BACKGROUND

• Timely, effective treatment of actinic keratoses (AKs) is important because chronically sun-exposed skin will become cancerous.

• Some topical treatments for AKs such as 5-fluorouracil and imiquimod are associated with uncomfortable and visible local skin reactions (LSRs), which have been linked to poor treatment tolerability and low treatment satisfaction.

• Clinical trials of AK have not typically included patient-reported outcomes (PROs).

• AK treatment-related factors such as skin reactions are known to impact QOL and adherence.

• Current assessments on topical treatment attributes in AK do not evaluate safety, effectiveness, and satisfaction from both clinician and patient perspectives, creating an unmet need for more comprehensive AK-specific measures that fully capture the patient experience.

• An AK-specific PRO instrument may help highlight patient-centric issues and outcomes in clinical studies and real-world clinical practices.

• Comparing current and previous AK treatments would be useful in gauging the relative impact of different treatments. Further, simultaneously assessing PROs and clinician-reported outcomes (ClinROs) on treatment attributes may enhance clinician-patient communication, providing great utility among clinical practitioners.

OBJECTIVE

• To create an expert panel questionnaire (EPQ) comprising of AK-specific PROs and ClinROs for use in research studies and clinical practices.

METHODS

• A 9-person consensus panel of dermatologists with expertise in the treatment of AKs was virtually convened using a two-step modified Delphi method to establish consensus on EPQ items.

• Input from AK patient interviews and targeted literature reviews was used to identify 11 EPQ items.

• In first round, EPQ items were distributed to the panel for discussion of each item and solicit comments individually and collectively.

• In the second round, the panel refined EPQ items which were distributed for feedback and approval.

RESULTS

The panel discussed nine PROs encompassing cosmetic outcomes, ‘overall appearance of the skin’, ‘ability to improve skin looks’, ‘ability to improve skin texture’, effects of Local Skin Reactions (compared to previous topical treatment experience), relative rating of ‘duration of skin reactions’, ‘severity of skin reactions’, ‘impact on your daily activities’, relative convenience index of use of new treatment, overall satisfaction with new treatment, and likelihood of future use.

• Two ClinROs encompassing Physician Global Assessment (PGA) of AK and severity of skin photodamage were also reviewed.

• The panel suggested wording changes to PROs and ClinROs as outlined in Table 1.

• For Subjects re-treated with another topical treatment at Week-24, questions 3-8 are rewired to enable the assessment of relative satisfaction associated with tirbanibulin in comparison to the ‘most recent topical treatment for AK’.

• The clinician version of the questions 1-9 were worded to refer to clinician experience / observation of tirbanibulin effects among their patients.

• Following refinement of EPQs, panels unanimously (100%) achieved consensus in approving each of the 11 EPQ items.

• Panels also suggested using the nine PROs as ClinROs to gather patient-experience from both patient and clinician perspective on identified domains.

REFERENCES


CONCLUSIONS

The newly developed EPQ may address important gaps in the existing PRO measures and help elicit patient-centric, AK-specific outcomes from patients and their clinicians to help optimize AK management and enhance patient outcomes.