Effects of topical piroxicam and sun filters in actinic keratosis evolution and field cancerization: a two-center, assessor-blinded, clinical, confocal microscopy and dermoscopy evaluation trial.


ABSTRACT
Background: Actinic keratosis (AK) is considered an "in situ" non-melanoma skin cancer induced by ultraviolet chronic exposure. Sunscreen and topical anti-inflammatory agents like diclofenac could improve the evolution of this kind of lesions. A topical product containing piroxicam 0.8% and sun filters (50 SPF) (ACTX) has been shown to be very effective in reducing AK lesions. So far, no data are available regarding the effects of this product on skin modifications evaluated by reflectance confocal microscopy (RCM) and dermoscopy at the lesion sites and on the skin around the lesions (field cancerization). Study aim: To evaluate in a two-center, assessor-blinded, prospective trial the effect of ACTX on AK number, RCM and dermoscopy parameter evolution of a target lesion in subjects with multiple AK lesions. Subjects and methods: A total of 54 subjects (42 men and 12 women; mean age 65 years) with AK lesions grade I-III located on the scalp (n=36) or face (n=18) were enrolled after their written informed consent. ACTX was applied twice daily on the face and scalp for six consecutive months. AK lesion count was performed at baseline and after 3 and 6 months. Lesion count was assessed in a blind fashion evaluating digital color high definition images performed at each visit and coded in a blinded fashion. RCM evaluations were performed at the same time-points. A dermoscopy evaluation was performed at baseline and after 6 months. RCM and dermoscopy were assessed on a pre-specified target lesion. The RCM severity score was used evaluating 11 items, examining stratum corneum, stratum granulosum, stratum spinous and dermal layers (maximum score 11 points). The dermoscopy score evaluated erythema, scaling and follicular plugs (from 0 to 4 for each item) and pigmentation (from 0 to 5). Results: Forty-nine subjects (90%) concluded the trial. At baseline, the mean (SD) number of AK lesions was 9.6 (5.2). AK lesions significantly decreased to 5.9 and to 5.6 after 3 and 6 months of ACTX treatment (p<.001; intention to treat analysis), representing a -42% reduction. A reduction of AK lesion numbers >50% in comparison with baseline was observed in 51% of subjects at month 6. New AK lesions appeared in five subjects (9%). The RCM mean (SD) severity score at baseline was 6.4 (2.0). ACTX treatment was associated with a progressive and significant (p<.002) reduction to 4.9 after 3 months and to 4.8 (2.3) at month 6 (a -25% reduction). The dermoscopy score at baseline was 5.5 (2) and it was reduced significantly (p<.007) to 4.5 (2) at the end of the study. The product was in general very well tolerated. Conclusion: A 6 month application of ACTX in subjects with AK lesions was associated with an improvement in AK lesion count and with a reduction in the RCM/dermoscopy severity scores of the target lesion. Trial registration number: ISRCTN22070974. KEYWORDS: Actinic keratosis; piroxicam; reflectance confocal microscopy; sunscreen PMID:31148490 DOI:10.1080/03007995.2019.1626227