DOI: 10.1002/ski2.388

RESEARCH LETTER

SKIN HEALTH AND DISEASE Open Access

The development and validation of a decision aid to enhance shared decision-making for the management of actinic keratosis

Abstract

Actinic keratoses (AKs) are common pre-malignant lesions. There are numerous management options including active surveillance, multiple topical therapies, cryotherapy, curettage and cautery, and photodynamic therapy, each with their own risks, benefits and efficacy. Best practice currently involves shared decision-making between patient and clinician, particularly in the setting of multiple management options. Patient decision aids have been shown to be beneficial in the shared decision-making process. In view of this, we have developed and validated a decision aid for the management of AKs, in concordance with the International Patient Decision Aids Standards.

1 | INTRODUCTION

Actinic keratoses (AKs) are pre-malignant keratotic lesions typically found on sun-exposed areas of skin. They are highly prevalent, with nearly a quarter of adults aged over 60 having at least one AK.[1] Management options include active surveillance, topical therapies such as diclofenac sodium, 5-fluorouracil and imiquimod, focal destructive treatment such as cryotherapy or curettage and cautery, and photodynamic therapy.[1,2] 5-fluorouracil and cryotherapy are commonly used first-line. A number of studies have evaluated these management options. Jansen et al conducted a randomised controlled trial comparing 5% fluorouracil cream, 5% imiquimod cream, methyl aminolevulinate photodynamic therapy (MAL-PDT), and 0.015% ingenol mebutate gel.[2] The primary outcome was the proportion of patients with a reduction of 75% or more in the number of actinic keratosis lesions from baseline to 12 months post-treatment, with fluorouracil found to be the most effective. Szeimies et al compared MAL-PDT with cryotherapy in a prospective, randomised study, finding that MAL-PDT had a similar response rate to that of cryotherapy, but superior cosmetic results and high patient satisfaction.[3] The British Association of Dermatologists (BAD) published guidelines for the management of AKs in 2017.[1] In addition to these treatments, active surveillance is also credited as a valid management option for AKs in lower risk groups. Costing information for the topical treatments are as follows: diclofenac sodium = £38.30 per 50 g tube, 5-fluorouracil = £32.90 per 40 g tube, and imiquimod 5% = £48.60 per 12 sachets.[4] For the procedures, cryotherapy = £142.00 per patient, curettage and cautery = £142.00 per treatment, and PDT = £458 per treatment as per the 2023—2025 National Health Service (NHS) Payment Scheme, excluding the market forces factor.[5]

The risks and benefits for each treatment option vary widely, and tailoring the management to the individual patient is key to optimising outcomes and patient satisfaction. Best practice involves shared decision making between patient and clinician, particularly in this setting where there are multiple management options. Patient decision aids (PDA) have been shown to be beneficial in the shared decision-making process, enabling patients to consider the advantages and disadvantages of the available treatment options whilst developing their own knowledge.[6–8]

2 | REPORT

A clinical need for a decision aid on AK management for patients was identified. Between December 2022—August 2023 we developed a novel PDA amongst clinicians and dermatology nurses across the South West London region, in concordance with the International Patient Decision Aids Standards.[9,10] Ethics approval

