Real-world treatment and patient-specific characteristics of actinic keratosis in the USA

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Synopsis

Background: Actinic keratosis (AK) is a sun-damage-induced field disease, which manifests as clinical and subclinical lesions.[1] If left untreated, AK may progress to squamous cell carcinoma.[2] Multiple treatment options are available.[3]

Study description: A retrospective medical chart review first determined what information related to AK was available in US patient records by 10 providers treating AK in a feasibility phase. Thereafter a total of 86 providers across the US provided medical records for 429 patients with a diagnosis of AK during a period of 12 months. The results were analyzed descriptively.

Results: The mean (SD) age at index AK diagnosis was 59.9 (±12.4) years. The Olsen Grading Scale (OGS) at baseline was OGS I for 136 patients (44.0%); 155 patients (50.2%) had OGS II and 18 patients (5.8%) had OGS III. In the first treatment cycle, 218 patients received a procedure (cryotherapy, phototherapy or Mohs surgery), 162 received topical therapy, and 49 had a combination of procedure and topical. A second treatment cycle was not initiated within the 12 months for 116 (53.2%) patients receiving a procedure in the first treatment cycle, 106 (65.4%) receiving topical therapy, and 23 patients (46.9%) treated with combination therapy.

Independent of the number of treatment cycles during the study period, 171 patients (39.9%) received a procedure to treat the AK index diagnosis, 150 (35.0%) received topical therapy, and 108 (25.2%) received a combination of procedure and topical. Efficacy assessment was based on the best response to treatment independent of the number of treatment cycles. Complete and partial clearance were achieved by 37.6% and 62.4% of patients treated with procedure, 25.0% and 61.4% treated with topical, and 18.3% and 56.6% treated with a combination of procedure and topical. For patients with more than five AK lesions at baseline, complete and partial clearance were achieved by 0% and 44.8% receiving a procedure (n=29) and 9.7% and 71% treated with topicals (n=31).

Conclusion: This chart review study, although with limitations, provides a level of understanding of how AK lesions are treated in a real-world setting. A procedure alone is the most common treatment approach, though most patients with AK received a topical treatment. With more than five AK lesions at baseline, procedure-only treatment became less effective; the opposite effect was seen with topical-only treatment, which showed a higher partial response to treatment with more than five AK lesions.

Objective

To describe and understand real-world treatment patterns, and patient-specific characteristics of actinic keratosis (AK) in the USA.

Methods

Phase 1. Feasibility assessment

- The study was pilot tested with 10 clinics
- Each provider abstracted six medical records and participated in interviews to assess the functionality of the data collection form and the availability of desired data in the medical records.

Phase 2. Medical record review

- This was a retrospective medical record review of information on patients with a diagnosis of AK
- The data were fully anonymized, no personal or identifiable information was collected and there was no patient contact or prospective follow-up.

Provider inclusion criteria

- Located in the USA
- Dermatologist or nurse practitioner/physician assistant specializing in dermatology with 3–35 years' practice experience
- Treated at least 40 patients with AK in the last year
- Main decision maker regarding treatment of AK
- Detailed information provided in the medical record regarding AK.

Patient inclusion criteria

- Confirmed diagnosis of AK
- Treatment initiated between January 1, 2012 and September 30, 2014
    - First diagnosis treated during this period was considered the 'index diagnosis'
- The AK index diagnosis must have met one of the following definitions on the diagnosis date:
    - AK was new to the anatomical region
    - AK was new in the patient
    - New treatment cycle
- ≥18 years of age at index diagnosis
- Received AK-related care from the same provider or treatment center for at least 12 months following the index diagnosis date.

Study measures

Physician characteristics

- Geographic practice region, number of years in practice, current case load of patients with AK.

Demographic characteristics

- Gender, age, history of malignancies (prior malignancies versus none).

Clinical characteristics

- Anatomical location, number of clinically viable AK lesions, type of lesions, grade of most representative lesion in region, size of treated area (small, <25 cm^2 versus large, ≥25 cm^2).

Treatment patterns

- Receipt of procedure versus topical treatment (with or without procedure), type and number of specific treatments received, treatment response: complete clearance (AKCLEAR 100), partial clearance (AKCLEAR 75); adverse reactions (ARs).

Results

Baseline characteristics

- In total, 86 providers provided medical records for 429 patients.
- Provider characteristics are presented in **Table 1** and patient baseline characteristics are presented in **Table 2**.

