Colloidal Oatmeal Formulations as Adjunct Treatments in Atopic Dermatitis

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ABSTRACT

Colloidal oatmeal has been used for decades to soothe and ameliorate atopic dermatitis and other pruritic and/or xerotic dermatoses. In-vitro and/or in-vivo studies have confirmed the anti-inflammatory, barrier repair, and moisturizing properties of this compound. A broad set of studies has been conducted in recent years to assess the effects of colloidal oatmeal as adjunct treatment in the management of atopic dermatitis (AD). This paper will review these studies. In these investigations, patients in all age groups (3 months to 60 years) with mild to moderate atopic dermatitis were included and allowed to continue their prescribed topical medications. These studies found that the daily use of moisturizers and/or cleansers containing colloidal oatmeal significantly improved many clinical outcomes of atopic dermatitis from baseline: investigator’s assessment (IGA), eczema area and severity index (EASI), itch, dryness, and quality of life indices. Safety results showed that the formulations were well tolerated in babies, children, and adults with AD.

INTRODUCTION

Atopic dermatitis (AD), or atopic eczema, is a chronic skin disorder with a high prevalence in children. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), 10% to 20% of all children suffer from AD. In many children, AD tends to resolve by 2 years of age, but in 60% of them some symptoms will continue into adulthood. 1 About 65% of patients develop AD within the first 12 months of life and 90% within the first 5 years. In 2004, approximately 15 million patients in the United States were affected by AD; this accounted for $154 million in AD prescription drugs or 15% of total direct costs, which is over $1 billion per year.

Atopic dermatitis has a complex pathogenesis but there is increased evidence that a genetically-impaired skin barrier plays a primary role in its development. 2,3 Mutations in the filaggrin gene, in particular, are strongly associated with AD (42% of FLG heterozygotes develop the disease). 2 The protein filaggrin is important for the correct formation of the stratum corneum barrier and filaggrin deficiency produces increased barrier permeability and other stratum corneum abnormalities. 3 Indeed, several clinical studies have found skin barrier defects and dry skin in both lesional and clinically normal skin of AD patients: increased transepidermal water loss (TEWL) and pH, 4 and decreased skin hydration. 4,5 A reduced content of ceramides in the stratum corneum has also been shown in both lesional and nonlesional skin. 6

The defective barrier allows penetration of irritants and antigens, which lead to the release of cytokines, causing secondary skin inflammation. 7 Skin inflammation can also derive in part from decreased stratum corneum hydration (xerosis). 8 These biological changes ultimately lead to the clinical manifestations of pruritus and eczema, which are key diagnostic criteria for AD. Intense pruritus is an initial symptom; this triggers scratching, which in turns generates an increased immune response that leads to the development of eczematous lesions. 9

Thus, soothing of pruritus, restoration of skin barrier and stratum corneum hydration, and reduction of inflammation are critical for the amelioration of AD and for an improved quality of life. Moisturization and barrier protection are paramount to prevent entrance of noxious agents into the skin, and to reduce pruritus and thus scratching. 10,11 In fact, the Consensus Conference on Pediatric Atopic Dermatitis suggested that emollients (ointments and creams in particular) can be used as first-line agents in the management of AD 12 and can be steroid-sparing. 10,11 The regular use of emollients in AD has also been recommended by the PRACTALL consensus report. 13

Oatmeal Properties

Colloidal oatmeal is approved by the Food and Drug Administration (FDA) as a skin protectant drug for over-the-counter (OTC) use. One of its approved labelings is that it can “temporarily protect and help relieve minor skin irritation and itching due to eczema.” 14 Colloidal oatmeal is produced as a fine powder from the grinding and processing of whole oat grains and it contains various dermatological active compounds with moisturizing, protective, anti-inflammatory, antioxidant, soothing, buffering, and cleansing properties. 15,16

The small particles of colloidal oatmeal, dispersed in water, form an occlusive barrier, protecting the skin against external agents. Its high concentration of starches and hydrocolloid β-D-glucan significantly contributes to the creation of an occlusive film and to its humectant (water-binding) activity and to its emollient effects. This coating allows water retention in the stratum corneum, improving skin barrier and moisturization, and alleviating itch.