Actinic Keratosis Treatment Decision Aid

	No treatment	A cream called Diclofenac sodium (Solaraze 3% gel)	A cream called Fluorouracil (Efudix 5% cream)	A cream called Imiquimod (Aldara 5% cream)	Freezing (Cryotherapy)	A surgical treatment called curettage and cautery	A light treatment called Photodynamic therapy (PDT)
What does it involve?	You don't have to treat AKs, you can just keep an eye on the area. Treatment can be started in the future if there are any concerning changes.	Putting this cream on the affected area twice a day for 60-90 days.[1]	Putting this cream on the affected area, once or twice a day for four weeks.[2]	Putting this cream on to the affected area, usually three times a week for four weeks.[3]	Cold liquid nitrogen is sprayed on to the affected area for 5 – 20 seconds. Sometimes this is repeated after a few weeks.[4]	The area is numbed with a needle injection and the AK is scraped off (curettage) with a sharp tool. Heat is applied (cautery) to seal the skin surface.	A cream is applied to the AK before placing it under a special type of light. This takes several hours to complete. One session is usually enough, but two are sometimes needed.
Who will administer this treatment?	You just keep an eye on the area yourself.	You can usually get this cream from your GP.	You can get this cream from your dermatology department. Sometimes GPs can prescribe it.	You can get this cream from your dermatology department.	Your dermatology department can provide this treatment. Some GPs can perform it too.	Your dermatology department will usually perform this treatment. Some GPs can do this too.	Some dermatology departments can do this treatment.
How does this treatment work?	You just keep an eye on the area yourself.	We don't fully understand how it works, but we think it might be because of its anti-inflammatory effects.[4]	It destroys sun-damaged cells in the skin.[4]	It encourages the body's own immune system to destroy the abnormal cells.[4]	This freezing is basically a cold burn which destroys the skin cells in the area and healthy cells develop afterwards.	The abnormal cells are surgically scraped off the skin.	The abnormal cells are damaged by the light and die off.[5]
How successful is it?	Around 1 in 5 AKs may improve on their own.[4]	At 3 months after treatment, 52% of patients are clear.[6]	At 3 months after treatment, 91% of patients are clear.[7]	At 3 months after treatment, three quarters (75%) of patients are clear.[7]	At 3 months after treatment, three quarters (75%) of patients are clear.[8]	It's estimated that the chance of complete clearance is about 95 - 99%, however we don't know much about recurrence rates.[9]	At 3 months after treatment, just over three quarters (76%) of patients are clear.[7]
What are the risks and side effects? Percentage of patients affected is in brackets.	There is a 0.075% (75 in a thousand) chance that the untreated AK could become a skin cancer over a one-year period. This risk increases when there are multiple AKs or wide areas of AKs.[10]	The main side effects include scaling (60%), dry skin (53%), redness (46%), crusting (33%), itching (13.3%) and discomfort (13.3%). It is generally tolerated better than the other creams.[11] These effects are usually less severe than the other cream treatments.	Common side effects are redness (82%), itching (62%), crusting (57%), burning sensation (48%), scaling (44%), broken skin (40%), pain (32%), swelling (30%) and blisters (24%).[7] For the medication to work, a reaction has to happen.	The main side effects are significant redness (73%), crusting (69%), itching (61%) broken skin (48%), swelling (44%), scaling (42%), a burning sensation (35%), blisters (31%), and pain (27%).[7] Some people also experience flu-like symptoms.[4]	Side effects vary. Most patients will experience mild to moderate pain for a few seconds during the treatment. It's common to develop a patch of lighter skin in the treatment area, and in dark skinned patients the area can become darker.[12] Sometimes, you might have a scar.	There will be some discomfort when the anaesthetic is injected, but then the area will go numb. Some patients may experience a small amount of bleeding from the wound afterwards. There is a small risk of infection after the procedure. You will be left with a scar roughly the same size as the AK.	The commonest side effects during treatment are a burning sensation (86%) and pain (80%).[7]
What will the area look like after treatment?	N/A	The area may be red and sore initially, and then gradually return to normal.	The area will be red and sore initially, and then gradually return to normal. When healed, there should be normal skin without AK. Redness can sometimes persist.	The area will be red and sore initially, and then gradually return to normal. Redness can sometimes persist.	Initially the area will look unchanged. Over the next few days a scab may form, which can take a few weeks to fall off. Some people develop a blister which heals over some time.	You will initially have a round flat wound, which will form a scab and then heal over 2-3 weeks. It may be red and sore initially.	The area may look red and inflamed for the first 48 hours.
How long will it take for my skin to go back to normal?	N/A	Complete healing may take up to 30 days after you've finished applying the cream.[13]	Complete healing may take one or two months after you've stopped applying the cream.[14]	Complete healing may take one or two months after you've finished applying the cream.[15]	Over the long term, the area may become pale and sometimes a scar may form.	There will be a round scar, the size of the AK. This will look paler than surrounding skin and may be a little sunken in.	After the first 48 hours the skin will start to peel and then heal over the next few weeks.
What else do I need to know about this treatment?	Continue to take precautions against sun damage: wear sunscreen and protective clothing.	This will normally be issued by your GP.	The cream can be toxic to pets if they lick it.			The sample will be sent off for analysis, and you will be informed of the result.	Between April and October, daylight PDT may be an option. The cream is applied but instead of using the machine, you sit outdoors for 2-3 hours which uses natural sunlight to achieve the same effect.

- **So, what's the most effective treatment?** If we exclude surgical treatments, several studies have shown that Efudix works better than the other treatments for AKs, and is usually a first-line treatment option.
- **Which treatment is the fastest?** Cryotherapy takes a few seconds to do and doesn't need anaesthetic. It may be a good option if a scar isn't much of a concern and you just want a treatment that is over and done with quickly.
- **Which treatment gives the best appearance?** Creams are best for this, especially gentler ones such as Solaraze. Photodynamic therapy also gives a good appearance following treatment.
- **What if you have a thick/lumpy (hypertrophic) AK?** You will usually be recommended to have curettage and cautery, which is the best treatment for this type.
- **How can I prevent further AKs?** Sun protection with long-sleeved clothing, hats, and at least SPF 30 sunscreen is important. You can find further information on sun protection measures on the British Association of Dermatologists' patient information leaflet with the following link: https://www.bad.org.uk/pils/actinic-keratoses/

Scan me on your phone for information about AKs

FIGURE 1 Actinic keratosis patient decision aid.

was not required. A literature search was undertaken to ensure evidence-based information was provided on the PDA.

