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ORIGINAL ARTICLE

If patients had a choice – Treatment satisfaction and patients' preference in therapy of actinic keratoses

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Summary

Background: Actinic keratoses (AK) are increasing in incidence and represent the most common (pre-)cancerous lesion in the fair-skinned population, with a high unmet medical need. In order to increase treatment adherence, it is very important to assess patients' therapy-related evaluations of different treatment options.

Patients and methods: 100 patients with AK who were treated with at least two different treatment options were included. They rated their therapies using the Treatment Satisfaction Questionnaire for Medication (TSQM, maximum 100 points per category) and a Likert scale (LS, 1 = very satisfied; 6 = not satisfied). Patients were also asked about their needs in terms of treatment goal, cost, type, duration, and location of treatment.

Results: 81% of the study participants were male and on average 74 years old. 95% had field cancerization. Eight frequently used therapy procedures were evaluated by the patients (surgery, cryotherapy, various topical agents, photodynamic therapy). The TSQM satisfaction scores ranged from 78.47 ± 16.07 (surgical procedures) to 53.03 ± 22.13 (diclofenac-HA). Statistically significant differences between the procedures were only found in the area of efficacy. Side effects were classified as low. Low recurrence rate and safe removal were the most important treatment goals (LS: 1.18 ± 0.44 and 1.27 ± 0.53, respectively).

Conclusions: Understanding patient preferences is essential for adherence and is therefore of great importance for the success of AK therapy. Personalized approaches should be considered in the choice of therapy.

KEYWORDS
actinic keratosis, NMSC, patient preference, treatment satisfaction

INTRODUCTION

Actinic keratoses (AK) are early forms of malignant epidermal neoplasia usually developing as a result of the cumulative lifetime exposure of sun-exposed skin areas in fair-skinned individuals to ultraviolet radiation in the form of sunlight.[1] From a histological viewpoint, they represent direct precursors of invasive cutaneous squamous cell carcinomas (SCC) (also, *carcinomas in situ*).[2] Actinic keratoses have a very high and constantly increasing prevalence in developed Western nations.[3–5] More accurate data are difficult to obtain and there is a high number of unreported cases. In Germany, the prevalence is currently estimated at 2.7% of all age groups. However, depending on the source, it is increasing significantly with increasing age in those above 60 to 70 years, reaching double-digit rates

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in this group.[3,4] Moreover, since 2015, multiple AKs have been recognized in Germany as an occupational disease for individuals who predominantly work or have worked outdoors (BK 5103), further emphasizing the impact of this disease on healthcare.[5]

As a direct consequence of the combination of the prevalence of AK and its nature as *carcinoma in situ*, treatment of AK plays a prominent role in tumor prevention, given that early diagnosis and therapy may prevent the development of invasive SCC thus effectively also preventing potential metastatic spread.[6] Currently, however, no standardized clinical markers are available to assess which AKs transform into SCC. The progression rate of each individual lesion is inconsistently reported in literature with values between 0.1% and 29% resulting in treatment of all lesions as the only logical consequence.[7] A large selection of highly diverse methods has been established as therapeutic standard. While these have proven their therapeutic effectiveness in the specific application, their advantages and disadvantages for the patient will vary. In general, lesion-directed procedures for the treatment of solitary lesions and field-directed procedures for the treatment of field cancerization are distinguished. The physicochemical ablative procedures are usually lesion-directed and include surgical therapies (excision, curettage, shave), cryotherapy, and laser ablation. The therapeutic objective is the physical (unspecific) destruction of the affected cells. Procedures with topical drugs utilize the selective destruction of atypical keratinocytes by the substance itself or by the drug-induced immune reaction. Approved options include imiquimod, 5-fluorouracil, diclofenac, tirbanibulin (not yet approved at the time of our study), ingenol mebutate (still approved in Germany at the time of our study), and the various types of photodynamic therapy (conventional with red light and daylight). They have the advantage that a larger area in the form of field cancerization can be treated in one treatment cycle. Apart from safety and tolerance aspects, the endpoints of clinical trials are usually concerned with response rates, tumor clearance, and recurrence risk within a certain period.[8] Only in recent years have treatment satisfaction and adherence been increasingly included in the studies. Therapy adherence refers to the level of accuracy adopted by patients to implement the recommendation developed by the physicians and the patients themselves. Apart from socio-economic, disease-related, systemic, and personal aspects, treatment satisfaction is also an influencing factor.[9–11]