In-vitro and in-vivo studies have demonstrated the anti-inflammatory activity of oat extracts; this activity seems to be linked to the high content in antioxidants (avenanthramides, vitamin E, ferulic acid, etc.). Avenanthramides, in particular, are phenolic compounds with potent anti-inflammatory activity; in-vitro studies have shown that they may decrease inflammation through inhibition of nuclear factor (NF)-κB in keratinocytes and inhibition of the release of the pro-inflammatory cytokine IL-8. Preclinical models have also shown that topical application of avenanthramides decreases inflammation in oxazolone-induced contact allergy ($P<0.05$) and reduces scratching in itch-induced models ($P<0.05$) compared to vehicle. The level of anti-inflammatory effect was similar to that of topical hydrocortisone 1%.22

**Colloidal Oatmeal Formulations in the Management of Atopic Dermatitis**

This review describes some of the most recent investigations on the benefits of colloidal oatmeal formulations as adjunct treatments in AD. In a study by Nebus et al.,23 25 patients aged 12 to 60 years (mean age 30 years), affected by mild to moderate AD according to the criteria of Hanifin and Rajka and with at least 8% body surface area (BSA) involvement, were enrolled in an 8-week study. They used a topical regimen consisting of twice-daily oat-based occlusive cream and once-daily oat-based body wash. Patients were allowed to continue their prescribed topical AD treatments; however, patients taking systemic medications that affected eczema were excluded. Outcomes included Investigators’ Global Assessment (IGA) (0=clear, 5=very severe), Eczema Area and Severity Index (EASI) composite score, Itch severity (0=None, 4=severe), and Dermatology Life Quality Index (DLQI). Dermatology Life Quality Index consisted of 10 questions on skin problems over the previous week (at weeks 0, 4, 8) and separate questionnaires were provided for adults (17+ years of age) and children (ages 12 to 16). The results showed that the daily use of the adjunct oat-based regimen significantly improved AD outcomes at all time points compared to baseline: IGA (Figure 1), EASI, and itching were significantly improved at weeks 2, 4, and 8. Dermatology Life Quality Index was significantly improved from baseline ($P<0.05$) at weeks 4 (39.4%) and 8 (54.7%), in accordance with the improvement in IGA, EASI, and itching during the same time points. Safety assessments showed that the regimen was well tolerated and compatible with various prescription topical medications.

Another study was conducted on 23 babies and children (3 months to 5 years old, mean age 2.4 years) with mild to moderate AD and at least 5% BSA involvement. Patients continued any topical prescription AD medication already in use, but discontinued previous cleansers and moisturizers. The adjunct 4-week regimen consisted of an occlusive colloidal oatmeal cream (with avenanthramides, ceramides, and panthenol), twice daily on the entire body, and a colloidal oatmeal-based glycerin cleanser for all routine bathing. Itch severity was assessed using a Visual Analog Scale (VAS). Quality of Life (QoL) improvement was determined using a standardized Baby/Child Quality of Life Index, addressing parameters such as mood, playtime, sleep, etc. Physician investigator evaluations for EASI and IGA were performed. The adjunct oat-based regimen was well tolerated and was able to significantly reduce itching ($P<0.05$) by over 45% (mean) as early as week 2 of use. Overall IGA and EASI composite score were significantly improved from baseline ($P<0.0001$ and $P<0.05$, respectively), both at week 2 and week 4 (Figure 2). IGA scores showed a progressive improvement in the disease condition: the percentage of patients with moderate scores decreased from 30% at baseline to 0% at week 4 (Table 1). Over 60% of patients were categorized as clear or almost clear at the end of the study. Baby/Child Quality of Life Index was also significantly better ($P<0.05$) by week 4, reflecting the improved skin condition of these young patients.
DISCUSSION

Emollients play a central role in the treatment of mild to moderate AD: international consensus reports and guidelines recommend their regular application in eczema and support their use as first-line treatment in mild AD, or in conjunction with other therapies in more severe cases. Additionally, emollients should be continued even after clearing of eczema, to address barrier protection and hydration. In fact, skin barrier abnormalities are found in both lesional and non-lesional skin of AD patients and skin barrier repair agents are important for healing and prevention of lesions.

