Clinical evidence for emollient bath and shower preparations

Brief

Emollient bath and shower preparations for dry and pruritic skin conditions are included in the NHS England consultation document published in November 2018: "Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs". These items are classified as being of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

This evidence review has been prepared in response to concerns about including emollient bath and shower preparations in the NHS England consultation, and following a request for a full review of the evidence base. This review focuses on the literature available for emollient bath and shower preparations, i.e. an emollient product designed specifically for washing with in the bath or shower, and will assess its quality.

Summary of clinical evidence

- Emollient bath and shower preparations are used in patients with atopic eczema/dermatitis and a variety of other dry skin conditions. A large number of proprietary preparations are available, all of which may be prescribed on an NHS prescription. See Appendix 1 for definition of emollient preparations.
- A literature search was undertaken by SPS of Medline, Embase, CINAHL, BNI, Cochrane Library, GREAT database, NICE Evidence and Google Scholar. Search strategy is shown in Appendix 2. The search was limited to randomised controlled trials (RCTs), systematic reviews or reviews. It was not limited by clinical indication. RCTs of leave-on emollients and soap substitutes were excluded; further exclusion criteria are listed in Appendix 3.
- We identified a single RCT assessing the efficacy of emollient bath additives – the BATHE study. We also identified three systematic reviews (conducted before BATHE was published) that assessed efficacy of emollients but identified no RCTs of emollient bath or shower preparations. The lack of evidence in support of emollient bath additives (prior to publication of the BATHE study) has been confirmed numerous times by authors of guideline development groups and narrative reviews.
- The BATHE study is a high-quality, UK general practice-based study that compared efficacy and safety of commonly used emollient bath additives plus standard eczema care with standard care alone in children aged 1 to 11 years with atopic eczema. It showed that using emollient bath additives, in addition to other leave-on emollients and emollient soap substitutes, does not result in a clinically significant improvement in eczema symptoms compared with standard care alone. The trial provides sufficient assurance that there is evidence to support not routinely using emollient bath additives in children with mild-to-moderate atopic eczema being managed in primary care.
- The BATHE study did not include adolescents or adults, but it would seem appropriate to extrapolate the study findings to older patients with atopic eczema being managed in primary care, in the absence of any conflicting trial data (of which there are currently none). Although it only included patients with atopic eczema, the findings are probably also applicable to patients with other dry skin conditions being managed by their GPs.
- Few patients with severe eczema were included in the BATHE study, and the findings may not be so directly applicable to patients with severe dry skin conditions being managed by secondary care specialists who are likely to require a combination of treatment modalities because of the severity of their disease.

Place in national/ international guidance

Guidance on use of emollients, including emollient bath and shower preparations, has been published by national and international organisations.

National guidance

- **National Institute for Health and Care Excellence (NICE) 2007**
  NICE guideline CG57 on treatment of atopic eczema in children aged under 12 years (2007) recommends that health professionals should offer children with atopic eczema a choice of unperfumed emollients to use every day for moisturising, washing and bathing.[1] This may include a combination of products or one product for all purposes.

The full NICE evidence review did not identify any controlled studies comparing emollients to placebo or active intervention, so it was not possible to quantify benefits and harms of emollient therapy.[2] The literature search found two uncontrolled studies using emollient bath additives (and two additional studies using emollient bath additives containing antimicrobials) but were judged by the guideline development group to be inadequate to inform the guideline.

- One study was a case series reporting on use of a bath oil preparation containing soya oil plus lauromacrogols in children and young people with dry, itchy dermatoses (n=3,566). Mean duration of treatment and follow-up was six weeks. The diagnosis was atopic eczema in 86% of the cases, and most (94%) of those included were aged under 15 years. Overall, 78% received other treatment for their skin condition, but because details of these treatments were not reported it is not known whether improvements in the children's global condition were due to the bath oil preparation or to other treatments.