Table 1. Provider characteristics

	Total
Total provider sample, n (%)	86 (100.0)
Mean number of patients with AK treated in the past year (SD)	482.1 (328.1)
Mean number of years in practice (SD)	13.8 (6.4)
Medical speciality, n (%)	
Dermatologist	67 (77.9)
Nurse practitioner specializing in dermatology	8 (9.3)
Physician assistant specializing in dermatology	11 (12.8)
Ultraviolet exposure in region of primary practice*, n (%)	
High exposure	46 (53.5)
Low exposure	40 (46.5)
Practice location, n (%)	
Urban	43 (50.0)
Suburban	43 (50.0)

*Physicians were asked to select the metropolitan region in which they practiced; AK, actinic keratosis; SD, standard deviation

Table 2. Patient baseline characteristics

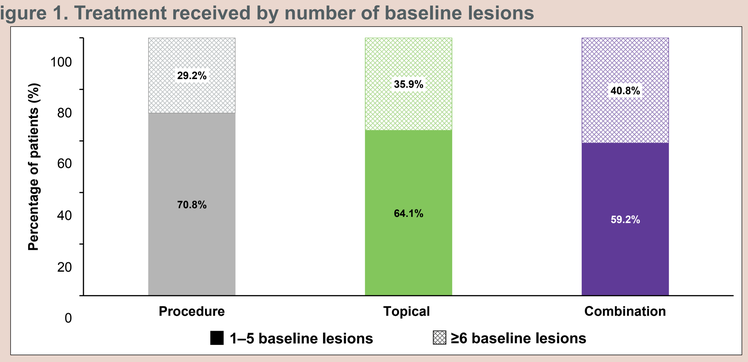
	Procedure (n=171)	Topical (n=150)	Combination (n=108)
Sex, n (%)			
Male	108 (63.2)	101 (67.3)	79 (73.2)
Female	63 (36.8)	49 (32.7)	29 (26.9)
Mean age at index diagnosis, n (SD)	60.3 (12.1)	58.3 (13.0)	61.5 (11.9)
Fitzpatrick classification of skin type at index date, n (%)			
I – Always burns, never tans (pale white skin)	43 (25.1)	31 (20.7)	20 (18.5)
II – Always burns easily, tans minimally (white skin)	100 (58.5)	78 (52.0)	71 (65.7)
III – Burns moderately, tans uniformly (light brown skin)	18 (10.5)	27 (18.0)	15 (13.9)
IV – Burns minimally, always tans well (moderate brown skin)	8 (4.7)	9 (6.0)	2 (1.9)
V – Rarely burns, tans profusely (dark brown skin)	1 (0.6)	2 (1.3)	0 (0)
Undetermined/don't know	1 (0.6)	3 (2.0)	0 (0)
History of malignancies prior to the index AK, n (%)	59 (34.5)	51 (34.0)	41 (38.0)
Mean number of baseline lesions (SD)	6.1 (7.5)	6.3 (7.8)	7.5 (8.6)
Field size, n (%)			
Small (<25 cm^2)	122 (84.7)	86 (65.7)	55 (77.5)
Large (≥25 cm^2)	20 (13.9)	32 (24.4)	16 (22.5)
Unknown	2 (1.4)	13 (9.9)	0 (0)
AK thickness (OGS), n (%)			
Grade I – mild	63 (43.8)	53 (40.5)	20 (28.2)
Grade II – moderate	53 (36.8)	56 (42.8)	46 (64.8)
Grade III – Severe	7 (4.9)	7 (5.3)	4 (5.6)
OGS was not recorded	21 (14.6)	15 (11.5)	1 (1.4)

AK, actinic keratosis; OGS, Olsen grading scale; SD, standard deviation

Treatment pattern

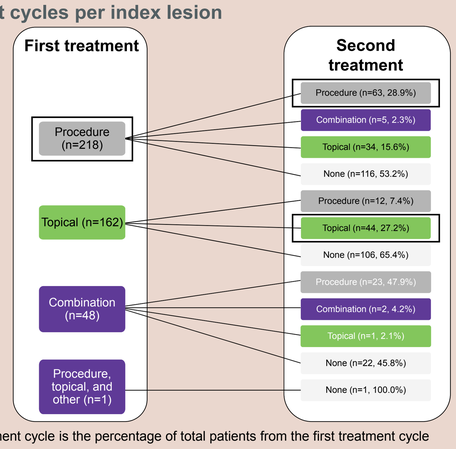
- The number of patients that received a procedure to treat the index diagnosis was 171 (39.9%), while 150 (35.0%) patients received topical treatment, and 108 (25.2%) received a combination of procedural and topical treatments.
- Patients receiving each treatment type, based on if they had 1–5 baseline lesions or ≥6 baseline lesions, are shown in **Figure 1**.

Figure 1. Treatment received by number of baseline lesions



- The treatment cycles for the index diagnosis are shown in **Figure 2**.

Figure 2. Treatment cycles per index lesion



% shown in the second treatment cycle is the percentage of total patients from the first treatment cycle

Efficacy

- The response to treatment was known for 249 of 429 patients included in the medical chart review.
- Thirty-eight (37.6%) patients receiving procedural treatment achieved AKCLEAR 100 and 63 (62.4%) achieved AKCLEAR 75. Twenty-two (25.0%) and 54 (61.4%) patients receiving topical treatment achieved AKCLEAR 100 and AKCLEAR 75, respectively. Eleven (18.3%) and 34 (56.6%) patients receiving combination achieved AKCLEAR 100 and AKCLEAR 75, respectively. Percent clearance by treatment group is shown in **Figure 3**.
- No patients with >5 baseline AK lesions (n=29) receiving a procedure achieved AKCLEAR 100; 9.7% of patients receiving topical treatment (n=31) achieved AKCLEAR 100. Percent clearance by number of baseline lesions and by treatment group is shown in **Figure 4**.
- As number of baseline lesions increased, procedure treatment became less effective (**Figure 5A**); the opposite trend was seen with topical treatment (**Figure 5B**). A similar result to topical treatment was observed with combination treatment (**Figure 5C**).