The benefits of colloidal oatmeal in AD have been known for decades. In the mid-1950s, several studies reported the protective, hydrating, soothing, and anti-irritant properties of colloidal oatmeal for the relief of various pruritic xerotic dermatoses, including AD. The anti-inflammatory activity of oats has later been confirmed by in-vitro studies with oat extracts and compounds such as avenanthramides, which demonstrated inhibition of NF-κB and inhibition of prostaglandin biosynthesis. Additionally, Vie et al. showed the in vivo anti-inflammatory effect of oatmeal extracts using a sodium lauryl sulfate (SLS) irritation model on the forearms. In the study, pre-treatment of skin sites with oat extracts significantly decreased SLS-induced irritation.

The studies reviewed here confirm the efficacy and safety of colloidal oatmeal formulations as adjunct treatments in AD, both in infants/children and in adults. Their daily use significantly improved many clinical outcomes of AD from baseline: IGA, EASI, itch, and dryness. Quality of Life indices, which monitor the general wellbeing of patients, were also significantly improved. It is noteworthy that itch was significantly improved as early as week 1 of use; in fact, reduction of pruritus is a key treatment goal, decreasing scratching and further barrier damage. This was associated with significant clinical improvement as early as week 2 of use, with a large number of patients becoming clear or almost clear by week 4 (more than 60% of babies/children, more than 30% adults).

The long history of dermatological use of colloidal oatmeal in eczematous diseases and the recent studies confirm that this compound is safe, well tolerated, and can be effective as adjunct treatment in AD.

Another clinical study was performed on the oatmeal-based body wash and a fragrance-free therapeutic oatmeal-based body cream with 21 patients (aged 15 to 60 years) presenting with the same AD criteria as in the previous two studies. In addition to the colloidal oatmeal, the therapeutic cream also contained glycerin as a humectant, ceramides for moisture retention, panthenol for skin conditioning, and petrolatum for occlusion. Patients used the body wash once daily and applied the therapeutic cream to the body twice a day for 2 weeks. Dermatologist evaluations showed a significant improvement (P<0.05) in the mean eczema severity score after 2 weeks of regimen use, with 62% of patients showing improvement from baseline. Itching was significantly decreased (P<0.05) at weeks 1 and 2, with over 40% improvement in the mean itch score at week 1. The regimen was well tolerated by the patients.

A number of prescription topical products have recently been introduced to potentially enhance skin barrier function. These products are approved by the US FDA as "devices," rather than "drugs." This prompted a new, double-blind, randomized study comparing a colloidal oatmeal skin protectant cream to a prescription medical device barrier cream for the improvement of skin barrier function and moisturization in subjects with moderate to severe dry skin. The results showed that sites treated with the oatmeal cream had significantly higher hydration values (P≤0.01) compared to sites treated with the medical device cream. Also, at the colloidal oatmeal sites, skin barrier (via TEWL measurements) was significantly improved from baseline (P≤0.05) and was better, though not statistically significant, than with the medical device cream.

FIGURE 2. IGA and EASI improvement in babies and children. The daily use of an adjunct colloidal oatmeal regimen in babies and children with AD significantly improved overall IGA and EASI composite score at both week 2 and week 4 of use.

TABLE 1.

<table>
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<tr>
<th>IGA Improvement In Babies and Children With AD</th>
<th>% of Patients in Each IGA Category</th>
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<tr>
<td></td>
<td>Baseline</td>
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<tr>
<td>Severe</td>
<td>-</td>
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<tr>
<td>Moderate</td>
<td>30%</td>
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<tr>
<td>Mild</td>
<td>70%</td>
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<tr>
<td>Almost Clear</td>
<td>-</td>
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<tr>
<td>Clear</td>
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DISCLOSURES

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