- The second study assessed the effects of using *Oilatum*® bath emollient daily (by soaking one arm in a basin of water with added emollient) in a within-patient (left–right side) comparison (n=9). All children had standardised treatment consisting of weekly whole-body bathing in a bath containing the same emollient, twice-daily application of an emollient and a topical corticosteroid, and use of emulsifying wax as soap substitute. The treated (daily treatment) and untreated (routine care) arms were evaluated by an assessor blind to treatment allocation. Mean difference in clinical score at four weeks (a measure of extent and severity of atopic eczema) was not significant, although the difference in mean change in score over the duration of the four-week study was reported to be significantly different.

The NICE guideline development group concluded that a complete emollient regimen provides optimum benefit. Emollient bath oils and other emollient wash products provide an essential method to clean the skin without the damaging effect of soap and detergents. They note some children may need additional products that can be applied indirectly to the skin, such as in the bath, to ensure that adequate amounts of emollient are absorbed into their skin. Healthcare professionals should offer a range of different products; the correct emollient is the one that the child will use.

Following publication of the BATHE study in 2018 (see below), NICE announced in February 2019 that it plans to update its guideline.[3]

- **Scottish Intercollegiate Guidelines Network (SIGN) 2011**
  In its guideline on management of atopic eczema in children and adults in primary care, SIGN notes that a systematic review in 2000 did not identify any high quality clinically relevant evidence in support of emollient monotherapy.[4] However, SIGN acknowledged that expert opinion (from NICE guideline CG57 in children, but applicable to adults) supports use of emollients. Emollient bath oils are included in their list of available types of emollients.

- **British Association of Dermatologists (BAD) *undated***
  BAD published a position statement on the place of bath emollients in treatment of atopic dermatitis.[5] They recommend that people with atopic dermatitis use a very mild wash product with some emollient ingredients – use an emollient cream as a soap substitute or, as an alternative, an emollient bath oil or shower product. BAD notes NICE advises patients, or their parents, should be allowed to choose either an emollient or a bath/shower product, as there is no evidence to separate the two choices. They also note that results from the then ongoing BATHE study will allow a more evidence-based approach to be used when developing prescribing policies.

- **Primary Care Dermatology Society (PCDS) 2018**
  PCDS clinical guidance on atopic eczema recommends complete emollient therapy to the whole skin every day – the correct use of moisturisers, bath or shower emollients, and soap substitutes.[6] Supporting evidence is not described.

- **Clinical Knowledge Summaries (CKS) 2018**
  CKS notes that emollient bath additives and shower products are an option for people with extensive areas of dry skin, although evidence to support their use is limited and there is no universal consensus as to their benefit.[7] The guidance cautions that if emollient bath additives are to be used, it is essential they do not replace standard emollients, but are used in addition to leave-on emollients.

- **Royal College of Nursing (RCN) 2013**
  The RCN, in its 2013 guidance for nurses, recommends that first-line treatment of atopic eczema should be complete emollient therapy (use of a bath or shower product, soap substitutes and leave-on emollients).[8] It refers to the NICE guideline on atopic eczema in support of this statement.

- **UK Emollient Consensus Group 2013** *(sponsored by Almirall)*
  As use of emollient therapy in dry skin conditions is supported only by limited or atopic dermatitis-specific guidelines and a best practice statement, an Emollient Consensus Group was set up to review current data and practice.[9] In 2013, they advised that patients should be given the opportunity to consider a variety of emollients from the whole spectrum of products available, and to identify the most suitable products for their skin. Emollient bath additives should be used in conjunction with leave-on emollients. No evidence in support of this recommendation is provided.

- **British Dermatological Nursing Group (BDNG) 2012** *(sponsored by Almirall)*
  In a best practice statement published in 2012 by BDNG with support from the International Skin care Nursing Group (ISNG), use of bath additives is advocated.[10] It notes there are also wash products designed for use in the shower. It states there is little evidence as to the efficacy of emollient bath additives, but that for patients they can be a useful way to get moisturisers onto the skin.

Research published on local guidance

A cross-sectional study designed to identify and compare emollient formularies across all clinical commissioning groups in England and local health boards in Wales (total n=216) identified 102 formularies.[11] Of the 82% that recommended an emollient bath additive (24 different ones), 75% (64/84) gave no rationale, six noted evidence to support use was lacking, eight recommended use in specific circumstances, and six cited 'possible benefit for some patients'. There was no mention of emollient bath additives in 7% of formularies, and 11% did not recommend routine use of emollient bath additives.

