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Randomized-Controlled Trial Comparing Safety and Efficacy of Repairing Balm Versus Topical Antimicrobial for Post-Procedural Wounds

Charles W. Lynde MD FRCPC,[a] Anneke Andriessen PhD,[b] Lyn Guenther MD FRCPC,[c] Nour Dayeh,[d] Sandra Skotnicki MD FRCPC,[e] Simon Nigen MD BPharm FRCPC,[f] Gary R. Sibbald MD FRCPC MACP FAAD MEd FAPWCA[g]

[a]Department of Medicine, University of Toronto, Toronto, ON; Lynderm Research, Markham, ON, Canada
[b]Radboud University Medical Center, Nijmegen, The Netherlands; RBC Consultants, Malden, The Netherlands
[c]Dermatology, Western University, London, ON; Guenther Research Inc London, ON, Canada
[d]Employee of L'Oréal, Montreal QC, Canada
[e]Department of Medicine, Divisions of Dermatology and Occupational and Environmental Health, University of Toronto, Toronto, ON, Canada; Bay Dermatology Centre, Toronto, ON, Canada
[f]Division of Dermatology, Department of Medicine, McGill University, Montreal, QC, Canada; Sima Recherche, Université de Montréal, Montreal, QC, Canada
[g]Project ECHO Ontario Skin and Wound. Medicine and Public Health, University of Toronto, Toronto, ON, Canada

ABSTRACT

Background: Actinic keratoses (AK) are pre-cancerous, intraepidermal lesions that exist on a continuum with squamous cell carcinoma. Cryotherapy using liquid nitrogen freezing is the most common method for treating AKs. Following cryotherapy, wound care often involves antimicrobial ointments as prophylactics against infection. However, given the rise in antibacterial resistance and possible contact dermatitis, equivalent alternatives should be identified. Cutaneous wound healing is important in dermatologic conditions.

Objective: Evaluate the safety (adverse events) and efficacy (erythema and oozing/crusting, speed of recovery) of post-procedural wound healing of AK lesions, when using either a topical antibiotic (PSO), or a nonprescription repairing balm containing panthenol, madecassoside, and metal salts (CB5).

Methods: A multicenter, intra-individual, randomized control trial was conducted. Sixty participants with at least 3 AK lesions on each arm were enrolled. Following cryotherapy, 3 lesions were selected on each arm for study and control treatment. The treatment of the right or left arm was randomly assigned to either the control group (PSO) or the investigational group (CB5), so that each subject participated in both the investigational and control arms. At each visit, the physician assessed the skin condition (erythema, oozing/crusting) and adverse events, and subject satisfaction was recorded.

Results: There were no clinically significant differences in time to lesion healing, erythema, or oozing/crusting between groups. On day 21, 100% of patients agreed that their lesions had improved. No adverse events related to the study products were reported throughout the trial.

Conclusion: Post-procedural treatment with CB5 and PSO demonstrated equivalent wound healing in participants undergoing liquid nitrogen cryotherapy for AKs without the potential for further adverse effects.

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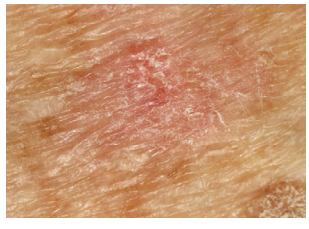
INTRODUCTION

Actinic Keratosis And Cryotherapy

Actinic keratosis (AK) is a concern worldwide and is associated with an increased risk of development of non-melanoma skin cancer.[1] Chronic sun exposure plays a central role in its pathogenesis.[2] AKs are among the most common skin lesions, accounting for a significant proportion of primary diagnoses made in dermatological practice. Relatedly, the treatment of AKs is the most common procedure performed in dermatology.[3] The prevalence of AKs has been estimated to be between 40 to 60% of the fair-skinned population aged > 40 years, with the average patient having six to eight lesions.[4] Clinically, AKs present as red, scaly macules and papules (Figure 1). In some cases, they

