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### 221 Treatment of dysplastic nevi with 5% imiquimod cream, a pilot study

Dusza SW, Delgado R, Busam KJ, Marghoob AA, Halpern AC. *J Drugs Dermatol.* 2006 Jan;5(1):56-62.

#### ABSTRACT

**OBJECTIVE:** To assess the clinical and histologic effects of topical imiquimod therapy on dysplastic nevi, and to determine the feasibility of using in vivo confocal microscopy (CSLM) to non-invasively monitor histological response of dysplastic nevi to imiquimod therapy. **DESIGN:** Single-blinded pilot study with patients not blinded as to treatment status. **SETTING:** Dermatology Outpatient Clinic, Memorial Sloan-Kettering Cancer Center, New York, NY. **PATIENTS:** The study population comprised of 10 patients with clinically dysplastic (atypical) nevi and at least 8 large nevi, (> or =5 mm) on their trunk. **INTERVENTION:** Sixteen weeks of imiquimod 5% cream applied to treatment lesions 3 times per week. **MAIN OUTCOME MEASURE:** Clinical response as gauged by comparison of baseline and week 20 1:1 standardized photographs for all study nevi and histological assessment of each patient's 4 largest study nevi at completion of therapy. **RESULTS:** There were no obvious clinical changes in the size and morphology of the study nevi. Subtle changes in nevus color could not be assessed due to imperfect spectral registration of images over the course of the study. Histologically, 4 of 14 treated nevi and 0 of 14 untreated nevi  $p=0.03$  showed a significant relative reduction of junctional and intraepidermal nevocytes accompanied by papillary dermal fibroses and variable inflammation suggestive of partial regression. Non-invasive CSLM imaging of study nevi demonstrated previously reported in vivo features of dysplastic nevi. but the imaging equipment and protocol utilized proved inconsistent across lesions and time. **CONCLUSIONS:** The histological changes seen in a subset of treated nevi suggest a possible role for the use of topical immune response modifiers for the treatment of dysplastic nevi with the intent of melanoma chemoprevention. The dose regimen of topical imiquimod utilized in this study failed to induce sufficient clinical or histological responses to warrant further study. Targeting of dysplastic nevi and intermediate endpoints for melanoma chemoprevention with more intense and/or prolonged treatment regimens with imiquimod or the use of other immune response modifiers seems promising. Technical improvements are required for the use of non-invasive CSLM imaging in lieu of invasive histology for the study of topical nevus therapies. PMID:16468293