ORIGINAL ARTICLE

# The proactive wet-wrap method with diluted corticosteroids versus emollients in children with atopic dermatitis: A prospective, randomized, double-blind, placebo-controlled trial

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***Background:*** Wet-wrap treatment (WWT) has been advocated as a relatively effective treatment in children with severe atopic dermatitis (AD). WWT often serves as crisis intervention for AD.

***Objectives:*** We sought to evaluate the use of WWT with diluted corticosteroids in comparison with emollient in children with severe AD during 4 weeks in a proactive schedule during which the frequency of corticosteroid applications was tapered.

***Methods:*** A randomized, double-blind, placebo-controlled study was performed in children aged 6 months to 10 years with severe AD (objective SCORAD at least 40 ± 5), comparing WWT with diluted corticosteroids (1:3 mometasone furoate 0.1% ointment and for the face 1:19 mometasone furoate 0.1% ointment under a mask) with emollient (petrolatum 20% in cetomacrogol cream). The primary outcome was improvement of the objective SCORAD; secondary outcomes included Patient-Oriented Eczema Measure and quality-of-life index.

***Results:*** WWT with diluted corticosteroids acted faster and was more efficacious than WWT with emollients. Best results were obtained in age groups 6 to 9 years and 0 to 3 years. The difference in efficacy evaluated by objective SCORAD was significant at all measuring points. This also applied to the quality-of-life index.

***Limitations:*** The study group was relatively small.

***Conclusions:*** WWT for severe AD is an effective therapy option for at least a period of 4 weeks. (J Am Acad Dermatol http://dx.doi.org/10.1016/j.jaad.2014.01.898.)

***Key words:*** atopic dermatitis; diluted corticosteroids; emollients; eczema; long-term-intervention; wet-wrap treatment.

Atopic dermatitis (AD) is characterized by exacerbations and remissions that, when severe, may require a multifaceted treatment strategy.[1] Wet-wrap treatment (WWT) to reduce severe AD is currently applied without solid evidence.[2,3] WWT has a prominent place as crisis intervention in routine practice.[2,4] Dry occlusive therapy has also been advocated, but the few

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available studies show no benefit over conventional open therapy.[5] WWT applied for a few days or weeks is considered as a relatively safe and efficacious crisis intervention in severe therapy-resistant childhood AD.[2] There is little evidence of the efficacy of WWT with diluted corticosteroids and emollients combined or with emollients alone. In a randomized controlled trial in 40 children comparing mometasone furoate 0.1% ointment and fluticasone propionate 0.005% ointment first without wraps (4 weeks) and next under wet wraps (2 weeks), both corticosteroids performed better under WWT.[6] In another controlled trial in 20 children investigating WWT with mometasone furoate 0.1% ointment and a vehicle preparation in a 5-day treatment period, results were significantly better in the corticosteroid group.[7] In a pilot study in 19 children comparing WWT with conventional therapy with hydrocortisone acetate 1% cream and emollients, the different regimens were equally effective in moderately severe AD.[8] In a left-right comparative study in 24 adults and children experiencing an acute episode of AD, 24 to 72 hours of WWT with undiluted prednicarbate performed significantly better than did standard prednicarbate only.[9] Hindley et al[10] did not find differences in outcome between application of wet-wrap bandages versus conventional topically applied corticosteroid or emollient ointments in 50 children with AD. Our group has performed many observational case series in which diluted fluticasone propionate 0.05% cream was applied, showing benefits of this treatment.[2-4,11]

This study was undertaken to prove the long-term (4 weeks) efficacy of diluted mometasone furoate 0.1% ointment in the treatment of AD with wet wraps, compared with treatment using wet wraps and emollients alone.[12,13]

**CAPSULE SUMMARY**

- Wet-wrap treatment (WWT) is a crisis intervention modality in severe atopic dermatitis.
- WWT with diluted topical corticosteroids is more efficacious than WWT with emollients only in atopic dermatitis (evidence level 3, grade B).
- WWT should be considered in therapy-resistant severe childhood atopic dermatitis if nurse support is available.

## METHODS

### Study design

From February 1, 2009, until February 1, 2012, we performed a multicenter, randomized, placebo-controlled, double-blind, prospective study in the Erasmus MC, Sophia Children's Hospital, and the KinderHaven outpatient clinic of Havenziekenhuis, both in Rotterdam, The Netherlands. Patients of the dermatology departments of the Sint Franciscus Gasthuis and Maasstad Hospitals in Rotterdam were referred to KinderHaven if wet-wrap therapy was indicated. Duration of treatment was 4 weeks (28 days). Computerized randomization was performed by our statistician (D.R.).

The study was conducted according to the principles of the Declaration of Helsinki and in accordance with the Dutch Medical Research Involving Human Subjects Act (WMO) and good clinical practice and was approved by the Medical Ethics Committee of Erasmus MC. All parents gave written informed consent for participation of their children. The study results were structured according to the CONSORT statement 2010.

### Wet-wrap therapy

WWT was applied in children with severe AD aged 10 years or younger. Severe AD is defined by an objective SCORAD greater than 40 ± 5 (see below for information on the SCORAD). WWT is normally performed with diluted corticosteroids and tapered off during several months. Earlier we have published our WWT protocol with Tubifast garments (Mölnlycke Health Care, Gothenburg, Sweden) in which ready-to-go suits are used for the body and the parents themselves cut the holes in the facemask using Tubifast.[14] For the face, mometasone furoate 0.1% ointment was diluted 1:19, although pimecrolimus 1% cream was used in some patients. For the body, a 1:3 dilution was used. These concentrations (diluted with petrolatum 20% cetomacrogol cream) were based on earlier studies with fluticasone propionate 0.005% cream.[11]

### Patient selection

A total of 39 children 6 months or older and 10 years or younger with severe AD (Hanifin and Rajka[15] criteria) were recruited in the above-mentioned sites. All parents of patients who qualified for WWT were invited to participate. The objective SCORAD was 35 to 40 or higher (indicating severe eczema) on 2 measuring points before start of treatment. In all, 35 children finished the complete study protocol.

Excluded were patients known with underlying severe illness, (secondary) infected eczema or signs of systemic infection, and abnormalities of the hypothalamic-pituitary-adrenal (HPA) axis. In addition those receiving systemic therapy with corticosteroids and those showing severe growth retardation were excluded. In case of overt