The objective of this study was the evaluation of the available therapeutic options with respect to treatment satisfaction of patients in order to provide the attending physician with an additional decision-making aid for individual therapy planning in the case of comparable clinical and therapeutic effectiveness. Another objective was to survey and illustrate the general treatment preferences of the patient collective with the aim to design future therapeutic recommendations in a personalized and patient-oriented manner.

PATIENTS AND METHODS

The present work is a monocentric cross-sectional survey. Data collection was performed on basis of a questionnaire at the Department of Dermatology of the University Medical Center Mainz from November 2016 to April 2018. Inclusion criteria were, apart from the diagnosis of AK, at least two different previous therapies for the disease. A history of metastatic skin tumors (N1 or M1 according to TNM classification) and the presence of a genetic syndrome with increased predisposition to skin tumors (like xeroderma pigmentosum) were specified as exclusion criteria.

The questionnaire consisted of three parts. In part A (general part), treatment preferences were addressed. For this purpose, available statements for the categories completeness of removal, freedom from recurrence, cosmetic outcome, side effects, costs, and effort were weighted by the patients (1 = very important, 6 = not important). In part B (specific part), the most recently received therapy was evaluated by *Treatment Satisfaction Questionnaire for Medication* (TSQM) version II.[12,13] This standardized questionnaire on treatment satisfaction includes eleven questions and is divided into the four categories effectiveness, complication, tolerance, and overall satisfaction. In each category, a score of 0 (completely unsatisfied) to 100 (completely satisfied) can be achieved. In addition, satisfaction with all utilized therapies was measured on a Likert scale by awarding school marks (1 = very satisfied, 6 = unsatisfactory). In part C (personal part), demographic data (gender, age, health insurance status, net household income, location of occupational activity [indoors/outdoors]), as well as the quality of life by *Dermatology Life Quality Index* (DLQI) were obtained.[14]

Demographic data were obtained, in part, by the medical history, but also by the electronic patient record of the hospital information system. This included age of the patients at the time of questionnaire survey and initial diagnosis, date of initial diagnosis, extent of the findings, histological severity, as well as current and previous malignancies of the skin. A positive vote of the ethics committee of the federal state of Rhineland-Palatinate was available for conduction of the survey.

The statistical evaluation was performed in a pseudonymized manner with the program IBM SPSS (version 23.0.03). The descriptive analysis is presented using absolute and relative frequencies, as well as minima and maxima. The significance analysis was performed after exclusion of potential confounders by Welch's ANOVA test. In addition, a Games-Howell post-hoc test was performed.

RESULTS

Study population

Overall, 100 patients were included in the study (Table 1). Of these, 81.0% were male and 19.0% female. Their age

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TABLE 1 Patient characteristics.

	n = 100
Age [years (range)]	75.0 (33–95)
Gender [n (%)]	
male	81 (81.0)
female	19 (19.0)
Health insurance status [n (%)]	
statutory health insurance	63 (63)
private health insurance	37 (37)
Distribution pattern	
single lesion	5 (5.0)
field cancerization	95 (95.0)
Disease duration [months (range)]	44.5 (1–323)
Histological confirmation [n (%)]	48 (48.0)
KIN I	3 (6.3)
KIN II	0
KIN III	45 (93.8)
NMSC in history	
basal cell carcinoma	30 (30.0)
squamous cell carcinoma	26 (26.0)
both	19 (19.0)
Mean number of therapies [n (range)]	3.7 (2–6)
Most recent therapy [n (%)]	
imiquimod	11 (11.0)
ingenol mebutate	16 (16.0)
5-FU	10 (10.0)
diclofenac-HA	11 (11.0)
daylight PDT	15 (15.0)
conventional PDT	11 (11.0)
surgical method	12 (12.0)
cryotherapy	14 (14.0)

