

# Colloidal Oatmeal Part II: Atopic Dermatitis in Special Populations and Clinical Efficacy and Tolerance Beyond Eczema

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## ABSTRACT

Colloidal oatmeal has a diverse array of applications, clinical benefits, and uses beyond atopic dermatitis. First and foremost, it has been shown to be of benefit in the treatment of atopic dermatitis in skin of color. It has also been shown to be of benefit in the treatment of hand dermatitis, xerosis, psoriasis, skin manifestations of diabetes, and in the treatment of cutaneous adverse effects associated with oncologic therapies. In Part II of this 2-part series, we examine the efficacy, safety, and expansive clinical applications of colloidal oatmeal.

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## INTRODUCTION

### Atopic Dermatitis in Skin of Color

In Part I, we examined the ways in which colloidal oatmeal can be beneficial in the treatment of AD. Colloidal oatmeal has also been found to be of benefit in patients with skin of color and AD. An understanding of how colloidal oatmeal is of benefit in these populations begins with examining the structural and functional distinctions of skin of color.

Patients with skin of color encompass a wide range of racial and ethnic groups, including but not limited to persons of African, African American, Afro-Caribbean, Chinese, Japanese, Native American, Navajo Indian, Southeast Asian, Indian, Middle Eastern, and Latino descent and heritage. Racial and ethnic differences in skin color are directly related to variations in the number, size, and aggregation of melanosomes within the melanocytes and keratinocytes. In subjects with skin of color, there is a trend for melanosomes to be large with greater distribution throughout the epidermis.<sup>1</sup> Gunathilake et al demonstrated that dendrites from melanocytes of patients with Fitzpatrick skin type IV–V skin were more acidic than those from type I–II subjects, and that those in type VI–V skin also transfer more melanosomes to the stratum corneum, suggesting that melanosome secretion could contribute to the more acidic pH of type IV–V skin.<sup>2</sup> It has been well established that the stratum corneum functions best at a highly acidic surface pH, which is thought to serve an antimicrobial function, regulate barrier homeostasis and desquamation, and allow for optimal activity of the ceramide-generating enzymes sphingomyelinase and  $\beta$ -glucocerebrosidase.<sup>2</sup> There are conflicting data regarding racial differences in the structure of the stratum

corneum. In one review article, it is argued that many of the studies cited in the literature have small patient populations and less-than-optimal study designs, which makes it difficult to draw definitive conclusions. In studies using tape-stripping techniques and microscopic visualization, patients with skin types V and VI were shown to have a stratum corneum with increased density but overall equal in thickness to types II and III. Taylor cites various studies, which posit that the increased density may be due to increased lipid content.<sup>1</sup>

As part of a larger trial comparing the efficacy of colloidal oatmeal with prescription barrier cream in the management of mild to moderate AD, 49 African American children aged 2–15 years were randomly assigned to twice-daily application of either colloidal oatmeal or prescription barrier cream. Colloidal oatmeal provided rapid improvement in baseline EASI score by day 7 (62.9% vs 53.7%) in addition to marked improvement in ratings of itch by day 7 (43.1% vs 33.3%) compared with prescription barrier cream.<sup>3</sup> Both treatments were clinically effective and well tolerated.

### Clinical Efficacy and Tolerance Beyond Eczema

Colloidal oatmeal has been demonstrated to be effective in several clinical conditions aside from AD. Hand dermatitis is a common and widespread condition that disproportionately affects occupational groups exposed to irritants or allergens. Mainstays of therapy include avoidance of irritants or allergens and use of topical corticosteroids, although long-term use can lead to tachyphylaxis and steroid-sparing agents are

of benefit. In a randomized, double-blind placebo-controlled trial study with 6 weeks follow up, patients were randomized to two-week use of fluocinolone 0.025% followed by either 1% colloidal cream or base cream for 4 weeks as monotherapy. At the end of six weeks, patients randomized to use of 1% colloidal oatmeal had a statistically significant improvement in eczema severity and quality of life scores (HESI, Hand Eczema Severity Index; DLQI, Dermatology Life Quality Index) compared to the control group.<sup>4</sup>