Following creation of the initial draft PDA, alpha testing was conducted with feedback from clinicians and patients. A questionnaire was provided to five

consecutive patients to establish whether the PDA was easy to read and understand, contained an appropriate volume of information, and inviting any further comments (Supplementary Figure S1). This prompted minor formatting changes including creating a colour version to improve readability, and removing a paragraph explaining what AKs are and replacing this with a quick-response (QR) code link to the BAD information leaflet on AKs. As the average reading age of the UK has been estimated at 11–16 years old, we used simple language and utilised the Gunning Fog Index to confirm readability of the text for someone aged 12.[11]

The final PDA (Figure 1) underwent beta testing using two validated outcome measures, the Decisional Conflict Scale (DCS) and the nine-item Shared Decision-Making Questionnaire (SDM-Q-9).[12,13] We used the PDA in 21 consecutive patients across three separate Hospital Trusts in dermatology clinics for patients over 18 years of age diagnosed with one or more AKs clinically or histologically. Patients where there was any suspicion of squamous cell carcinoma, or had tender or hypertrophic AKs were excluded. The DCS questionnaire was first given to the patients following diagnosis, but before the discussion of management took place. The patient was given time to read the PDA outside the clinic room. After the consultation was completed and a management plan agreed upon, a post-consultation DCS questionnaire was performed. The SDM-Q-9 was completed last to establish the effect the PDA had on shared decision-making.

Data were obtained from 21 consecutive patients who met the inclusion criteria. One patient was subsequently excluded due to filling in the questionnaires incorrectly. 10/20 (50%) of patients were men. 15 patients had data on their age, with mean ages 69 years for men and 59 years for women. The majority of patients (75%) indicated a high level of decisional conflict prior to using the PDA, with a total mean DCS score of 52.97 (95% CI 43.2–62.8), where an increasing value corresponds with increasing decisional conflict. Following use of the PDA, the total mean DCS score improved to 12.97 (95% CI 8.0–17.9). This represents a significant reduction in DCS score ($p < 0.0001$), with the majority of responses as "strongly agree" and "agree" that the PDA facilitated their management decision. The largest improvement between pre- and post-PDA scores was seen in the "uncertainty" subscale, demonstrating the PDA improves the clarity, certainty and ease in which patients are able to make a decision on their treatment. The total SDM-Q-9 score was 791/900 (87.9%) which indicates a high level of shared decision-making following use of the PDA. No further changes were made to the PDA. References used within the PDA are included separately (Supplementary Table S1).

There are some limitations to our study. The literature on the management of AKs is heterogenous with varying inclusion and exclusion criteria, endpoints, and outcomes measures. We included only high-quality prospective studies and randomised controlled trials, and used our judgement in assessing these when creating the PDA. We excluded topical tirbanibulin (Klisyri®) due to limited experience among our clinicians and lack of long-term data, and 5-fluorouracil plus salicylic acid (Actikerall®) due to its uncommon use. The PDA was validated in the secondary care setting, and further studies would be required to assess its use in primary care. However, we suggest it may be useful at the interface between the two such as with Advice and Guidance services. Finally, this patient decision aid is not intended to be used for all patients, and should be used when appropriate for the clinical context.

Actinic keratoses can be managed in various ways and the information given to patients can be overwhelming which may make the decision more challenging. A PDA given to the patient can reduce decisional conflict and improve the shared decision-making process. We suggest that this novel validated decision aid can be used in various settings to facilitate informed care, particularly in secondary care in dermatology specialist nurse and physician-led clinics. Additionally, the PDA can be used at the interface of primary and secondary care when responding to Advice and Guidance queries. Further studies would be useful to assess the PDA in a primary care setting, and on its effectiveness in Advice and Guidance services.

ACKNOWLEDGEMENT

Not applicable.

CONFLICT OF INTEREST STATEMENT

None to declare.

AUTHOR CONTRIBUTIONS

Geoffrey Brent: Conceptualization (supporting); data curation (equal); formal analysis (equal); investigation (equal); methodology (equal); project administration (lead); validation (equal); writing—original draft (lead); writing—review and editing (equal). **Caroline Beardmore**: Project administration (supporting); writing—original draft (equal); writing—review and editing (supporting). **Kate Mayers**: Data curation (equal); investigation (supporting); writing—review and editing (equal). **Alberto Barea**: Conceptualization (supporting); methodology (equal); writing—review and editing (equal). **Venura Samarasinghe**: Conceptualization (supporting); methodology (equal); writing—review and editing (equal). **Vanessa Pinder**: Conceptualization (supporting); methodology (supporting); writing—review and editing (equal). **Julia Soo**: Conceptualization (supporting); methodology (supporting); writing—review and editing (equal). **Victoria Akhras**: Conceptualization (equal); data curation (equal); investigation (equal); methodology (equal); validation (supporting); writing—

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FUNDING INFORMATION

This article received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Not applicable.

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