

COMPARISON OF PATIENT AND CLINICIAN SATISFACTION WITH TIRBANIBULIN TREATMENT'S ABILITY TO IMPROVE 'HOW SKIN LOOKS' AND 'SKIN TEXTURE' IN THE TREATED AREA, AMONG PATIENTS WITH ACTINIC KERATOSIS TREATED WITH TIRBANIBULIN IN COMMUNITY PRACTICES ACROSS THE U.S (PROAK STUDY)

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SYNOPSIS

Introduction: The objective of this analysis was to compare patient and clinician satisfaction with tirbanibulin treatment's ability to improve 'how skin looks' and 'skin texture' in the treated area, among patients with Actinic Keratosis (AK) treated with tirbanibulin in community practices across the U.S.

Methods: A single-arm, prospective cohort study (PROAK) was conducted among adult patients with AKs on the face or scalp who were newly initiated with once-daily tirbanibulin treatment (5-day course) in real-world community practices in the U.S., as part of usual care. Patients and clinicians completed surveys and clinical assessments at baseline, Week-8 (timeframe for main endpoints) and Week-24. Patient's self-reported satisfaction and clinician satisfaction with tirbanibulin treatment's ability to improve 'how skin looks' and 'skin texture' in the treated area at individual patient-level were assessed among study patients at Week-8 on a seven-point adjectival response scale of 1 (extremely dissatisfied) – 7 (extremely satisfied).

Results: A total of 290 patients with AKs completed the study assessments at Week-8. Patient self-reported skin-texture at baseline was – dry: 39.66%, smooth: 47.59%, rough: 19.66%, bumpy: 18.62%, scaly: 35.17%, blistering/peeling: 6.55%. All patients (100%) completed their 5-day once-daily treatment course. At Week-8, 75.86% & 78.97% of the patients and clinicians respectively reported extremely/very/satisfied with tirbanibulin's ability to improve 'how skin looks', while 14.14% & 14.14% respectively reported somewhat satisfied, and 10.00% & 6.55% respectively reported extremely/very/dissatisfied. At Week-8, 74.83% & 80.69% of patients and clinicians respectively reported extremely/very/satisfied with tirbanibulin's ability to improve their 'skin texture', while 15.52% & 12.41% respectively reported somewhat satisfied, and 9.65% & 6.55% respectively reported extremely/very/dissatisfied.

Conclusion: Majority of patients with AKs and their clinicians reported satisfaction with the ability of 5-day treatment course of tirbanibulin to improve 'how skin looks' or 'skin texture' in the tirbanibulin-treated area, at Week-8.

OBJECTIVE

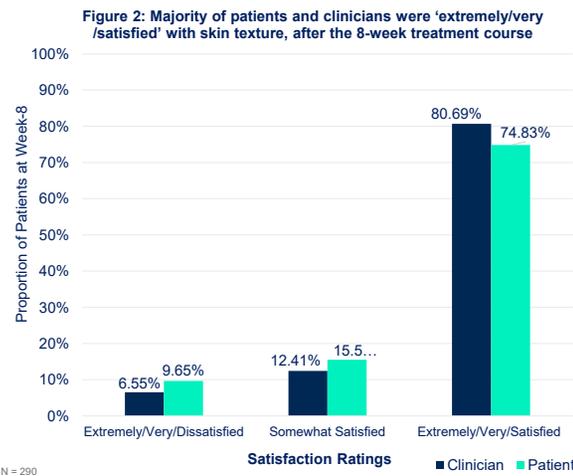
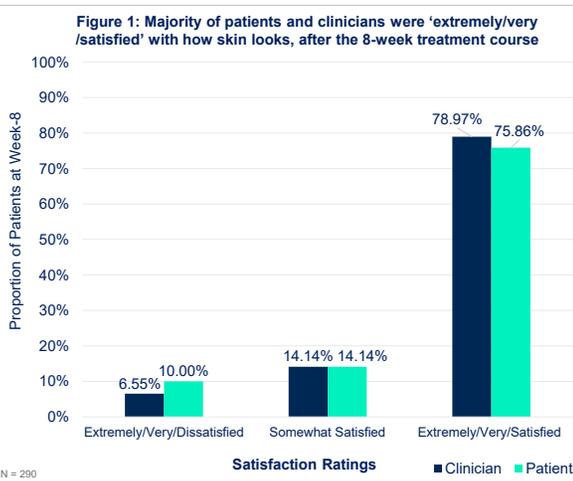
- The objective of this analysis was to compare patient and clinician satisfaction with tirbanibulin treatment's ability to improve 'how skin looks' and 'skin texture' in the treated area, among patients with Actinic Keratosis (AK) treated with tirbanibulin in community practices across the U.S.

