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INNOVATIVE MEDICINE

Best Practices

Colloidal Oatmeal: Optimal Skin-Directed Care for Atopic Dermatitis

A review of a Product Theater presentation by Dr. Zeichner.

Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease, often highly pruritic, which has a typical eczematous distribution pattern that changes with age.^{1,2} This disease affects approximately 10% of US children (≤ 18 years).^{1,3} Due to limited access to dermatologists, pediatricians and primary care providers are likely to be a first point of contact for children with AD.^{1,4} Along with physical discomfort, AD has a significant negative impact on quality of life (QOL) that worsens with disease severity.⁵ Recommendations by the American Academy of Dermatology (AAD), the American Academy of Pediatrics (AAP) and others suggest skin-directed treatment to help repair and maintain healthy skin barrier as fundamental to disease management.^{1,6-9} Colloidal oatmeal has long been used as a topical treatment for AD and modern research confirms the benefits of colloidal oatmeal formulations to significantly improve symptoms.¹⁰⁻¹² In fact, colloidal oatmeal is listed as a skin protectant and is recognized as safe and effective in treating AD by the FDA.^{12, 13}

Patient Presentation

Diagnosis of AD is based mainly on clinical features to differentiate it from other conditions.¹⁴ Research suggests that breakdown of the skin barrier can be instrumental in development of AD.¹⁵ A family history of atopy is also strongly associated with AD.¹⁴ African Americans and Hispanics are at higher risk for severe AD, and prevalence of AD is higher among African Americans than Caucasians.¹⁶

Clinical findings may differ but may include erythema, itching/pruritus, erosions/excoriations and xerosis.¹⁴ AD lesions are typically seen on the face and extensors in infancy with flexors being the characteristic locations in puberty.¹ Early age onset supports the diagnosis of AD, with approximately 65% of onset occurring before age 1 year and 95% before age 5.¹⁷

Quality of Life

AD can have a profound impact on QOL for children and families. In a study that compared AD with other chronic diseases, AD was second only to cerebral palsy in QOL impact.¹⁸

Almost half of AD children report they are negatively affected.¹⁹ Symptoms include fatigue, sleep deprivation, and depression.^{20,21} Other evidence suggests children with AD have increased risk of delayed social development.¹⁸⁻²⁰ Their parents report sleep disturbance and anxiety.²²

Skin Barrier and the Skin Microbiome

One of the main components in the development of AD is skin barrier disruption.^{1,23} Additional factors in the development of AD include environmental factors, genetic predisposition, filaggrin mutations, and immune dysfunction.^{1,23}

The skin barrier is critical to preventing water loss, as well as protecting against irritants, allergens and skin pathogens.¹ Additionally, the skin provides an important immunological barrier function, with the skin's microbiome acting to modulate its innate immune response, thereby providing a first line of defense.²⁴ Recent research suggests some disease states may be linked to the absence of commensal bacteria and both the richness and diversity of the skin microbiome are decreased in patients with AD.²⁵⁻²⁷ Maintaining a healthy skin barrier and a healthy skin microbiome are both important in managing AD.¹

Skin pH may also play a role in skin barrier health. Typically, the stratum corneum is mildly acidic, with a pH level of 4.1 to 5.8, and this acidic state helps maintain skin structure and decrease bacterial activity.^{24,28,29} Research has shown pH levels in AD patients are elevated, and increased pH levels can lead to altered immune response.^{29,30} Study results have shown that colloidal oatmeal may act as a buffer to decrease the alkaline conditions often seen in skin of AD patients.^{10,31,32}

Skin Moisturization Is the Top-Level Recommendation

According to guidelines from the AAD, moisturizers should be the foundation of AD treatment.⁹ Clinical trials demonstrated moisturization may help reduce symptoms—such as pruritus, erythema, fissuring, and lichenification—and the amount of prescription anti-inflammatory treatments required for disease control.⁹

According to a clinical report by the AAP, the 4 main approaches to skin-directed management of AD should be skin barrier repair and maintenance, use of topical anti-inflammatory agents, itch control, and management of infectious triggers.¹ Parent education is recommended and associated with better outcomes.³³

Additionally noted is that early skin-directed AD treatment may prevent entry of allergens into the skin, and thus possibly prevent or slow progression to subsequent allergic disorders. Additional evidence indicates the role allergic contact dermatitis plays in AD is underestimated.¹

Topical anti-inflammatory medications such as steroids, prescribed to treat active AD, are generally considered safe and effective when used properly. However, when used improperly, potential risks include cutaneous atrophy, systemic absorption, and local effects when used around the eyes or mouth.¹ These concerns may contribute to “steroid phobia” for both parents and health care providers, which in turn may lead to undertreatment of AD.^{1,34}

Topical calcineurin inhibitors, immunosuppressive agents that inhibit T-cell function, also are a treatment option. Topical antihistamines are considered ineffective and may exacerbate dermatitis.¹

