Review article

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CPD

Use of nicotinamide in dermatology

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Summary

Nicotinamide (niacinamide) is the water-soluble, amide form of vitamin B3. We review the evidence underlying the use of nicotinamide for various dermatological indications, including nonmelanoma cancer prophylaxis, blistering disorders, acne vulgaris and cosmetic indications, and speculate upon its future role in dermatological practice.

Introduction

Nicotinamide has a long heritage of use in dermatology. In addition to its role in blistering diseases and acne vulgaris, recent interest in its use has focused on its chemopreventative role in nonmelanoma skin cancer (NMSC) and cosmetic applications.[1] We provide a contemporary review of the applications of nicotinamide in dermatology, and evaluate the evidence underlying these uses. Only studies on humans are included (Table 1).

Nicotinamide (niacinamide) is the water-soluble, amide isotype of vitamin B3; niacin (nicotinic acid) is the corresponding acid isotype.[1] Nicotinamide is sourced from the diet, and a lack of this vitamin can cause pellagra, presenting with the triad of dementia, dermatitis and diarrhoea. Dietary sources of nicotinamide include meats, liver, yeast, dairy products, legumes, beans, nuts, seeds, green leafy vegetables, fortified bread, cereals, coffee and tea.[2]

Nicotinamide is the catalyst for multiple molecular reactions throughout the body, and is converted into several coenzymes, including nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP), both of which are essential for metabolism. Also of note is the inhibitory effect of nicotinamide upon poly-ADP-ribose-polymerase (PARP)-1, granulocytes and multiple molecules within the cell signalling cascade, including intercellular adhesion molecule-1, major histocompatibility complex II, interleukin (IL)-1, IL-12, tumour necrosis factor-α and macrophage migration inhibitory factor-1. Importantly, PARP-1 activity helps regulate DNA repair, but if not rigorously controlled (by nicotinamide-mediated inhibition), mutations and cellular dysfunction can ensue.[3] PARP-1 activation enhances DNA repair through interaction with p53 protein, causing cell-cycle cessation and enabling DNA repair enzymes to access damaged DNA. When DNA damage is irreparable, PARP-1 activation induces apoptotic cell death by activating the nuclear factor κB pathway and preventing adenosine triphosphate (ATP) depletion and DNA repair through caspase-mediated PARP-1 cleavage.[2]

Nicotinamide and niacin differ in their isomeric forms, and consequently their adverse effect (AE) profiles are distinct. Nicotinamide can cause flushing and headaches, but less frequently than niacin. Infrequent AEs include fatigue, blurred vision and gastrointestinal disturbances. Daily doses of up to 3 g are generally well tolerated.

Use of nicotinamide as prophylaxis against NMSC

There have been several randomized controlled trials (RCTs) on the use of oral and topical nicotinamide as prophylaxis against NMSC.[2,4] The largest trial to date comprised 386 patients and found a 23% reduction ($P = 0.02$) in development of new NMSCs (30%

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reduction in development of new squamous cell carcinomas, 20% reduction in new basal cell carcinomas) with oral nicotinamide 500 mg twice daily for 12 months versus placebo. Importantly, the benefits stopped on discontinuation of treatment.[4] In a study of 24 immunosuppressed renal transplant recipients randomized to receive nicotinamide (250 mg three times daily) or placebo, nicotinamide appeared to reduce incidence of actinic keratoses and prevent worsening of photodamage.[5]

The ability of nicotinamide to protect against NMSC is attributed to its ability to hinder immunosuppression caused by ultraviolet (UV) radiation and prevent oxidative stress secondary to UV rays.[6] As a precursor of NAD, nicotinamide is also thought to prevent UV-induced depletion of ATP in keratinocytes, thus accelerating energy-dependent DNA repair processes.[7] The ability of nicotinamide to inhibit PARP-1 and regulate DNA repair mechanisms has led to suggestion of its inclusion within regular sunscreens.

Blistering disorders

The ability of nicotinamide to inhibit proinflammatory cytokine pathways has been proposed as the underlying mechanism for its beneficial effects in blistering disorders. There have been multiple case studies reporting the use of nicotinamide as an adjunct (to tetracycline antibiotics) in a host of bullous dermatoses, most notably bullous pemphigoid and linear IgA bullous dermatosis,[8,9] with therapeutic benefit reported with doses up to 2 g/day. There is only one case report of niacinamide as monotherapy leading to remission of bullous pemphigoid post-mastectomy.[10] The largest trial to date reported that oral nicotinamide (500 mg three times daily) in combination with tetracycline antibiotics was comparable to prednisolone (40–80 mg daily), but with fewer AEs.[8] However, the British Association of Dermatologists guidelines for the management of bullous pemphigoid does not include nicotinamide in its summary of treatment choice. Although this treatment is promising, the aforementioned studies had small sample sizes and were not well powered.