METHODS

- A single-arm, prospective cohort study was conducted among adult patients with AKs on the face or scalp who were newly initiated with once-daily tirbanibulin treatment (5-day course) in real-world community practices in the U.S., as part of usual care.
- A total of 300 subjects were enrolled from 32 community practices across the U.S.
- Main treatment assessment timepoints were at baseline and Week-8, while patients were followed for up to week-24.
 - Subjects completed self-assessment questions at baseline and Week-8 about their skin appearance and texture.
 - Clinicians completed surveys and clinical assessments at baseline and week-8, concerning attributes and effectiveness of tirbanibulin.
- Patient and clinician satisfaction was assessed at week-8 concerning the ability of tirbanibulin treatment to 'improve how skin looks' and 'improve skin texture' in comparison to baseline.
 - Patients and clinicians reported satisfaction in individual patient treatment outcomes in the tirbanibulin-treated area (compared to baseline), using a seven-point adjectival response scale of 1 (extremely dissatisfied) – 7 (extremely satisfied).
- Patient and clinician reported outcomes were analyzed descriptively using data from Week-8, for all study patients with available data, as observed.

RESULTS

- PROAK study (NCT05260073) was initiated in 2022, with more than 75% of the study patients treated with tirbanibulin between April and August of 2022.
- Out of 300 enrolled patients, a total of 290 patients with AKs completed the study assessments at Week-8, and hence included in the analyses.
- All patients (100%) completed their 5-day once-daily treatment course.
- Ten patients were not included in the week-8 analyses: 1 patient had missing data, and 9 patients were discontinued from the study due to patient voluntary withdrawal of consent or lost to follow-up.
- No discontinuations were related to adverse drug reactions (ADRs), and there were no Serious ADRs reported at week-8.



CONCLUSIONS

- A majority of patients with AKs and their clinicians reported satisfaction with the ability of 5-day treatment course of tirbanibulin to improve 'how skin looks' or 'skin texture' in the tirbanibulin-treated area, at Week-8.
- The demonstrated effectiveness and the safe and tolerable profile of once-daily tirbanibulin treatment highlights the benefits associated with this novel therapeutic option in routine community practice settings, for optimal management of AKs.

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Table 1: Baseline Patient Characteristics

		N=290
Age, mean years [min, max]		66.30 [30.00, 90.00]
Gender, %	Female Male	31.38 68.62
Primary health insurance, %	Private Insurance Medicaid Medicare Uninsured	41.72 3.10 53.79 1.38
History of skin cancer, %		61.72
Fitzpatrick skin type, %	Type I Type II Type III Type IV Type V	7.59 71.38 18.62 1.38 1.03
Baseline patient self-reported skin-texture, %	Dry Smooth Rough Bumpy Scaly Blistering Peeling	39.66 47.59 19.66 18.62 35.17 0.34 6.21
Baseline severity of skin photodamage in AK affected area, %	Absent Mild Moderate Severe	1.03 21.38 56.55 20.34

Table 2: Site Characteristics (N=32)

Current workplace: Private, office-based practice, %	100
Total number of board-certified dermatologists in the clinic/practice, Mean	3.53
Number of patients with AKs managed by the clinic in a given month, Mean	136.34
Number of years practicing dermatology, Mean	15.66