FIGURE 1. A typical case of actinic keratosis. Photo courtesy of *DermNet.*



may be pigmented, lichenoid, or present as a cutaneous horn. In addition, the skin surrounding AKs often displays signs of sun damage (eg, lentigines, freckles, wrinkles).[5] Therefore, AKs also pose an aesthetic problem. Several guidelines concerning AK treatment have been published in the past years.[2,3] Available treatments include lesion- and field-directed therapies. Lesion-directed treatments eliminate atypical keratinocytes in single AKs, while field-directed therapy aims to treat multiple AKs in the field of cancerisation.[5]

Cryotherapy using liquid nitrogen freezing is the most common method for treating isolated AKs.[6,7] Its mechanism of action is based on the destruction of abnormal tissue through cold-induced apoptosis. This treatment option has been proven to effectively destruct AKs while being minimally invasive, well-tolerated (ie, complication rates are low), and cost-effective. A use and cost analysis of AK destruction in the United States revealed more than 35.6 million AK lesions were treated in 2015, increasing from 29.7 million in 2007. Averaged across the assessment period, annual Medicare charges for AK treatment totaled $564.7 million; and in 2015, payments for AK destruction comprised 14.8% of the $2.5 billion expenditure devoted specifically to dermatology.[8]

Aftercare

Wound care remains an important component of attaining positive outcomes after routine dermatologic procedures, and with the incidence of AKs and skin cancer (and thus abnormal tissue excisions) on the rise, optimizing post-procedural wound care becomes paramount.[9,10] Appropriate wound care promotes healing and prevents infection. Topical antibiotics are commonly prescribed for application to post-procedural wounds as prophylaxis against infection. However, topical antibiotic use is often based on anecdotal perception and scientific dogma. Previously, authors have noted that the use of topical antibiotic therapy is supported by a conspicuous absence of scientific evidence and little to no concentrated clinical observation.[11] This is a significant limitation of current clinical practice as these frequently applied adjunctive medications are not risk-free.

According to data on prescribing habits, United States dermatologists write 3 to 4 million topical antibiotic prescriptions each year.[10] The reasons for and methods of prescribing antibiotics have been scrutinized by government organizations and the medical, public health, and lay communities.[5,10] The increased emergence of antibiotic-resistant bacteria and the challenge of creating new antibiotics to combat the abundance of resistant microorganisms are the main causes of concern. Moreover, it is well established that contact dermatitis is an undesirable side effect that may result from using topical antibiotics, affecting up to 20% of patients.[12] As a result, a "call to action" has encouraged clinicians to reconsider how and when they prescribe antibiotics and become more judicious with their use in clinical practice. Nonetheless, post-procedural infections and antibiotic resistance are inseparable threats, and both contribute to a significant amount of deaths and disability-adjusted life-years worldwide. Strategies to address antibiotic resistance include employing preventative measures (eg, improved sanitation), avoiding inappropriate use of antimicrobials, and investigating nonpharmacological alternatives. Such measures generally reduce the frequency of antibiotic-resistant and antibiotic-susceptible infections equally.[13]

The most frequently used topical antibiotic agents contain compounds of several medications for adequate antibacterial coverage.[14] Bacitracin zinc/polymyxin B sulfate [Polysporin ointment (PSO)] is a commonly used compound of topical antibiotics. Bacitracin is a bactericidal isolated from *Bacillus sp.* bacteria. It disrupts various Gram-positive and Gram-negative bacteria by inhibiting cell wall synthesis. Although rare, there have been some reports of bacterial resistance to bacitracin in strains of *staphylococci*.[15] Individuals with a neomycin allergy may be predisposed to bacitracin-induced contact dermatitis, and rare occurrences of delayed hypersensitivity, acute IgE-mediated allergic reactions, and anaphylactic reactions have been reported following the use of bacitracin.[16,17] Polymyxins are similarly isolated from *Bacillus sp*, so there is potential for allergic cross-reactivity between polymyxin and bacitracin. Polymyxin's mechanism of action results in increased permeability of the bacterial cell membrane, which ultimately leads to bacterial lysis. Polymyxins are bactericidal against some Gram-negative bacteria, but their spectrum of activity is limited against most Gram-positive bacteria.[18] For this reason, manufacturers commonly combine polymyxin with zinc, bacitracin, or neomycin to increase the spectrum of activity.