Acne vulgaris

Acne vulgaris is purported to improve following topical nicotinamide application,[11] owing to a combination of anti-inflammatory action and reduction of sebum production, both critical in controlling the disease. Several trials have used topical nicotinamide (at doses of 2–4% with duration of treatment of 4–8 weeks) compared with placebo or topical clindamycin.[12–15] One open-label, multicentre, prospective cohort study investigated the use of oral nicotinamide 740 mg alongside zinc (25 mg), copper (1.5 mg) and folic acid (0.5 mg) in 198 patients,[14] and found that overall, 79% reported improvement in disease as 'better/much better'.[14] Several RCTs have reported that nicotinamide gel was comparable in efficacy to both topical erythromycin (4%) and clindamycin (1%)[13,15] in reduction of acne and seborrhoea scores. Of note, one study of 80 patients found no additional benefit of topical nicotinamide over topical nicotinamide and clindamycin in combination.[16]

Cosmetic applications

Nicotinamide has been shown to be beneficial in treating melasma[17] and hyperpigmentation,[18] and in abrogating features of ageing, with trials reporting a reduction in objective indices, which included wrinkles, lentigines and improvement in elasticity, following topical nicotominade application,[19,20] The ability of nicotinamide to improve melasma and hyperpigmentation is postulated to be secondary to reduced melanosome transfer within both melanocytes and keratinocytes.[21] A pilot study found that a metabolite of nicotinamide (1-methylnicotinamide) 0.25% applied topically twice daily for 4 weeks showed an observed improvement in rosacea in 26/34 patients.[22]

Pruritic disorders

Nicotinamide is thought to alleviate pruritus via several mechanisms. First, it is able to stabilize mast cells (via cyclic adenosine monophosphate inhibition) and thus reduce histamine release. Second, it is thought to enhance bioproduction of cutaneous ceramides, deficiencies of which worsen dry skin and pruritus. Third, it suppresses the T helper-1 overactivity that is thought to cause uraemic pruritus. A prospective, randomized, double-blind study investigated the use of oral nicotinamide 500 mg twice daily for 4 weeks versus placebo for refractory uraemic pruritus, but found no significant benefit. However, the authors postulated that a longer treatment duration might have shown more positive outcomes.[23]

Topical nicotinamide has also shown to be beneficial in treating atopic dermatitis, owing to its ability to reduce transepidermal water loss (TEWL), possibly as a result of ceramide production.[24] A recent RCT ($n = 292$) demonstrated that oral nicotinamide 500 mg twice daily reduced TEWL on the forehead by 6% ($P = 0.039$) and on the limbs by 8% ($P = 0.04$) in

Table 1 Summary of key clinical studies using nicotinamide for dermatological indications.

Study	Indication	Nature of study	Patients, *n*	Dose	Findings
NMSC prophylaxis					
Chen *et al.*, 2015[4]	Use of nicotinamide as NMSC prevention	Phase 3, double-blind RCT	386	Nicotinamide 500 mg twice daily versus placebo for 12 months	23% reduction in NMSC ($P = 0.02$); 11% ($P = 0.02$), 14% ($P < 0.001$), 20% ($P < 0.001$) and 13% ($P = 0.001$) fewer AKs at 3, 6, 9 and 12 months, respectively, in the nicotinamide group versus the placebo group. Benefits halted once nicotinamide discontinued
Surjana *et al.*, 2012[2]	Use of nicotinamide to reduce AK	Phase 2, double-blind, controlled trial (Study 1)	34	Nicotinamide 500 mg twice daily versus placebo for 4 months	35% reduction in AK at 4 months ($P = 0.0006$)
Surjana *et al.*, 2012[2]	Use of nicotinamide to reduce AK	Phase 2, double-blind, controlled trial (Study 2)	41	Nicotinamide 500 mg once daily versus placebo for 4 months	29% reduction in AK at 4 months ($P = 0.005$)
Drago *et al.*, 2016[5]	Use of nicotinamide versus placebo in immunosuppressed renal transplant recipients as prophylaxis against AK	RCT	24	Nicotinamide 250 mg three times daily	After 6 months, 88% taking nicotinamide demonstrated clinical regression in some or all AKs, compared with 91% taking placebo, who demonstrated worsening photodamage
Moloney *et al.*, 2010[27]	Use of topical nicotinamide 1% for AK	RCT	30	Topical nicotinamide 1% twice daily versus placebo for 6 months	22% reduction in AK at 3 months versus 10% reduction with placebo ($P = 0.3$) but no difference seen at 6 months
Bullous dermatoses					
Fivenson *et al.*, 1994[8]	Nicotinamide as adjunct with tetracycline compared with prednisolone to treat BP	Open-label clinical trial	18	Nicotinamide 500 mg three times daily plus tetracycline 500 mg four times daily versus prednisolone 40–80 mg daily	Results found to be comparable to prednisolone group, but with fewer adverse effects
Kolbach *et al.*, 1995[9]	Nicotinamide as adjunct with tetracycline to treat BP	Case report	7	Tetracycline 2 g and nicotinamide 2 g daily	Total remission at 6–8 weeks
Honl and Elston., 1998[10]	Niacinamide use as monotherapy in BP	Case report	1	–	BP following left breast mastectomy and reconstruction successfully responded to niacinamide alone
Shan *et al.*, 2015[28]	Linear IgA dermatosis treated with tetracycline and niacinamide	Case study	1	Tetracycline 500 mg three times daily and niacinamide 600 mg three times daily (oral) for 18 days, then tapered over 2 months	Complete resolution and no recurrence at 1 year