Colloidal Oatmeal

Oatmeal as a remedy for conditions such as itch, skin rashes, erythema, and eczema dates back centuries.^{10,11} Oat is a polyphenolic compound with many potential benefits to soothe and relieve dry skin. Oats have a high concentration of starches and beta-glucans that have protective and water-holding properties.^{10,35} Lipids and fatty acids play a role in skin barrier function. Avenanthramides, vitamin E, ferulic acid and other antioxidants in the oats provide an antioxidant and anti-inflammatory effect.¹²

Oat Benefits

Scientists have long studied oat and reported on the benefits of its different components. Through careful processing and scientific understanding, formulations having a combination of



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3 oat components can be designed to deliver efficacious and well-tolerated products used in skin-directed therapies for AD patients. Such formulations utilize specially processed oat flour, oat extract, and oat oil.

- Colloidal oatmeal (oat flour), with its high concentration in starches and beta-glucans, provide protective and water holding properties to the skin barrier.¹⁰
- Oat extract has been shown to contain avenanthramides, which are nitrogen-containing phenol compounds with antioxidant and anti-inflammatory properties.¹¹
- Oat oil contains oat lipids, which contain various components including linoleic acid. Linoleic acid has been shown effective in reducing transepidermal water loss and restoring the skin permeability barrier.³⁶⁻³⁸

Skin microbiome dysbiosis, or changes in the skin's microbiota, may also play a role in the pathogenesis of AD.³⁹ Therefore, topical prebiotics may help contribute to improving the homeostasis of a healthy skin microbiome.⁴⁰ Components of oat may contribute a prebiotic activity which supports the skin microbiome.⁴¹

Specially formulated skin protectant products that combine specially processed ingredients of oat flour, oat oil and oat extract have been shown to have additional properties compared to other skin care treatments



Products that combine specially processed ingredients of oat flour, oat oil and oat extract have been shown to be well tolerated and effective as skin directed therapy in managing AD.

including, antioxidant, anti-irritant, and potentially the benefits of prebiotic activity.¹⁰ Other skin protectants, such as dimethicone and petrolatum, focus primarily on maintaining the skin barrier and providing an occlusive layer to help prevent water loss. The same may also be said for other skin conditioners, (eg, ceramides and cholesterol), and for humectants (eg, hyaluronic acid and glycerin), which primarily work to maintain and protect the skin barrier and aid in skin moisture retention.

Oat Studies

The effects of oat have been extensively studied. As part of a larger study of over-the-counter colloidal oatmeal, Nunez and colleagues randomized 49 African American patients ages 2 to 15 years with mild to moderate AD to colloidal oatmeal cream or a prescription barrier repair cream to be used twice daily as needed for 3 weeks.⁴² The tested colloidal oatmeal cream provided improvement by Day 7 in Eczema Area and Severity Index (EASI) score in near

63% of patients in the colloidal oatmeal group, compared with 54% of patients using prescription cream. Subjective rating of itch by Day 7 also improved in 43% and 33% of patients in the colloidal oatmeal and prescription cream groups, respectively.⁴²

Lisante and colleagues conducted 2 single-center, single-arm clinical trials for mild-to-moderate AD, one in 29 patients ages 8 years and older and one in 30 patients ages 10 or older.⁴³ An OTC 1% colloidal oatmeal cream was administered for 14 days. In Study 1, improvements in EASI and Investigator's Global Atopic Dermatitis Assessment (IGADA) scores improved at Day 3 by 20% or more over baseline in 53.6% and 25.0% of patients, respectively. Itch severity using a visual analogue scale (VAS) improve immediately after application in 37.9% patients. On Day 14, improvements in these measures were seen in 82.8%, 62.1%, and 85.7% of patients, respectively. In Study 2, itch severity and EASI score were significantly improved following product application. Improvements continued until Day 14. All assessments showed a significant reduction in water loss values and a significant increase in skin hydration.

Lisante and colleagues also conducted a double-blind, active-controlled study.¹⁷ Ninety patients ages 6 months to 18 years (46% boys; 54% African American) were randomized to OTC 1% colloidal oatmeal cream or a prescription barrier cream for three

weeks. Results showed that EASI scores were non-inferior in the OTC group, compared with the prescription cream group, and improvement in IGADA and VAS scores were seen in both groups, without safety issues.

Conclusion

Preventing and repairing damage to the skin barrier, maintenance of normal skin pH and supporting a healthy skin microbiome are essential to managing AD. Colloidal oatmeal has a long history of safe use and is recognized by the FDA as a skin protectant.^{12,13} Colloidal oatmeal containing formulations have been shown to safely reduce symptoms commonly associated with AD and those using specially processed oat flour, oat extract, and oat oil combinations have been shown effective and well-tolerated as a skin directed therapy in managing AD.

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