Given the impetus to find equivalent non-antibiotic topicals suitable for use in post-procedural lesions commonly observed in dermatology practice, the current trial was designed to compare PSO to a nonprescription repairing balm [Cicaplast Balm B5 (CB5)]. CB5 contains different ingredients that could be important in human wound healing. One of these ingredients is madecassoside, a concentrated excerpt from the tropical plant Centella Asiatica, which has been shown to accelerate epidermal repair.[19] Moreover, it includes zinc and manganese, which are anti-bacterial agents; shea butter and glycerin for reconstituting the hydrolipidic film and moisturizing the skin; and 5% panthenol (vitamin B5), which acts as an anti-inflammatory and analgesic.[20]

MATERIALS AND METHODS

Study Design

This was a multicenter, intra-individual (left-right arm), randomized controlled trial. Six research sites participated in the trial. Blinded evaluators performed all safety and efficacy assessments related to post-procedural wound healing of AK lesions treated with liquid nitrogen.

Objectives

Evaluate the safety (adverse events) and efficacy (erythema and oozing/crusting, speed of recovery) of post-procedural wound healing of AK lesions treated with liquid nitrogen, when using either a topical antibiotic (PSO, control treatment), or a nonprescription repairing balm containing panthenol, madecassoside, and metal salts (CB5), investigational treatment].

Primary endpoint: Physician assessed time to lesion healing (ie, crust has gone), between groups.

Secondary endpoints:

- Physician assessed skin condition (erythema and oozing/crusting scores).
- Patient-reported pain, and handling features of the treatment regimens.
- Adverse events and serious adverse events were reported during the study.

Sample Population

Sixty (60) participants with at least three AK lesions on both arms were recruited. Three lesions per arm were assessed.

Procedures

Pre-study survey: To determine appropriate indications and contraindications for topical antibiotics for post-procedural wound care, physicians experienced in conducting procedures for AK removal were invited to participate in a survey in October 2022.

Study conduct: Table 1 provides an overview of study procedures. Baseline AK lesions were identified on clinical examination, and only those on the arms were selected for treatment. Methods for selecting lesions for inclusion in the evaluation were provided to physician-evaluators to ensure the sensitivity of the study design and accurately measure therapeutic response in both arms. For example, it was mandatory for lesion severity to be clinically similar (eg, degree of erythema, oozing/crusting) between both arms at baseline. Clinical evaluations were supported by confirming no statistically significant differences between the physician-scored lesion condition of both arms at baseline. All AK lesions of all enrolled participants were treated with liquid nitrogen cryotherapy according to the treating investigators' usual protocol. Following cryotherapy, the treating investigator recorded the location and size of the lesions using transparent acetate sheets. Each lesion was outlined and numbered (1-3) on the transparency sheets. Anatomic landmarks placed the sheets directly on the participant's skin and ensured consistent orientation between visits. Two-dimensional photographs were also captured at all visits.

Prior to randomization and administration of adjunctive therapy, and at all follow-up visits [weeks 1 (day 7) and 3 (day 21)] a blinded evaluator graded the severity of the lesions using a five-point grading scale for erythema and oozing/crusting (Table 2). Post-procedural wound care (control versus investigational treatment) was allocated within subjects and between the left and right arms using randomization (accounting for hand dominance). Each subject participated in both the investigational and control arms. Participants were instructed to use the adjunctive skincare twice daily (morning and night), after cleansing the areas with a gentle cleanser (Lipikar Syndet Cleansing Body Cream-Gel). Participants followed the adjunctive skincare regimen for 21 days or until the lesions healed. Participants were observed at up to four-time points: Screening (Visit 1), baseline (Visit 2, day of cryotherapy), day 7 (Visit 3), and day 21 (Visit 4). At all visits, participants reported their degree of

TABLE 1.