Table 1. continued

Study	Indication	Nature of study	Patients, *n*	Dose	Findings
Yomada *et al.*, 1999[29]	Sublamina densa-type linear IgA BP treated with oral tetracycline and niacinamide	Case report	1	Oral minocycline 100 mg once daily and niacinamide 900 mg once daily for 2 months and then oral tetracycline 1 g once daily and niacinamide 900 mg once daily, followed by maintenance dose of tetracycline 500 mg once daily and niacinamide 400 mg once daily	Clearing of skin lesion within 2 weeks with combination of tetracycline and niacinamide
Acne					
Kaymak., 2008[11]	Efficacy of topical niacinamide in mild/moderate acne	Outpatient setting	38	Topical 4% nicotinamide gel applied for 8 weeks	Reduction in pustules, papules and comedones ($P < 0.05$). AE profile included pruritus and mild burning
Draelos *et al.*, 2006[12]	Comparison of topical niacinamide 2% versus placebo	Double-blind, placebo-controlled trial (Study 1)	100 (Japanese)	Nicotinamide 2% applied for 4 weeks versus placebo	Nicotinamide group demonstrated lower sebum excretion rate at 2 and 4 weeks of application in Japanese subjects
	Comparison of topical niacinamide 2% versus placebo	Randomized split-face study (Study 2)	30 (white)	Nicotinamide 2% applied for 6 weeks versus placebo	Nicotinamide group demonstrated lower causal sebum levels at 6 weeks but sebum excretion rate not reduced (unlike in Japanese)
Weltert *et al.*, 2004[13]	Treatment of acne with nicotinamide gel	Double-blind RCT	160	Nicotinamide 4% gel versus erythromycin 4% gel twice daily for 8 weeks	Comparative reduction in acne appearance, but nicotinamide group seborrhoea scores had greater reduction than erythromycin group
Niren and Torok., 2006[14]	Efficacy of nicotinamide and zinc in acne and rosacea	Open-label, multicentre, prospective cohort study	198	Oral ncotinamide 750 mg once daily, zinc 25 mg, copper 1.5 mg, folic acid 500 μg	79% reported improvement as better/much better, while 55% reported moderate/substantial improvement at 4 weeks ($P < 0.001$)
Shalita *et al.*, 1995[15]	Efficacy of topical niacinamide in acne compared with clindamycin 1%	Double-blind study	76	Topical niacinamide 4% twice daily or topical clindamycin 1% for 8 weeks	Comparable significant reduction in acne between the two treatments. 82% and 62% reduction in acne for niacinamide and clindamycin respectively
Dos *et al.*, 2003[16]	Comparison of clindamycin 1% vs. clindamycin 1% with nicotinamide 4% gel	Comparative study	80	Half of patients treated with clindamycin alone and half with clindamycin + niacinamide combination	No added benefit shown of dual therapy versus single therapy
Cosmetic applications					
Navarette-Solis *et al.*, 2011[17]	Use of nicotinamide in melasma	Double-blind, split-face study	27	Nicotinamide 4% to half the face and hydroquinone 4% to the other half for 8 weeks	Both treatments improved melasma. AEs were seen in 18% of the nicotinamide and 29% of the hydroquinone groups