Figure 3. Percentage of patients achieving different levels of clearance per treatment group

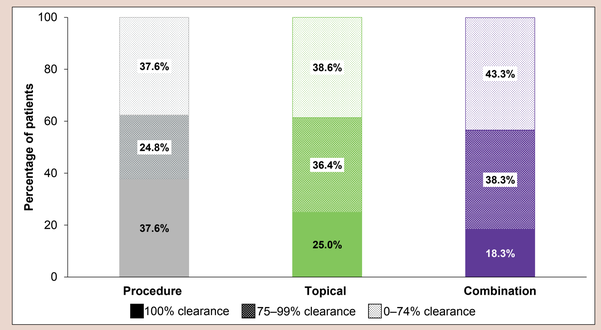


Figure 4. Percentage of patients achieving different levels of clearance per treatment group and by number of baseline lesions

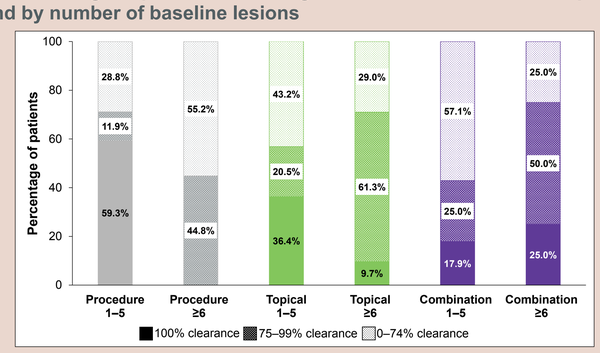
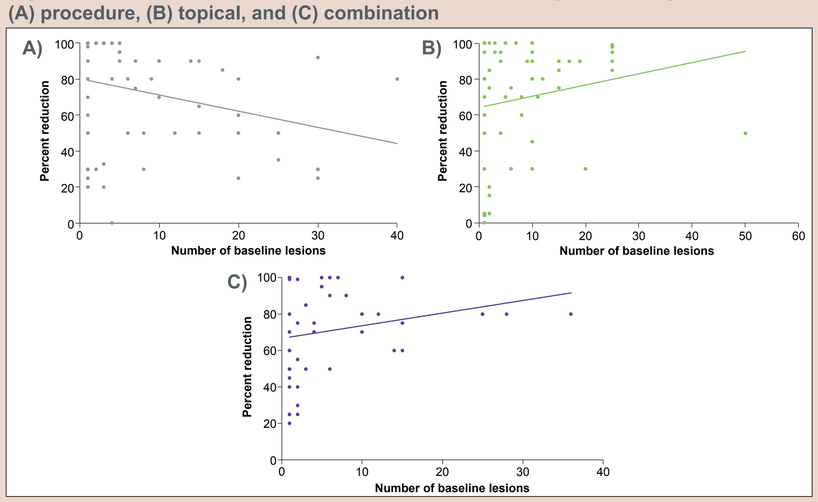


Figure 5. Percent reduction in number of baseline lesions by treatment group: (A) procedure, (B) topical, and (C) combination



Safety

- ARs were more common in the topical group, with 32.0% of patients reporting ≥1 AR.
- In the procedural treatment group, 9.4% of patients reported ≥1 AR and in the combination group, 23.2% reported ≥1 AR.
- The three most common ARs by treatment group are presented in **Table 3**.

Table 3. Most commonly reported ARs by treatment group

	Procedure (n=171)	Topical (n=150)	Combination (n=108)
Total number of patients reporting an AR, n (%)	16 (9.4)	48 (32.0)	25 (23.2)
Total number of ARs reported	24	82	55
Three most commonly reported ARs by treatment group*			
Pain	10 (41.7)	0	4 (7.0)
Blistering	7 (29.2)	0	2 (4.0)
Erythema	1 (4.2)	40 (48.8)	20 (36.0)
Headache	4 (16.7)	0 (0)	0
Pruritus	1 (4.2)	18 (22.0)	8 (15.0)
Edema	0	12 (14.6)	2 (4.0)
Dermatitis	0	6 (7.3)	9 (16.0)

*Most commonly reported ARs are shown as a percentage of the total ARs reported; AR, adverse reaction

Conclusions

- The chart review provided a level of understanding of how AK lesions are treated in a real-world setting.
- A procedure is the most common treatment approach although most patients with AK received a topical treatment.
- With more than five AK lesions at baseline, procedure-only treatment became less effective; the opposite effect was seen with topical-only treatment, which showed a higher partial response to treatment with more than five AK lesions.

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