Study Procedures				
Visit # Timeline	Visit 1: Screening (Day -30 to 0)	Visit 2: Baseline (Day 0, Cryo-procedure and start of treatment)	Visit 3: Day 7 (+/-2 days)	Visit 4: Day 21 (+/-2 days)
Informed Consent	x	--	--	--
Medical History	x	--	--	--
Demographics	x	--	--	--
Physical Exam	x	--	--	--
Physician assessment of skin area using a [1]Clinical scale	x	x	x	x
Eligibility Assessment	x	--	--	--
Twice daily treatment and prevention measures	--	x	x	x
Subject Satisfaction Patient diary	--	x	x	x
Concomitant Medications	x	x	x	x
Assess AEs/SAEs	x	x	x	x
End of Study	--	--	--	x

Note: Screening and Baseline could be combined to occur on the same day.

TABLE 2.

Clinical Grading of Lesioned Skin (Erythema and Oozing/Crusting)		
Erythema		
Grade	**Severity**	**Description**
0	None	Healthy skin
1	Minimal	Scant, rare erythema
2	Mild	Pink coloration in some of the treatment areas
3	Moderate	Bright-red color involving some of the treatment areas, or pink-color involving all of the treatment areas
4	Severe	Areas of very red coloration, or bright-red coloration of all of the treatment areas
Oozing/Crusting		
Grade	**Severity**	**Description**
0	None	Healthy skin
1	Minimal	A single area of oozing or crusting 3 mm or less in size
2	Mild	More than a single area of oozing or crusting 3mm or less in size
3	Moderate	One or more areas of oozing and crusting larger than 3 mm in size
4	Severe	Congruent areas of oozing and crusting

pain in the treatment areas using a ten-point visual analog scale (VAS), a validated, subjective measure of acute or chronic pain. Scores of the VAS represent a continuum between "no pain" and "worst pain imaginable." At all follow-up visits, participants also reported their level of satisfaction with various treatment parameters. Additionally, at all visits adverse events (AEs) and severe adverse events (SAE) were assessed and documented if present.

Study Products

In the present trial, PSO was used as the control treatment, and CB5 was used as the active/investigational comparator.

Statistical Analyses

Statistical analyses were performed by a blinded and independent contractor using SPSS-IBM. Where appropriate, tests were carried out at the 5% significance level with paired sample tests. The confidence interval was set to 95%. Responses to a single item were treated as ordinal data.

Sample Size Calculation

A sample size calculation was performed for matched pairs using G*Power (Version 3.1.9.7), where the input parameters included: Tails = one; Effect size (dz) = 0.50; α err prob = 0.05; and Power (1-β err prob) = 0.95. The resulting output parameter revealed a necessary sample size of 45 participants. The sample size was increased to N = 60, to account for a possible dropout rate of up to 25% (n = 15 participants).

RESULTS

Initial Survey

A total of 450 (male 37%, female 63%) physicians responded to the survey [dermatology (51%), general practice (38%), medical aesthetics (19%), dermatosurgery (10%), others (10%)]. The majority of respondents indicated that while they do manage open superficial secondary intention healing wounds (85.19%) and sutured wounds (85.68%), they do not routinely use prophylactic antibiotics (78.45% and 89.24%, respectively). Before procedures, isopropyl alcohol (~40%) and chlorhexidine (~60%) are often applied to the surgical site. After the procedure, the most common method of cleaning the wound was with normal saline (~40%). Immediately post-procedure, applying Vaseline and/or a wound dressing were commonly reported. It was recommended by >50% of respondents to use sunscreen to improve results, once the wound has healed.