ranged from 33 to 95 years with a median of 75.0 years (females 72.0 [45–84] years, males 76.0 [33–95] years). 63.0% of the patients were insured by statutory health insurance and 37.0% by private health insurance. 50.0% of the respondents provided details about their monthly net household income. This was below 1000 € in 2.0%, between 1001 and 2000 € in 22.0%, between 2001 and 3000 € in 26.0%, between 3001 and 4000 € in 22.0%, between 4001 and 5000 € in 10.0%, and above 5000 € in 18.0%. When comparing the health insurance status with the available monthly income, it was noted that the percentage of privately insured patients increases with increasing income, although in the group with the highest income almost the same number of patients was insured by statutory as by private health insurance. In 20.6% of the patients, the location of occupational activity was reported as "predominantly outdoors, outside of enclosed rooms". In 10.3% of these, a report of a suspected occupational disease of the skin pursuant to BK 5103 had been filed, and in 3.1% of the patients, a treatment order existed at the time of the survey.

Tumor data

When looking at the clinical distribution pattern and the histological severity in the patient collective, markedly advanced stages were apparent. 95 patients (95.0%) presented with field cancerization, and only 5 patients (5.0%) required treatment of solitary lesions. Histological findings were available for 48 patients (48.0%); 45 findings (93.8%) were classified as keratinocytic intraepidermal neoplasia (KIN) III, no finding as KIN II, and three findings (6.3%) as KIN I. In 52 patients (52.0), no histological diagnosis was performed, and the diagnosis was purely based on clinical appearance. The initial medical diagnosis of the disease had been made, on average, 44.5 months earlier (median: 37.0 months, range: 1–323 months). 30 patients (30.0%) had a history of basal cell carcinoma, 26 patients (26.0%) of cutaneous SCC, and 19 patients (19.0%) of both types of skin tumor (Table 1).

Quality of life

The quality of life in dermatological disease was assessed by DLQI. A median DLQI of 1 (mean: 2.27 ± 3.06, n = 98) was found. 55 patients (56.1%) reported that they experience no relevant impairment of their current quality of life due to the presence or treatment of AK (DLQI of 0 or 1). 34 patients (34.7%) reported mild impairment, five patients (5.1%) moderate impairment, four patients (4.1%) severe impairment, and no patient very severe impairment. Accordingly, a total of 89 patients (90.8%) reported that they experience at most a mild impairment of their quality of life due to AK or its treatment.

Treatment methods

Including the most recent therapy, each patient had received a median of 3.7 (2–6) different types of AK treatment in the past. Overall, 365 therapies had been performed in the collective. The most recently performed therapies (n = 100) divided as follows: ingenol mebutate 16.0% (no longer available on the German market since 01/2020), photodynamic therapy (PDT) with daylight 15.0% cryotherapy 14.0%, surgical therapy 12.0%, imiquimod (3.75% or 5%) 11.0%, diclofenac-HA 11.0%, conventional PDT 11.0%, 5-fluorouracil (5-FU; 5%) 10.0% (Table 1).

Treatment evaluation

The most recently performed therapy was evaluated by the patients with the TSQM (Table 2a, Figure 1). In the

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TABLE 2 (a) TSQM scores for the four different categories of overall satisfaction, effectiveness, complications and convenience (maximum value 100 each), mean value (standard deviation [SD]). (b) Mean treatment satisfaction measured on a Likert scale (1 = very satisfied, 6 = unsatisfactory) with SD.

