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Sun exposure monitoring by ultraviolet sensor in patients with actinic keratosis treated with tirbanibulin 10 mg/g ointment or diclofenac sodium 3% gel: a Phase IV randomized study

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Introduction & Objectives: Patients with actinic keratoses (AK) were monitored for sun exposure by wearing an ultraviolet (UV) sensor device fully integrated with a validated data capture platform¹. The system captures the intensity of UV radiation and measures it as UV Index (UVI) allowing to generate personalised alerts based on the skin type about the daily maximum UV dose reached. The study aims to determine whether the UV sensor and mobile app help patients become aware about daily solar radiation and its impact on health, and whether they have an impact on overall exposure, promote sun protection habits and engage patients into a long-term safety study.

Materials & Methods: This is a Phase IV multi-centre, randomized, evaluator-blinded, active-controlled, parallel group study (EudraCT: 2024-514394-22-00) to determine the incidence of invasive squamous cell carcinoma after treatment with tirbanibulin and to evaluate the long-term safety of tirbanibulin administered on the face or scalp in patients with AK. Adults with a contiguous field measuring 25 cm² that contains 2-8 clinically typical, non-hypertrophic, non-hyperkeratotic, visible, discrete, AK lesions were included in the study. Patients were randomized 1:1 to receive tirbanibulin 10 mg/g for 5 days or diclofenac sodium 3% for 60-90 days. UV sensor use was optional. Patients that accepted to wear the UV sensor were monitored for sun exposure from baseline up to day 57 (short-term use). These patients were monitored from March 1st to September 30th of each year (long-term use). The UV sensor is paired with a mobile app, and the smartphones display a real-time UVI, real-time cumulative UV exposure, as well as historical data of daily UV exposure during the week. Patients were instructed to wear the sensor on the wrist during the day regardless of whether they were indoors or outdoors. Collection of UV exposure was performed in both treatment arms.

Results: A total of 197 patients (average age: 70 years; male: 86.8%) from France, Germany, Italy, Poland, Spain and United Kingdom accepted to wear the UV sensor and use the App in 2023 (N=161) and 2024 (N=97), which is 44% of the overall patients in the study (64% used both; 29% only the app; 7% only the sensor). Overall retention rate for the study is 84%, but for patients who have been wearing the sensor is 91.3%. Most patients (83.6%) used it for a long-term period (>57 days). Average overall UVI exposure was 0.82 (based on WHO UVI scale 1-11+). This average decreased in 2024 in comparison with 2023 (reduction rate: 13%). Additionally, it was observed that UVI average was higher during spring (April and May) than during summer (July and August) in both 2023 and 2024. The sensor was used on average 115 days. Overall, average number of days with a UVI exposure higher than recommended (UVI<2)² was 46 days. Short-term users (N=23 [16.4%]) used the sensor an average of 10 days, and for 4 days the sensor registered an UV higher than the recommended. Long-term users (N=117 [83.6%]), used it on average 135 days and had UV above recommended for 52 days on average (38.5%).

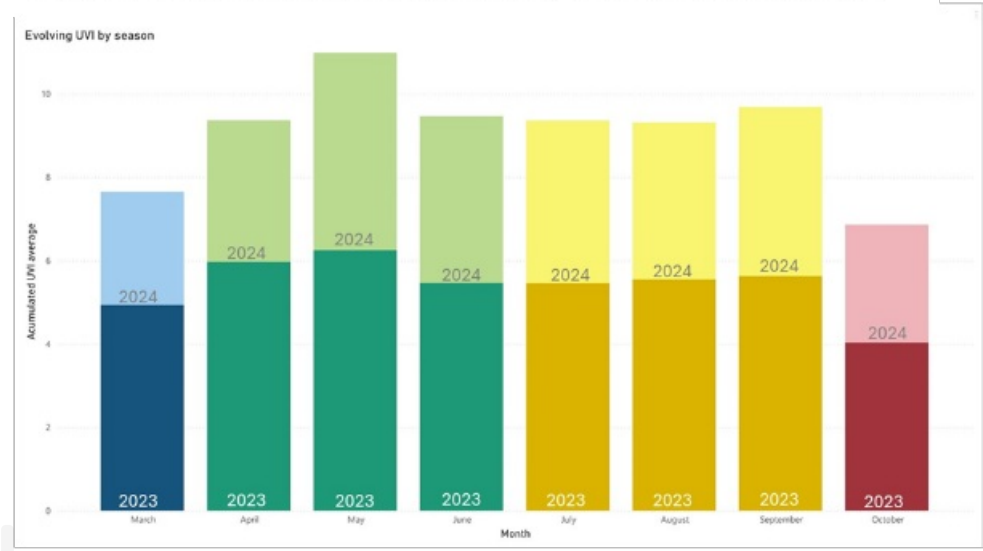
Conclusion: UV sensor might be a potential tool to visualize the risks associated with sun overexposure. In spring the UVI average was higher than in summer. Moreover, patients were exposed to UVI higher than recommended

but improving habits from one year to another.

1Replior: Data Collection Solutions for Clinical Trials

2World Health Organization. Radiation: The ultraviolet (UV) index. 2022

Figure 1: Sun exposure monitoring (UVI). Overall evolving by season (2023-2024).



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