Study Sample

Of the sixty participants who received liquid nitrogen treatment for their AK lesions, eleven (18.33%) did not continue with randomization. Forty-nine patients (81.67%) between the ages of 59 to 92 (mean: 77.18) were randomized to either the control (n = 49 unilateral arms) or investigative (n = unilateral 49 arms) post-procedural treatment (34.7% male and 65.3% female). After the baseline visit, 3 participants were lost to follow-up. Forty-six (93.88%) participants completed the study (Figure 2).

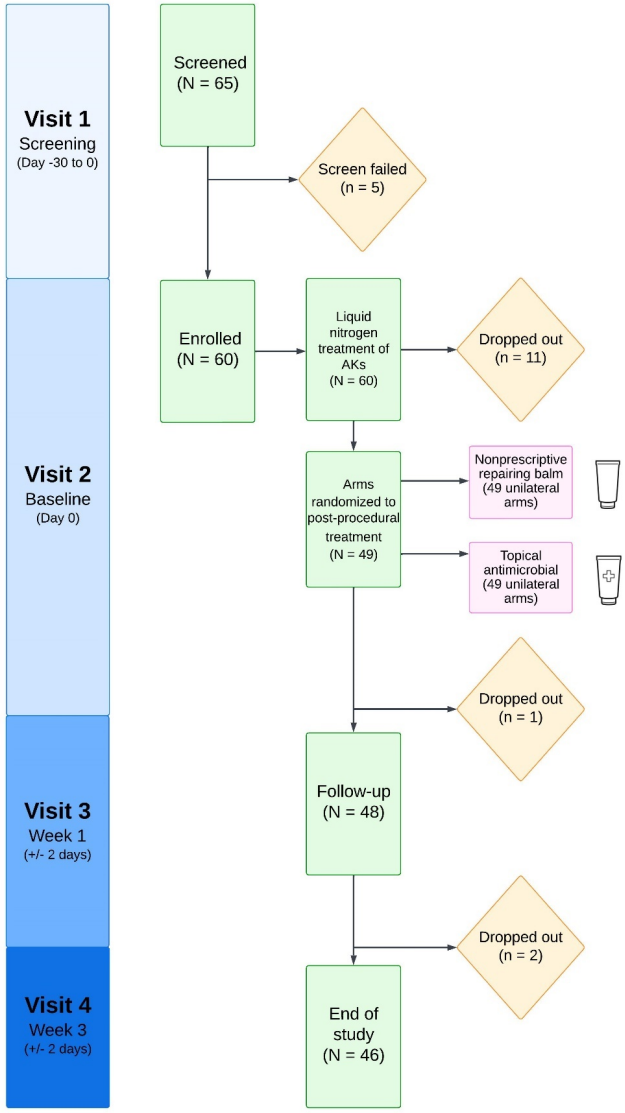
Physician Scored Lesion Healing

The total number of lesions treated in both groups was 276 [138 (50.0%) in the CB5 group and 138 (50%) in PSO]. When comparing groups for time to lesion healing, no statistically significant differences were observed (Tables 3 and 4).

Pain

All participants noted that pain resolved after day 1 post-procedure. At day 21, all participants agreed that their lesions had improved in appearance (erythema, oozing/crusting) since baseline (Tables 5 and 6).

FIGURE 2. Study flowchart.



AKs = Actinic keratosis lesions.

TABLE 3.

Physician Scored Lesion Condition at Baseline (Day 0)					
	Group 1 (PSO)		Group 2 (CB5)		*P*-value
Patients N = 46 Total number of lesions: N = 276 (100%) Lesions per group: n (%)	138 (50.0)		138 (50.0)		NS
	Left arm	Right arm	Left arm	Right arm	--
Lesions per arm: n (%)	N = 69 (n = 23)	N = 69 (n = 23)	N = 69 (n = 23)	N = 69 (n = 23)	--
Erythema score peri-lesion skin: mean (SD) Lesion 1: Lesion 2: Lesion 3	 1.27 (0.77) 1.27 (0.77) 1.27 (0.77)	 1.23 (0.75) 1.23 (0.75) 1.23 (0.75)	 1.29 (0.69) 1.25 (0.66) 1.25 (0.67)	 1.29 (0.69) 1.21 (0.59) 1.21 (0.59)	NS
Oozing/Crusting score peri-lesion skin: mean (SD) Lesion 1: Lesion 2: Lesion 3:	 0.36 (0.79) 0.36 (0.79) 0.36 (0.79)	 0.32 (0.72) 0.32 (0.72) 0.32 (0.72)	 0.33 (0.76) 0.25 (0.53) 0.21 (0.51)	 0.33 (0.76) 0.33 (0.76) 0.33 (0.76)	NS

