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Photodynamic therapy with δ -aminolevulinic acid and blue light for the treatment of actinic cheilitis

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Background/Objectives: Actinic cheilitis is a common precancerous malformation of the lower lip caused by ultraviolet radiation. Photodynamic therapy (PDT) is a potential treatment option for actinic cheilitis. However, controlled clinical trials assessing the efficacy of PDT for actinic cheilitis are lacking. PDT is based on the combined use of photosensitizers and photoradiation. Topically applied δ -aminolevulinic acid (ALA) is theorized to be taken up by premalignant cells. Upon irradiation with a light source, photoactivated porphyrins produce singlet oxygen and other potent oxidizers, resulting in cell death.^{1,2} We hypothesized that the use of PDT with blue light and topical ALA treatment is a safe and effective treatment for actinic cheilitis.

Methods: We conducted a single center, investigator-initiated, nonrandomized, open-label, proof of concept study of topical ALA and PDT with blue light for the treatment of actinic cheilitis. We enrolled 24 subjects with a diagnosis of actinic cheilitis; 20 of these subjects met inclusion and exclusion criteria for participation in the study. One subject withdrew from the study prior to treatment. The study consisted of a screening visit, one to three scheduled treatments with ALA followed by PDT, and two follow-up visits. The primary outcome was assessed by the investigator at each visit as clinical

improvement of actinic cheilitis from baseline. Improvement was estimated as no (0%), mild (25%), moderate (50%), marked (75%), or excellent improvement (100%). Post-treatment assessments based upon visual observation of swelling, vesiculation/pustulation, erosion/ulceration, erythema, flaking/scaling, and crusting were also completed. Subjects completed the Dermatological Life Quality Index (DLQI) questionnaire and a subject global assessment of improvement at each visit. Pain was also assessed at each treatment visit.

Results: Of the 19 subjects that completed the study, 84.2% achieved clinical improvement of 75% or better based on investigator assessment (primary outcome). Five subjects (26.3%) achieved 100% improvement by the end of the study. Based on the subjects' assessment of improvement, 68.4% achieved improvement of 75% or better by the end of the study. Treatments were well tolerated with minimal discomfort. Many subjects had transient adverse effects of treatment including swelling, erythema, and flaking/scaling; few subjects had more serious adverse effects such as vesiculation/pustulation or crusting. No subjects experienced erosion/ulceration.

Conclusion: Overall our study supports the use of topical ALA and PDT as a therapeutic option for the treatment of actinic cheilitis.

References:

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