thebmj

BMJ 2018;361:k1791 doi: 10.1136/bmj.k1791

EDITORIALS

New evidence challenges use of bath emollients for children with eczema

Are we wasting millions on an ineffective treatment?

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Eczema (also known as atopic eczema or atopic dermatitis) is the commonest inflammatory skin condition in childhood, affecting around 20% of UK children and having a substantial impact on patients' and families' quality of life and National Health Service resources.[1] The regular application of leave-on emollients is a cornerstone of treatment,[2] based at least partly on evidence from intervention studies.

Little good evidence exists on the benefits of emollient bath additives,[3] although the National Institute for Health and Care Excellence recommends regular use of "emollient wash products" for children with eczema.[4] This is probably one of the reasons why emollient bath additives are commonly prescribed, costing the English NHS more than £17m a year in primary care alone.[5] But do emollient bath additives really reduce the severity of eczema and improve quality of life, in conjunction with standard care?

To answer these important questions, Santer and colleagues (doi:10.1136/bmj.k1332) conducted a pragmatic randomised controlled trial (n=482) comparing standard care with and without regular use of an emollient bath additive among children aged 1-11 years.[6] The study was conducted across 96 general practices in England and Wales. For one year, local general practitioners regularly prescribed one of three bath additives to children in the intervention group. In the control group, use of emollient bath additives was discouraged but all participants received written instructions to use emollients as soap substitutes and to continue eczema care as usual, including leave-on emollients and topical corticosteroid application as required.

Most participants had moderate eczema and all were followed-up for 12 months. The primary outcome was change in disease severity during the first four months, measured using the patient oriented eczema measure (POEM) score. Disease severity at one year, disease specific quality of life, overall use of topical anti-inflammatory treatment, and resource utilisation were important secondary outcomes. In their main analyses the authors report no statistically significant difference between the groups for any outcome.

The bath additives for the treatment of childhood eczema (BATHE) trial answers an important question, included in the James Lind Alliance list of high priority research questions for eczema, to which both experts and patients contributed.[7] Patient presentation was also strong in the development of the study protocol and conduct of the trial. Rather than just using one specific product, general practitioners had a choice between the three most commonly prescribed emollient bath additives, closer reflecting clinical practice. The trial team deserve particular credit for their one year follow-up period, which is unusually long and gave a full chance for the intervention to show any potential effects.

Remaining questions

Interestingly, the prespecified subgroup analysis by age showed a significant improvement in children aged less than 5 years, with an adjusted mean POEM score difference of 1.29 (95% confidence interval 0.33 to 2.25). Although the upper limit of the confidence interval is below the minimal clinically important difference of the POEM (3 points), this leaves open the question of whether younger children might still benefit from bath emollients, especially infants who are often bathed daily but were excluded from this trial.

Only 36% of participants in the trial had five or more baths each week and 13% of the control group admitted using bath additives, at least occasionally. Both factors might have limited the trial's ability to detect any benefit associated with the intervention. Most importantly, the control group were encouraged to use emollient soap substitutes and standard leave-on emollients, potentially attenuating any small beneficial effect from emollient bath additives.

The authors comment that it was not feasible to produce a placebo, so the control group received standard care alone. If anything, the use of a placebo would have resulted in further reduction in the effect size. The same applies to the severity assessments conducted solely by the children or parents themselves, Ideally, the authors should have included an additional more objective outcome, measured by blinded

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assessors assessors, as recommended by the Harmonising Outcome Measures for Eczema (HOME) initiative.[8]

The trial was not powered to compare the effectiveness of individual emollient products, but they all have a similar mode of action and would be expected to have largely similar effects The trial did not assess the optimal regimen for leave-on treatments, soap substitutes, and frequency of bathing or washing in children with eczema. Although there does not seem to be any additional benefit from standard emollient bath additives, those with antiseptic properties might still have a part to play in children with recurrent skin infections.

So there is still some room for further work, but it is heartening to see that an important evidence gap has been closed. Both the NHS and families of children with eczema can now better invest in more effective treatments for this common and distressing condition.

Competing interests: We have read and understood the BMJ policy on declaration of interests and declare: CF's department has received funding from Sanofi for research unrelated to the topic of this editorial. AM has no conflict of interest. AA is a portfolio manager for Boots, with responsibilities unrelated to the topic of this editorial.

Provenance and peer review: Commissioned; not peer reviewed.

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