TABLE 4.

Physician Scored Lesion Condition at Visit 3 (Day 7 +/- 2 days) and Visit 4 (Day 21 +/- 2 days)					
	Group 1 (PSO)		Group 2 (CB5)		*P*-value
Patients N = 46 Total number of lesions: N = 276 (100%) Lesions per group: n (%) Lesions per treated arm: n N = 69	138 (50.0)		138 (50.0)		NS
	Left arm	Right arm	Left arm	Right arm	--
Score at visit 3 – day	N = 69 (n = 23)	N = 69 (n = 23)	N = 69 (n = 23)	N = 69 (n = 23)	--
Erythema score peri-lesion skin: per treatment group: mean (SD)	2.30 – (0.75)		1.87 – (0.84)		*0.004
Erythema score peri-lesion skin: per treatment group and per arm: mean (SD)	2.18 (0.75)	2.42 (0.75)	2.09 (0.78)	1.65 (0.89)	*0.0059
Erythema score peri-lesion skin: mean (SD) Lesion 1: Lesion 2: Lesion 3:	 2.14 (0.77) 2.27 (0.70) 2.14 (0.77)	 2.41 (0.73) 2.50 (0.74) 2.36 (0.79)	 2.13 (0.68) 2.04 (0.75) 2.09 (0.90)	 1.71 (0.91) 1.63 (0.88) 1.61 (0.89)	 *0.006 *0.001 *0.004
Oozing/Crusting score peri-lesion skin: Per treatment group: mean (SD)	1.68 (1.11)		1.44 (1.05)		*0.005
Oozing/Crusting score peri-lesion skin: Per treatment group and per arm: mean (SD)	1.52 (1.19)	1.85 (1.25)	1.50 (1.09)	1.38 (1.00)	*0.005
Oozing/Crusting score peri-lesion skin: mean (SD) Lesion 1: Lesion 2: Lesion 3:	 1.55 (1.18) 1.59 (1.22) 1.41 (1.18)	 1.77 (0.92) 2.00 (1.07) 1.77 (1.07)	 1.58 (1.06) 1.50 (1.14) 1.43 (1.08)	 1.38 (1.06) 1.38 (0.92) 1.39 (1.03)	 *0.039
Score at visit 4 – day 21 (end)	Left arm	Right arm	Left arm	Right arm	--
Erythema score peri-lesion skin: per treatment group: mean (SD)	1.30 (0.69)		1.23 (1.01)		NS
Erythema score peri-lesion skin: per treatment group and per arm: mean (SD)	1.22 (0.68)	1.40 (0.70)	1.48 (1.03)	0.98 (0.66)	**0.054
Erythema score peri-lesion skin: mean (SD) Lesion 1: Lesion 2: Lesion 3:	 1.20 (0.62) 1.25 (0.71) 1.20 (0.70)	 1.40 (0.75) 1.50 (0.69) 1.30 (0.66)	 1.52 (0.99) 1.48 (0.99) 1.43 (1.12)	 1.00 (0.67) 1.04 (0.71) 0.91 (0.60)	 **0.038 **0.049
Oozing/Crusting score peri-lesion skin: Per treatment group: mean (SD)	0.25 (0.75)		0.32 (0.64)		**0.058
Oozing/Crusting score peri-lesion skin: Per treatment group and per arm: mean (SD)	0.17 (0.37)	0.35 (0.52)	0.36 (0.70)	0.26 (0.57)	**0.048
Oozing/Crusting score peri-lesion skin: mean (SD) Lesion 1: Lesion 2: Lesion 3:	 0.25 (0.44) 0.15 (0.37) 0.10 (0.31)	 0.30 (0.57) 0.40 (0.50) 0.35 (0.49)	 0.26 (0.54) 0.35 (0.78) 0.48 (0.79)	 0.22 (0.52) 0.30 (0.56) 0.26 (0.62)	 **0.04

