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Malignancy and psoriasis treatment with apremilast: Retrospective chart review

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We performed a retrospective chart review of patients with psoriasis and history of malignancy that where treated with apremilast, from January 1, 2013, to July 31, 2019, at the Psoriasis Center, Bari Policlinico Department of Dermatology and Venereology. We selected 10 patients, according to 3 inclusion criteria: psoriasis (disease severity measures, BSA, and PGA), treatment with apremilast and history of malignancy excluding nonmelanoma skin cancer. Average time from cancer diagnosis to initiation of apremilast was 20.9 months and average time on apremilast was 12.4 months. Six patients received concurrent cancer therapy during psoriasis treatment. Most patients had improvement of their psoriasis and no clinical or radiographic recurrence or progression of their cancer during apremilast treatment.

Commercial disclosure: None identified.

18272

DaxibotulinumtoxinA for Injection is similarly effective in experienced botulinum neurotoxin patients and in those naïve to treatment

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Introduction: Clinical trials for glabellar lines (GL) have classically recruited subjects who are naïve to treatment to maintain population homogeneity. The DaxibotulinumtoxinA for Injection (DAXI) phase 3 GL program did not restrict enrollment in this way and included subjects with previous botulinum neurotoxin (BoNT) treatment experience as well as those naïve to treatment. Comparing these two subgroups will help determine if prior experience is an influential baseline characteristic.

Methods: Two 36-week, double-blind, randomized, placebo-controlled trials (RCTs) and an 84-week, open-label, repeat-dose safety study (OLS) were conducted. In the RCTs, subjects with moderate or severe GLs were randomly assigned (2:1) to receive DAXI (40U) or placebo. Subjects with prior BoNT experience were required to wash-out for at least 6 months following previous treatment.

Results: In the RCTs, 47.8% of subjects were naïve to BoNT; 52.2% had prior treatment with 25.5 months mean time since previous treatment. In OLS, 39.9% had prior treatment with an average of 32.1 months since last treatment. More than 95% subjects in each group had none/mild GL on the Frown Wrinkle Scale at week 4 in the RCTs and OLS, with no difference between the naïve and experienced groups. No differences were observed between cohorts in time to loss of clinical effect, and no between-group safety differences were seen.

Conclusions: No difference was found in the magnitude or duration of efficacy between subjects with previous treatment and treatment-naïve subjects. This suggests that future studies need not restrict recruitment based on treatment history if an appropriate wash-out period is observed.

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3D rendering of lentigo maligna features in vivo

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Reflectance confocal microscopy (RCM) is now available for clinical use to evaluate cutaneous lesions in vivo before biopsy. This technology is particularly valuable for patients where there is concern of melanoma on sun damaged skin (lentigo maligna) versus a benign lentigo or seborrheic keratosis. Trained physicians can identify lentigo maligna tumors using 2D horizontal RCM image stacks or mosaics. However, there is valuable information missing when assessing lesions in 2D. Instead of reviewing only the 2D confocal images, we have generated 3D renderings of image stacks to augment our ability to visualize relevant features. Presently our efforts are focused on 3 areas of interest. 1) The extent of melanocytic dendricity: a hallmark of lentigo maligna tumors evident in RCM. Dendrites reside in multiple planes, therefore their morphology can only be fully revealed with 3D reconstructions. 2) The location of melanocytic cells within the context of the 3D volume: making upper (epidermal) regions and lower (dermal) regions simultaneously apparent. 3) The normal undulation of the dermal-epidermal junction: this wave-like interface becomes flattened or eroded in lentigo maligna as compared with benign neoplasms. Visualization of the DEJ structure (or lack of) which transects the horizontal planes of RCM image stacks is only possible in 3D. The impact of 3D confocal images on clinical care and potential artificial intelligence (AI) diagnostic algorithms has yet to be fully determined. Currently 3D processing provides critical data regarding location, structure and morphology, thereby supporting the diagnostic capabilities of RCM.

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18282

Improper potency and impurities in compounded polidocanol

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Commercially available polidocanol is a US Food and Drug Administration (FDA)—approved sclerosant indicated for the treatment of uncomplicated spider veins and reticular veins in the lower extremities. In contrast, compounded polidocanol are essentially copies of commercially available products. These formulations are not FDA approved and have not undergone review for safety, effectiveness, and quality. Despite restrictions against compounding drugs, polidocanol remains available from compounding pharmacies, potentially exposing patients to series health risks. The objective of this study was to obtain and analyze samples of compounded polidocanol for potency and purity. Seven samples of compounded polidocanol were obtained from 3 compounding pharmacies. Labeled concentrations ranged from 1.5% to 5%. Each sample was analyzed for potency of lauromacrogol 400 (polidocanol) and purity with reversed-phase high pressure liquid chromatography (HPLC) with refractive index (RI) detection. The results were compared with an FDA-approved polidocanol 0.5% and 1% product (Asclera Injection). Among the seven samples analyzed, six were below the labeled concentration and one was above the labeled concentration. Five contained a 10-fold excess of foreign fatty alcohol ethoxylate impurities and four exceeded the limit for unknown impurities. Regarding potency and purity, none of the samples were equivalent to the commercially marketed product. Seven analyzed samples of compounded polidocanol had concentrations that differed from their labeled concentrations. In addition, five samples had excessive contaminant levels. Unreliable potency and the presence of impurities poses a significant risk to patient safety and treatment efficacy, but also presents medicolegal implications for the practitioner in cases of adverse outcomes.

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