A	*n = 100*	Overall satisfaction	Effectiveness	Complications	Convenience
Surgical methods	12	78.47 (± 16.07)	81.95 (± 14.14)	99.30 (± 2.40)	87.50 (± 14.04)
Daylight PDT	15	76.11 (± 24.77)	57.78 (± 31.25)	98.33 (± 4.67)	84.81 (± 13.84)
Ingenol mebutate	16	75.00 (± 16.10)	67.19 (± 25.54)	93.23 (± 9.73)	86.81 (± 17.43)
Imiquimod	11	74.24 (± 22.50)	68.18 (± 28.82)	92.42 (± 17.26)	84.34 (± 18.39)
5-FU	10	67.50 (± 27.90)	65.00 (± 26.29)	97.50 (± 5.63)	86.67 (± 17.01)
Cryotherapy	14	66.08 (± 14.42)	63.69 (± 15.19)	92.26 (± 17.74)	75.00 (± 15.52)
Conventional PDT	11	65.15 (± 25.77)	67.42 (± 23.11)	88.64 (± 10.72)	78.79 (± 18.06)
Diclofenac-HA	11	53.03 (± 22.13)	54.54 (± 21.85)	91.67 (± 11.78)	77.27 (± 16.75)
B		**n = 340**		**mean satisfaction**	
Surgical method		44		2.09 (± 0.91)	
Ingenol mebutate		54		2.46 (± 1.08)	
Daylight-PDT		34		2.62 (± 1.23)	
Imiquimod		43		2.67 (± 1.57)	
Cryotherapy		47		2.70 (± 1.10)	
5-FU		17		2.71 (± 1.21)	
Conventional PDT		49		3.00 (± 1.58)	
Diclofenac-HA		52		3.54 (± 1.55)	