TABLE 5.

Patient-Scored Lesion Condition at Baseline (Day 0)					
	Group 1 (PSO)		Group 2 (CB5)		*P*-value
Patients N = 46 Total number of lesions: N = 276 (100%) Lesions per group: n (%)	138 (50.0)		138 (50.0)		NS
	Left arm	Right arm	Left arm	Right arm	--
Lesions per arm: n (%)	N = 69 (n = 23/ n = 23/n =23)	N = 69 (n = 23/ n = 23/n =23)	N = 69 (n = 23/ n = 23/n =23)	N = 69 (n = 23/ n = 23/n =23)	--
AK lesions on your LEFT arm are oozing/ crusting: Mean (SD)	2.00 (1.07)	1.86 (0.99)	2.29 (1.30)	2.42 (1.21)	NS
Are the AK lesions included in the study painful? Yes = 1 No = 0	15	16	14	13	NS
Pain score: N mean (SD) on a 10-point VAS*	15 – 0.80 (1.27)	16 – 0.69 (1.20)	14 – 1.21 (2.12)	13 – 0.62 (1.45)	NS
Your AK lesions on your arms limit your daily activities. Mean (SD)	1.18 (0.40)	1.18 (0.40)	1.54 (0.98)	1.38 (0.65)	*0.005
Your AK lesions on your arms negatively influence your professional life. N – mean (SD)	1.18 (0.50)	1.18 (0.50)	1.35 (0.65)	1.39 (0.66)	NS

5-Point Likert scale: 1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly agree
*Numeric 10-point visual analog scale (VAS)
0 = no pain, 5 = insect sting type of pain, 10 = slamming the car door shut on your thumb.

TABLE 6.

Patient-Scored Lesion Condition at the End of the Study (day 21 +/- 2 days).					
	Group 1 (PSO)		Group 2 (CB5)		*P*-value ANOVA
Patients N = 46 *Total number of lesions:* N = 276 (100%) Lesions per group: n (%)	138 (50.0)		138 (50.0)		NS
	Left arm	Right arm	Left arm	Right arm	--
Lesions per arm: n (%)	N = 69 (n = 23/ n = 23/n =23)	N = 69 (n = 23/ n = 23/n =23)	N = 69 (n = 23/ n = 23/n =23)	N = 69 (n = 23/ n = 23/n =23)	--
AK lesions on your arm have improved: Mean (SD)	3.65 (0.99)	3.95 (1.00)	4.04 (0.88)	4.26 (0.62)	NS
I liked the smell of the product I used on the AK lesions on my arm: N – mean (SD)	3.25 (0.55)	2.95 (0.39)	3.22 (0.67)	3.43 (0.73)	*0.011 **0.004
I liked the texture of the product I used on the AK lesions on my arm: N – mean (SD)	3.20 (0.83)	3.20 (0.83)	3.09 (1,04)	4.00 (0.80)	**0.003
The product I used on the AK lesions on my arm felt good on my skin and did not sting: N – mean (SD)	2.65 (1,90)	2.85 (2.01)	3.35 (1.82)	3.39 (1.98)	NS

Safety

No AEs related to the study products nor SAEs were reported throughout the trial.