Many studies have also evaluated the effectiveness of colloidal oatmeal in the treatment of moderate to severe xerosis, or dry skin. These studies have collectively demonstrated significantly greater improvements from baseline in skin barrier function (via corneometer measurements of transepidermal water loss), overall dryness, and itch, compared to either vehicle alone, similar ceramide cream, or prescription barrier cream.<sup>5-7</sup> Treatment with colloidal oatmeal lotion has also been found to have rapid and lasting efficacy, with a study by Nebus et al of thirty patients between the ages of 18 and 55 demonstrating significant improvement in measurements of transepidermal water loss and xerosis after only 4 days of use. Improvements were maintained after a 48-hour regression period.<sup>8</sup>

Psoriasis is a common, chronic skin disease affecting approximately 2% of the population that is characterized by dysregulation of the innate immune system and uncontrolled keratinocyte proliferation.<sup>9</sup> Patients often suffer from dryness and roughness, which leads to significant psychosocial distress. Colloidal oatmeal has also demonstrated benefit in patients with mild psoriasis. In a 4-week study of 60 adult females with psoriasis and self-reported sensitive skin, subjects were instructed to apply 1% colloidal oatmeal at least once per day to the whole body with a focus on dry patches. After 4 weeks of use, participants reported 45% improvement in itch and desquamation compared to baseline scores. 96% of patients reported that the 1% colloidal oatmeal lotion helped to reduce both the severity and number of appreciable patches.<sup>10</sup>

Successful treatment of molluscum contagiosum (MC) with colloidal oatmeal has also been described. Molluscum contagiosum, a skin infection caused by a DNA poxvirus, is one of the most common viral skin infections seen in children. In an open study, 6 children aged 5–11 years with at least 10 cutaneous lesions of MC were treated with a zinc oxide cream containing colloidal oatmeal extracts (*Avena rhealba*). After 4 weeks of therapy, 4 of the 6 patients had complete resolution of their lesions and the 2 remaining patients had a >50% decrease in the total number of their lesions.<sup>11</sup> Pazyar et al posit that the antiviral properties of colloidal oatmeal extract are likely due to the inhibitory effects on eicosanoid formation, expression of cytosolic phospholipase A2, and arachidonic acid mobilization in human keratinocytes.<sup>12</sup>

Aside from its demonstrated benefit in a variety of dermatoses, colloidal oatmeal has also been continuously reported as safe and effective. Twelve independent studies evaluated irritant and allergic reactions via patch testing of various skin care products containing oatmeal in various formulations including lotions, creams, serums, and cleansers. Of the 2565 participants, only 20 subjects demonstrated transient low-level reactions such as faint erythema, and only 3 subjects demonstrated grade 1 reactions with edema.<sup>13</sup> Criquet et al further described two studies evaluating the ocular tolerance of a facial cleanser in 43 female subjects with normally sensitive eyes. Eye reactions were documented in only 3 subjects and confirmed by clinical ophthalmologic evaluation.<sup>13</sup> In a total of 47 patients, clinical efficacy was demonstrated over the course of six weeks via skin hydration, reduced desquamation index, and subjective evaluation of signs of skin dryness after application. Dermatologist assessment demonstrated significant improvement of skin dryness, desquamation, and skin roughness in treated areas compared to controls.<sup>13</sup> Ultimately, the U.S. Food and Drug Administration generally recognizes colloidal oatmeal as safe and effective.

#### Systemic Conditions With Skin Manifestations

Colloidal oatmeal has been reported to be of benefit in the treatment of skin manifestations of systemic diseases. Diabetes mellitus is commonly responsible for skin changes including diabetic dermopathy and discrete to mild xerosis. Pierard et al describe a continuum between a sensation of dry skin, xerosis, and ichthyosiform presentations of the shins and feet of diabetic patients.<sup>14</sup> In a study of 46 patients with diabetes and moderate dryness of the lower legs, twice daily use of an oatmeal lotion with avenanthramides and oat oil resulted in significant improvements in erythema, fissuring, scaling, and tactile roughness as early as 1 week into use. Improvements continued through 4 weeks of treatment.<sup>15</sup>