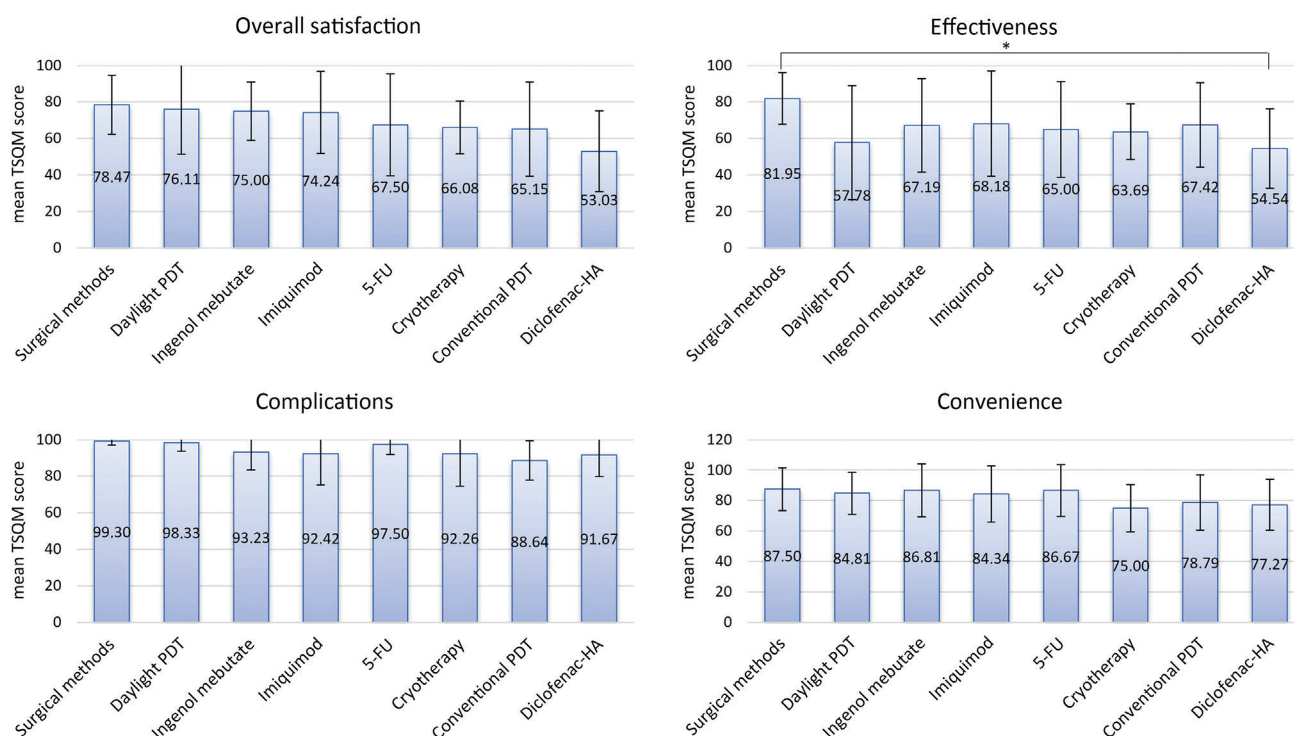

FIGURE 1 TSQM scores for the four different categories of overall satisfaction, effectiveness, side effects and convenience (maximum value 100 each). In the effectiveness category, there was a significant difference between "surgical methods" and "diclofenac-HA" ($p = 0.038$) ($n = 100$: surgical methods $n = 12$, daylight PDT $n = 15$, ingenol mebutate $n = 16$, imiquimod $n = 11$, 5-FU $n = 10$, cryotherapy $n = 14$, conventional PDT $n = 11$, diclofenac-HA $n = 11$).

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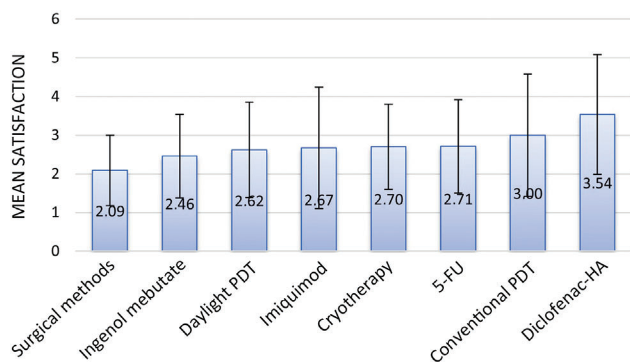

FIGURE 2 Mean treatment satisfaction measured on a Likert scale (1 = very satisfied, 6 = insufficient) with SD (n = 340: surgical methods n = 44, Ingenol mebutate n = 54, daylight PDT n = 34, imiquimod n = 43, cryotherapy n = 47, 5-FU n = 17, conventional PDT n = 49, diclofenac-HA n = 52).

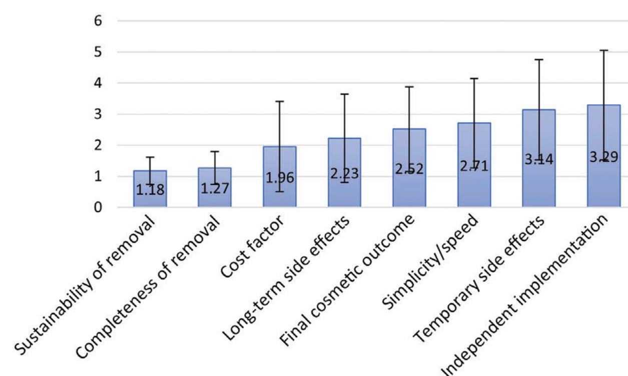

FIGURE 3 Therapy preferences surveyed using a Likert scale (1 = very important, 6 = not important) with SD (n = 100).

category "overall satisfaction", surgical methods achieved the highest score (78.47 ± 16.07), closely followed by daylight PDT (76.11 ± 24.77), ingenol mebutate (75.00 ± 16.10), and imiquimod (74.24 ± 22.50). Topical diclofenac-HA achieved the lowest score (53.03 ± 22.13). In the category "effectiveness", surgical methods achieved the highest score (81.95 ± 14.14), while diclofenac-HA achieved the lowest score (54.54 ± 21.85). In the category "complications", generally very high scores were achieved, indicating a low rate of side effects or minor impairment due to adverse drug reactions. Most complications were reported for conventional PDT (88.64 ± 10.72). In the category "convenience", surgical methods took again the first place with a score of 87.50 ± 14.04.

Post-hoc evidence for a significant difference at the 5% level was only found within the TSQM subcategory "effectiveness". Here, significance was obtained between surgical methods and topical diclofenac-HA ($p = 0.038$). No significant difference between therapies was found in the other categories.