DISCUSSION

Wounds created secondary to dermatologic procedures are typically classified as either clean (Class I) or clean-contaminated (Class II). The prophylactic use of topical antibiotics for Class I or II wounds is no longer recommended by guidelines.[21-23] In addition, numerous studies have demonstrated cost- and risk-benefit analyses against antibiotic prophylaxis in this group.[22,24] In line with these recommendations, the majority (> 75%) of surveyed physicians who treat AKs indicated that they do not routinely use prophylactic antibiotics.

Importantly, there is no definitive evidence to show that the practice of using topical antimicrobials as prophylaxis for Class I or II wounds is of clinical benefit.[23] Previously, an evaluation of ~6000 dermatologic procedures reported the rate of postoperative wound infection to be extremely low (ie, 1.3%).[16] Even the use of extensive cryosurgery (ie, cryo-peeling) over large surface areas has an excellent safety profile.[3] In fact, there has been only one case of an infection secondary to liquid nitrogen cryotherapy for AKs reported in the literature.[25] Furthermore, most of the wound infections that develop in this setting are mild and easily treated, frequently with basic wound care management alone and without antibiotics.[26] When considering the low post-procedural infection rate reported after office-based dermatologic procedures, and the prevalence of bacitracin-induced allergic contact dermatitis (8%), it becomes apparent that routine prophylactic use of topical antibiotics may not be supported.[16,26] Yet a number of providers continue to use topical antibiotics in postoperative care of clean surgical wounds.[27] Thus, it has become necessary to investigate equivalent, non-antibiotic alternatives for topical post-procedural wound care.

CB5 has been used as an auxiliary in wound healing after many different dermatological procedures. For example, it has been shown to be safe and effective for use in skin healing after high-energy laser application,[17] microneedling,[28] Intense Pulsed Light treatment,[20] and pulsed radiofrequency.[29] In consideration of its many beneficial properties, CB5 has been referred to by investigators as barrier repairing, lipid regenerating, and moisturizing.[19] In the present equivalency trial, post-procedural wounds occurring after cryotherapy were treated successfully with brief courses of topical PSO and CB5. It was shown that PSO was not superior to CB5 for overall time to lesion healing. Prophylaxis PSO is (i) not definitively superior in preventing infection, (ii) is more expensive and represents a significant cost to the health care system, (iii) is a common cause of allergic contact dermatitis (iv) does not improve wound healing, as compared to CB5, and (v) may promote wound infections caused by pathogens that may be more problematic or costly to treat (eg, gram-negative bacilli) and lead to antibiotic resistance. [14,16] For these reasons, CB5 is recommended in place of topical antibiotics for post-procedural use in Class I and Class II wounds. Importantly, this recommendation aligns with the Call to Action to limit the use of prophylactic antibiotics in dermatology.[22]

Strengths, Limitations, and Future Directions

The findings of this study reinforce the message that Class I and Class II wounds do not require prophylactic antibiotics.[22,30-32] However, their use in contexts that fall outside the scope of this study (eg, in immunocompromised or trauma patients) remains controversial. Moreover, as Class III (contaminated) and IV (infected) wounds were excluded from the sample, the authors recommend that therapeutic antibacterials be used for such lesions.

As most physicians in this study reported not routinely managing open, superficial, secondary intention wounds or sutured wounds with prophylactic antibiotics, a potential sampling bias may be present. Therefore, collecting additional survey information, such as how specific procedural settings, patient demographics, or pre-existing conditions influence providers' decisions regarding prophylactic antibiotic use, may have been useful.

Future studies could investigate the use of CB5 for skin healing following common dermatological procedures other than cryotherapy, such as aesthetic treatments (eg, energy-based devices, injectables).

CONCLUSION

Post-procedural treatment with CB5 and PSO demonstrated equivalent wound healing in participants undergoing liquid nitrogen cryotherapy for AKs. Therefore, CB5 repairing balm should be considered an effective and safe alternative to topical antibiotics for post-cryotherapy skincare.

DISCLOSURES

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AUTHOR CORRESPONDENCE

Anneke Andriessen PhD

E-mail:..... anneke.a@tiscali.nl