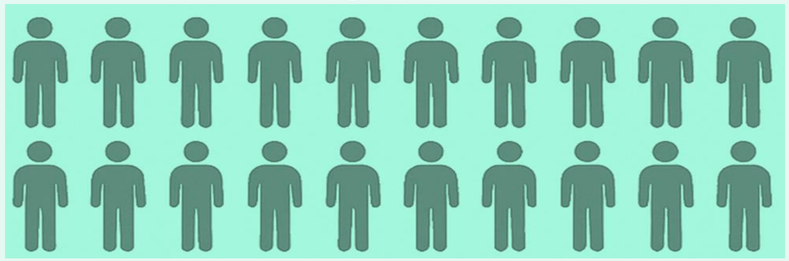
Figure 1. Squamous cell carcinoma in-situ before and after treatment with ALA HCl and PDT



Results

All patients (n=20) achieved complete histological clearance of SCCis at end of treatment (EOT). CCC was observed in all patients prior to excision, with a medium time of 62 days (range 42-90 days; SD 14 days). Moderate erythema was the most common LSR, while mild flaking/scaling was also reported. Both resolved by EOT. Occasional mild erosion was also observed but resolved by the next visit. No pigmentary changes were observed. Post-treatment median pain scores were 0 (range 0-3) within 15 minutes after 10% ALA gel application and 3.5 (range 0-10) within 15 minutes after red light illumination. The majority of patients (19/20) reported no AEs; one patient experienced mild contact dermatitis secondary to adhesive use at the surgical site.

100 % Complete Histological Clearance



Conclusion

Topical 10% ALA-PDT is a well-established treatment for actinic keratosis (AK) and has previously shown promise as a non-invasive option for SCCis. In this study, red light PDT with 10% ALA gel achieved 100% histological and clinical clearance of facial SCCis, with excellent tolerability and favorable cosmetic outcomes.

The greater depth of tissue penetration achieved with red light may enhance activation of PpIX within the lower epidermal layers, where atypical keratinocytes frequently reside. Our findings demonstrate that 10% ALA gel in combination with red light achieved 100% histologic and clinical efficacy, with superior cosmetic outcomes compared to surgery.

References & Disclosures

1. Lee MM, Wick MM. Bowen's disease. Clin Dermatol. 1993;11(1):43-46. doi:10.1016/0738-081X(93)90080-V
2. Sharma A, Birnie AJ, Bordea C, et al. British Association of Dermatologists guidelines for the management of people with cutaneous squamous cell carcinoma in situ (Bowen disease) 2022. Br J Dermatol. 2023;188(2):186-194. doi:10.1093/bjd/ljac042
3. Nestor MS, Han H, Ceci FM, Lawson A, Gade A. Evaluating the safety and efficacy of aminolevulinic acid 20% topical solution activated by pulsed dye laser and blue light in the treatment of facial cutaneous squamous cell carcinoma in situ. J Cosmet Dermatol. 2023;22(9):2471-2475. doi:10.1111/jocd.15886
4.Nestor MS, Berman B, Patel J, Lawson A. Safety and Efficacy of Aminolevulinic Acid 10% Topical Gel versus Aminolevulinic Acid 20% Topical Solution Followed by Blue-light Photodynamic Therapy for the Treatment of Actinic Keratosis on the Face and Scalp: A Randomized, Double-blind Study. J Clin Aesthet Dermatol. 2019;12(3):32-38.

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