In addition, treatment satisfaction regarding the individual procedures was measured on a Likert scale (in school grades) (Table 2b, Figure 2). Analogous to the evaluation of TSQM scores, surgical methods received the best rating (2.09 ± 0.91), followed by ingenol mebutate (2.47 ± 1.08). Conventional PDT (3.00 ± 1.58) and topical diclofenac-HA (3.54 ± 1.55) received the worst rating by the patients, although they still achieved a "satisfactory" result, while the ratings were in general relatively close to each other. Essentially, a correlating picture was observed, when comparing the achieved ratings with the reached TSQM scores. Only cryotherapy received a better rating in the Likert scale than in the TSQM. Furthermore, daylight PDT received a better rating than conventional PDT in both scenarios.

Patients' preferences

In addition, the patients were asked specifically for their treatment preferences in the form of direct questions (Figure 3). The results show that sustainable and complete removal of the lesions had the highest priority for the studied patient population (1.18 ± 0.44 and 1.27 ± 0.53, respectively). Costs, cosmetic outcomes, and chronic side effects represented secondary goals. The occurrence of temporary side effects and the possibility to perform the therapy independently were least important for the patients (3.14 ± 1.61 and 3.29 ± 1.76, respectively). No gender-specific differences were observed with respect to the order of preference. Concerning the insurance status, it was found that patients with private health insurance regarded the cost factor as less important than patients with statutory health insurance (2.31 ± 1.60 and 1.77 ± 1.33, respectively). Due to the low case number (n = 3), it was not possible to determine whether this parameter will shift if a treatment order from accident insurance providers, within the framework of occupational disease recognition, exists. Furthermore, it was observed that the absence of temporary and chronic side effects was more important for patients with DLQI ≥ 2 than for patients with a DLQI of 0 or 1. Against the background of the available, sometimes painful therapeutic options, the willingness to accept pain for the treatment was also addressed. 67 patients (67.68%, n = 99) reported that they favor a short, but painful therapy over a long-term, but gentle therapy. 59 patients (63.44%) specified topical therapy with cream or tincture as preferred type of treatment. Surgical interventions were only preferred by eleven patients (11.83%) (n = 93) (Figure 4). When asked about the preferred duration of treatment, preferred location of treatment (at home, office, clinic), and willingness to contribute to payment, no unusual responses were obtained, or the answers were very diverse.

DISCUSSION

In recent years, the importance of treatment satisfaction and the knowledge of patients' treatment preferences have been recognized as important parameters for adherence.[9–11] Satisfactory treatment of a disease can only be achieved with sufficient adherence. Particularly when

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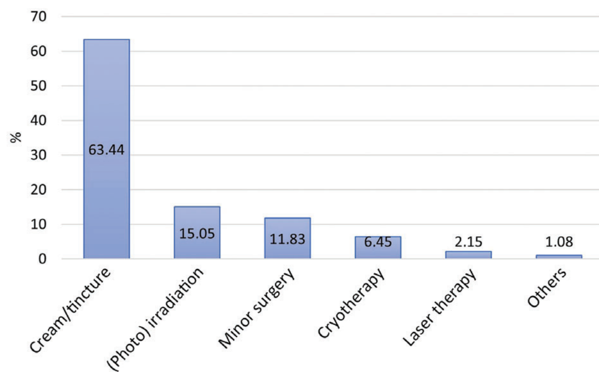

FIGURE 4 Patients' preferred type of treatment in percent (n = 93).

treating a disease that, like AK, is associated with only few acute problems, it is important to know and address the needs of the patients to provide them with optimal support during therapy. The requirement for patient orientation and the development of patient-oriented decision criteria is also becoming increasingly clear in the dermato-oncological literature.[15,16] New clinical trials usually include the collection of these parameters in their study design. However, a comparison between the various treatment options is not yet widely available. It was, therefore, the objective of our survey to have the common procedures used in the therapy of AK evaluated by the patients and to obtain at the same time insights into the needs of the patients.

