A-360 - Relationship between efficacy and cosmetic outcome in tirbanibulin-treated patients with actinic keratosis over a field up to 100 cm²: subanalysis from TirbAKare study [Abstract]

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A-360

Relationship between efficacy and cosmetic outcome in tirbanibulin-treated patients with actinic keratosis over a field up to 100 cm²: subanalysis from TirbAKare study

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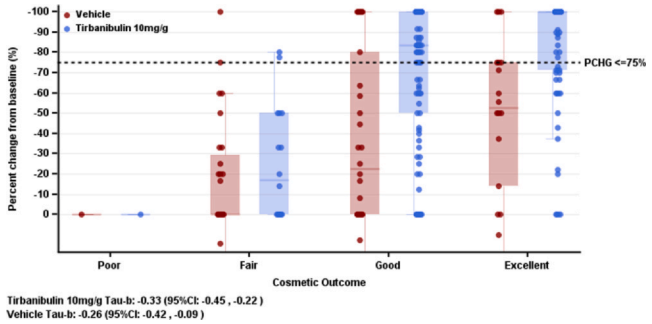
Background: Actinic keratosis (AK) is a common precancerous skin condition. Tirbanibulin demonstrated efficacy and tolerability over a field up to 100 cm2 in TirbAKare study[1] and recent evidence suggests that tirbanibulin may also confer substantial cosmetic benefits to patients[2]. This analysis aimed to evaluate the relationship between lesion clearance and cosmetic outcome in patients treated with tirbanibulin 1% ointment.

Methods: This post-hoc analysis of the phase III TirbAKare study (NCT06135415) included 280 patients randomized 2:1 to tirbanibulin or vehicle. Treatment was applied over a field of up to 100 cm² on the face or scalp for 5 consecutive days. A second cycle was administered on Day (D)57 if complete clearance (CC) was not achieved. Efficacy was measured as mean percentage change from baseline in AK lesion count. Cosmetic outcome was rated by both patients and investigators using a 4-point scale (excellent, good, fair, poor) at D57 and D113. Post-hoc analyses assessed the relationship between efficacy (% reduction in AK lesion) and cosmetic outcome using Kendall's Tau-b correlation coeficient, and the proportion of patients achieving both, ≥75% reduction in AK lesions and good/excellent cosmetic outcome.

Results: The relationship between efficacy and cosmetic outcome showed a moderate tau-b correlation of -0.33 (95%CI: -0.45, -0.22) at D57 in tirbanibulin-treated population (Figure).



Relationship between efficacy (% reduction in AK lesions) and patients' cosmetic outcome assessment at D57. PCHG: percentual change.

Similar results were observed at D113 (-0.26; 95%CI: -0.44, -0.08).

Conclusions: These results suggest a clinical relationship between AK lesion clearance and cosmetic outcome in tirbanibulin-treated patients at both, D57 and D113. Most of tirbanibulin treated patients appeared to achieve both, ≥ 75% reduction in lesion count and good/excellent cosmetic outcome, aligning with treatment expectations of both, patients and investigators.

References: [1] Welzel et al., (2025), EADV, Poster 2337 [2] Li Pomi et al., (2025), Dermatol Ther, 95-110, 15

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A-374

Sequential keratolytic pretreatment enhances tirbanibulin efficacy in field cancerization assessed by line-field confocal optical coherence tomography: a pilot study

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Background: Field cancerization with actinic keratoses (AK) showing advanced intraepidermal atypia remains challenging to treat. Tirbanibulin is currently approved for grade I–II AK, while evidence in higher-grade lesions and combination regimens is limited1. This pilot study aimed to evaluate the clinical and microstructural effects of a sequential keratolytic pretreatment followed by tirbanibulin in patients with field cancerization using line-field confocal optical coherence tomography (LC-OCT)2.

Methods: Ten patients with field cancerization were included. Target lesions exhibited PRO score III on LC-OCT and were classified as grade I–III according to the Roewert-Huber system. Treatment consisted of topical 5% salicylic petrolatum for 2 weeks, followed by tirbanibulin 1% ointment once daily for 5 consecutive days on a maximum treatment area of 25 cm². LC-OCT imaging was performed at baseline and 3 months after treatment completion. Two blinded expert evaluators independently assessed field clearance rate, PRO score and Roewert-Huber grade, as well as hyperkeratosis, dyskeratosis, and dermo-epidermal junction alteration, each graded as mild, moderate, or severe (numerical scale 1–3).

Results: At 3-month follow-up, PRO score improved in 9/10 lesions, with a median reduction from III to I ($p < 0.05$). According to the Roewert-Huber classification, grade III lesions decreased from 6/10 at baseline to 1/10, while grade I lesions increased from 2/10 to 6/10. The complete field clearance rate, defined as the absence of clinically and LC-OCT–detectable AK features within the treated field, was 60% (6/10 patients) at 3 months. LC-OCT evaluation showed a ≥1-grade reduction in hyperkeratosis and dyskeratosis in 8/10 lesions and improvement in dermo-epidermal junction architecture in 7/10 cases. Interobserver concordance across all LC-OCT parameters was 85%. Clinical improvement consistently paralleled microstructural normalization (Figure 1, 2).