#### Dermatologic Side Effects Associated with Cancer Therapy

Oats have also been described in the literature to be of benefit in addressing skin toxicities associated with oncologic therapies. Targeted therapies, a newer genre of cancer treatment that specifically targets tumor cells, are well known for their significant dermatologic toxicities.<sup>16</sup> Over 50 distinct dermatologic toxicities have been reported in association with more than 30 anti-cancer agents, the most common of which include hand-foot skin reactions, nail changes, papulopustular (acne-like) eruptions, pruritus (severe itching), secondary malignancies, new neoplasms, and chemotherapy-induced alopecia (hair loss or spot baldness).<sup>17-18</sup> Of particular interest and study are epidermal growth factor receptor (EGFR) inhibitors and tyrosine kinase inhibitors, which are used to treat a broad range of solid organ malignancies. Treatment and optimal management of these cutaneous effects is important, as they can be severe enough to cause patients to discontinue treatment.

Among patients treated with EGFR inhibitors, up to 90% have experienced papulopustular eruptions.<sup>19</sup> The rash usually developed in the first 2–4 weeks after initiation of therapy as pruritic and tender erythematous papules and pustules on the scalp, face, neck, chest, and back.<sup>20</sup> Interestingly, there is a relationship between the development of the rash and the response to chemotherapy and ultimate survival.<sup>21</sup> Pruritus is another common adverse event with EGFRIs, affecting up to 54.9% of patients based on particular EGFRi treatment, and which can have a significant impact on quality of life.<sup>22</sup> Alexandrescu et al reported treatment with colloidal oatmeal of 11 patients with a rash induced by cetuximab, erlotinib, panitumumab, and sorafenib. Colloidal oatmeal was applied three times a day for 7 days. The overall response rate was 100%, with a complete response of 60%. The authors argue that the observed eruptions in these patients may represent an inflammatory reaction to EGFR inhibitors, thus explaining the response to colloidal oatmeal given its anti-inflammatory properties.<sup>23</sup> An additional study in Taiwan studied the benefit of colloidal oatmeal in a sample of 30 patients with dermatologic toxicities associated with EGFR inhibition. Patients applied colloidal oatmeal three to five times a day for 4 consecutive weeks. Dermatologic toxicity severity, body surface area involvement, and pruritus all improved at 4 weeks with no adverse events reported.<sup>24</sup> Unlike more potent topical treatments such as topical steroids, metronidazole, erythromycin, salicylic acid, and benzoyl peroxide, colloidal oatmeal is not associated with any toxicity.<sup>23</sup>

Radiation therapy is used in the treatment of various forms of cancer and is associated with acute and chronic skin changes. Early skin reactions usually occur within days to weeks, initially manifesting as transient to generalized erythema. If the cumulative radiation dose reaches 20 gray, dry desquamation can develop characterized by pruritus, scaling, and flaking of the skin.<sup>25</sup> Colloidal oatmeal has been studied as a treatment for radiation-induced skin reactions. In a study of 24 patients undergoing radical radiotherapy for anal cancer, patients were randomized to treatment with either colloidal oatmeal or aqueous cream. Skin reactions for both cohorts were comparable, but the colloidal oatmeal cohort had an appreciable response with regards to epidermal regeneration at follow up.<sup>26</sup> As treatments for cancer continue to evolve, so must treatments for their cutaneous adverse effects. Colloidal oatmeal has shown promise with an excellent safety profile.

## CONCLUSIONS

In Part II of this two-part series, we examined the diverse range of clinical applications of colloidal oatmeal. Colloidal oatmeal has been shown to be beneficial in the treatment of atopic dermatitis in African American patients. It also has been shown to be of benefit in the treatment of hand dermatitis, xerosis, psoriasis, skin manifestations of diabetes, and in the treatment of cutaneous adverse effects associated with onco-

logic therapies. This wide-ranging efficacy and use is backed by proven safety and tolerability, making colloidal oatmeal an ideal treatment option in many case scenarios.

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