As precancerous lesions of SCC, actinic keratoses require treatment, although it is currently not possible to predict their progression risk.[7] A range of therapies are known as treatment options. In Germany, an S3 guideline addressing and assessing the various options has been available since 2020.[17,18] At the same time, new procedures and topical agents are being developed (further) at breathtaking speed. Also, or especially against this background, knowledge of the patients' preferences in accordance with the objective efficacy of these drugs should, therefore, be contemplated upon. All therapeutic options analyzed in our survey had in common that they were rated consistently as good or satisfactory by the patients (school marks from 2.09 to 3.54) and that the quality of life of these patients was not impaired (median DLQI 1).

With a mean age of 75 years and a proportion of males of 81.0%, our collective corresponded largely to the average population for this disease. However, the majority of patients had field cancerization with longer disease duration and had received multiple therapies in the past, providing an explanation for the higher disease severity in our study population.

With its eleven questions, the TSQM depicts treatment satisfaction in the categories overall satisfaction, complications, effectiveness, and convenience in a standardized manner. In our survey, generally high scores ranging from 53.03 ± 22.13 to 78.47 ± 16.07 were achieved with respect to overall satisfaction. The TSQM has already been used in various studies to evaluate several of the assessed procedures and therapies. Consistent with our results, high scores for overall satisfaction were observed.[19–23] The results in the areas convenience (75.00 ± 15.52 to 87.50 ± 14.04) and complications (88.64 ± 10.72 to 99.30 ± 2.40) should also be emphasized. The patients consistently experienced their AK therapy as having few complications and not being too complex. Overall, *patient-reported outcomes* are increasingly included in clinical trials and non-interventional studies, as the importance of these parameters moves further into focus. Independent comparative studies with an overview of approved procedures are scarce.[22,24–27] The procedures receiving particularly good ratings in our survey, such as surgery, ingenol mebutate, and daylight PDT represent short treatment regimens. In large comparative therapeutic studies, the shorter procedures (PDT and ingenol mebutate in Jansen et al.; surgery and PDT in Ahmady et al.) were also associated with higher adherence.[27,28] It is plausible that these are preferred by patients if the treatment success is high and the side effect rate is low. Presumably, conventional PDT with a relatively short regimen received a significantly poorer rating because of the considerable pain.

When the procedures with good ratings are compared with the general patient preferences of our collective, it soon becomes apparent why surgical therapies emerge as favorites. Complete removal of the lesion and freedom from recurrence were specified as primary goals. This is also reflected by data of Steeb et al. on a total of 403 German AK patients,[29] and contrasts with therapeutic studies where cosmetic outcome was often preferred over freedom from recurrence.[27,28] The paradigm shift from acute disease to chronicity of AK or field cancerization should, therefore, play an important role in patient education to set the therapeutic goals realistically. Future information campaigns should address the fact that regular treatment will be required. In contrast to the high satisfaction scores for surgical procedures, the specific question on the preferred type of therapy reveals a desire for topical options. A conceivable – in practice, already often used – treatment pathway that would meet the patient's wishes would, therefore, be the downgrading of lesions with topical agents with subsequent surgical treatment of recalcitrant residual lesions.[30]

Limitations of the presented data are primarily the collective of our severely affected clinic patients, which restricts the transferability to all patients with AK. Moreover, it would be desirable to have even larger groups available for evaluation in the future. Due to the lack of a sufficient number of available patients, some procedures, such as laser therapy or peeling, were not assessed. In addition, newly approved therapeutic options, such as simulated daylight PDT or 4% 5-fluorouracil, are now available.

In summary, our collective of patients with pronounced AK prefers short therapeutic regimens with few side effects, but only if they also have a sustainable effect. Especially in the collective of severely affected patients, personalized medicine with implementation of procedures tailored to the patients' needs is essential.

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CONFLICT OF INTEREST STATEMENT

B.M.L. received honoraria and/or travel allowance from Almirall, Biofrontera, Galderma, LeoPharma, Pierre Fabre, and Meda. S.G. received honoraria, research support, and/or travel allowance from BMS, MSD, Sun Pharma, Novartis, Pierre Fabre, Klinge Pharma. P.S. received honoraria, research support, and/or travel allowance from Leo Pharma, Almirall, Galderma, Novartis, Klinge Pharma, Pierre Fabre. S.Z. and H.S. declare no conflicts of interest.

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