Table 1. continued

Study	Indication	Nature of study	Patients, *n*	Dose	Findings
Kimball *et al.*, 2010[18]	Use of nicotinamide in hyperpigmentation	Double-blind RCT	202	Topical N-acetyl glucosamine 5% and nicotinamide 4% versus placebo for 10 weeks	Significant improvement in facial spots and pigmentation versus placebo ($P < 0.05$)
Kawada *et al.*, 2008[19]	Review of nicotinamide gel for anti-ageing	Double-blind split-face RCT	30	Nicotinamide 4% cream versus placebo to Japanese women for 8 weeks	Significant improvement in skin wrinkles ($P < 0.001$) and skin texture ($P < 0.05$)
Bissett *et al.*, 2005[20]	Review of nicotinamide gel for anti-ageing	Double-blind split-face RCT	50	Nicotinamide cream 5% versus placebo to white women for 12 weeks	Improved skin improvement overall and improvement of skin elasticity in nicotinamide group
Pruritic disorders					
Omidian *et al.*, 2013[23]	Oral nicotinamide to relieve refractory uraemic pruritus	Prospective, randomized, double-blind study	50	Nicotinamide 500 mg twice daily for 4 weeks versus placebo in patients with chronic kidney disease with refractory uraemic pruritus	No significant reduction in pruritus between groups, but authors hypothesized longer application time would change this outcome
Soma *et al.*, 2005[24]	Nicotinamide cream compared with white petroleum cream in patients with atopic dermatitis	–	28	Nicotinamide 2% cream to left forearm versus white petroleum to right forearm for 4 or 8 weeks	Nicotinamide significantly decreased transepidermal water loss; authors concluded that nicotinamide cream is a more effective moisturizer
Levine *et al.*, 2010[26]	Treatment of psoariasis with combination of nicotinamide and calcipotriene	Pilot, multicentre (seven-arm), double-blind, randomized, placebo-controlled, bilateral comparative study	Unknown	Patients randomized to two out of the following possible treatments: placebo, calcipotriene 0.005%, nicotinamide 1.4%, calcipotriene + nicotinamide 0.7% or calciprotriene + nicotinamide 1.4% for 12 weeks	50% patients in the calcipotriene + nicotinamide combination group had clear/almost clear outcome at 12 weeks versus 18.8% in the placebo group ($P = 0.002$), 25% treated with nicotinamide 1.4% alone ($P = 0.02$) and 31.5% treated with calcipotriene alone ($P = 0.096$)

AE, adverse effect; AK, actinic keratosis; BP, bullous pemphigoid; NMSC, nonmelanoma skin cancer; RCT, randomized controlled trial.

patients in the nicotinamide arm compared with the placebo arm at 12 months.[25]

Another RCT suggested that topical nicotinamide and calcipotriene in combination was more effective than placebo or either constituent as monotherapy when used as a steroid-sparing topical treatment for psoriasis, with 50% of patients reporting 'clear to almost clear' outcome with combination therapy.[26]

Conclusion

Nicotinamide appears to be a well-tolerated medication whose potential as a systemic agent in prophylaxis against NMSC is founded but yet to be fully exploited by dermatologists. Its mechanism of action in other indications remains to be fully elucidated. Nicotinamide as an adjunctive treatment of inflammatory (notably bullous) dermatoses shows promise; however, further well-powered studies with greater numbers of patients are needed before drawing definitive conclusions as to its efficacy. As the population ages and such presentations become more prevalent, we expect that this apparently safe and inexpensive agent may form an increasingly important part of the dermatologist's armamentarium.

What's already known about this topic?

- Nicotinamide is the water-soluble, amide form of vitamin B3.
- Nicotinamide is a safe drug that has been used for over 50 years with few reported side-effects.
- The use of nicotinamide for treatment of pellagra is established, as is the use of nicotinic acid for lipid regulation.

What does this study add?

- We provide an up-to-date review of the evidence underlying the use of nicotinamide for a range of dermatological indications.
- The latest evidence for the uses of nicotinamide have been tabulated.
- There is growing evidence suggestive of the utility of nicotinamide in other dermatological disorders, including prophylaxis of NMSC, pruritus, blistering disorders and melasma, as well as anti-ageing effects.

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CPD questions

Learning objective

To gain more knowledge of the role of nicotinamide and its possible use in skin cancer.

Question 1

Nicotinamide is synonymous with which of the following names?

(a) Niacinamide.
(b) Niacin.
(c) Nicotine.
(d) Nicotinic acid.
(e) Pellagra.

Question 2

Nicotinamide is the amide isoform of which vitamin?

(a) B1.
(b) B2.
(c) B3.
(d) B6.
(e) B12.

Question 3

In a recent phase 3 trial, what dose of nicotinamide was used as chemoprophylaxis against nonmelanoma skin cancer in high-risk individuals?

(a) 500 mg once daily.
(b) 500 mg twice daily.
(c) 500 mg three times daily.
(d) 1 g twice daily.
(e) None of the above.

Question 4

What is the highest level of evidence supporting the use of nicotinamide monotherapy in bullous pemphigoid?

(a) Case report.
(b) Case series.
(c) Cohort study.
(d) No evidence.
(e) Randomized controlled trial.

Question 5

Systemic (oral) nicotinamide has been trialled in which of the following dermatoses?

(a) Acne vulgaris.
(b) Atopic dermatitis.
(c) Lichen planus.
(d) Psoriasis.
(e) Rosacea.

Instructions for answering questions

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