International guidance

- **European Consensus Group 2018**
  In an update to its 2012 guidance on atopic dermatitis, this consensus-based guideline developed as a joint interdisciplinary European project, recommends use of emollient bath oils and soap substitutes in addition to leave-on emollients.[12] It notes that bath oils are a valuable addition for skin care, especially in babies and children. It does not present any evidence in support of the recommendation to use emollient bath additives.

- **American Academy of Dermatology 2014**
  The American Academy of Dermatology, in its 2014 evidence-based guideline for management of atopic dermatitis in adults and children, states that the addition of oils and emollients to bath water cannot be recommended at this time, because of insufficient evidence.[13] The quantity of emollient deposited on the skin via a bath additive is likely to be lower than that from direct application. Bathing with water can hydrate the skin and remove scale, crust, irritants and allergens, which can be helpful for patients with atopic dermatitis. However, if the water is left to evaporate from the skin, greater trans-epidermal water loss occurs. Therefore, application of moisturisers soon after bathing is necessary to maintain good hydration status.

Evidence for this SPS review

A literature search for emollient bath and shower preparations identified a single RCT[14] that assessed the efficacy of emollient bath additives (see Appendix 2).

Prior to publication of this study,[14] several narrative reviews have concluded there is no published evidence from RCTs evaluating the efficacy of emollient bath additives in atopic eczema and other dry skin conditions.[2,13,15-18] This lack of evidence, until recently, has been common to leave-on emollients and emollient bath additives.[15] However, whereas there is consensus among clinicians and long-standing clinical experience that leave-on emollients are effective, it is not the case with emollient bath additives.[7,15,18] There is also no evidence that complete emollient therapy is effective.[16]

Despite the lack of evidence and consensus of opinion, use of emollient bath and shower preparations in England is significant.[18,19] In 2015, total spend on these products in England was nearly £23.1 million.[18] A cross-sectional study published online in December 2018, involving 13,618 children with atopic eczema in England, found that 34% of children with active atopic eczema were prescribed an emollient bath additive by their GP during the 1-year study period (29% received both bath additive and leave-on emollient, and 5% received a bath additive but no leave-on emollient).[19] Overall, 75% received a leave-on emollient and 20% received neither a leave-on emollient or an emollient bath additive.

Systematic reviews

Four systematic reviews have assessed the efficacy of emollients.[20-23] However, a Cochrane review of emollients and moisturisers for eczema focussed only on leave-on moisturisers.[23]

- **Nankervis *et al*. 2017**
  A systematic scoping review of all systematic reviews and RCTs for atopic eczema treatments (designed to map existing evidence and identify gaps in the literature) found no RCTs on non-antiseptic emollient bath additives or shower emollients.[20] This review was commissioned by the National Institute for Health Research (NIHR) to update a previous review published in 2000.[22]

- **Hoare *et al*. 2000**
  This initial NIHR-commissioned systematic scoping review of treatments for atopic eczema identified only five published RCTs for emollients, none for emollient bath or shower preparations.[21]

- **Jacobi *et al*. 2015**
  A systematic review of keratolytics and emollients in patients with psoriasis found no RCTs for emollient bath or shower preparations.[22]

Published randomised controlled trials

- **Santer M *et al.* (BATHE study)**
  A UK-based, open-label, pragmatic RCT (n=482) compared emollient bath additives plus standard eczema care with standard care alone in children aged 1 to 11 years (mean age 5.3 years; 51% female) with a diagnosis of atopic dermatitis (according to UK diagnostic criteria).[14] Children with very mild (score ≤5 on Nottingham eczema severity scale) or inactive eczema (over last 12 months) and those who bathed less than once weekly were excluded.

  Children were randomised in a 1:1 ratio to their group using an automated on-line software package (with a back-up phone option). From the detail available it appears that allocation concealment was achieved and the investigator would have had no opportunity to influence whether the patient was allocated to the emollient bath additive (intervention) group or the control group. Overall, randomisation resulted in two groups similar at baseline. However, there is an unexplained disparity in numbers allocated – 264 patients were allocated to the intervention group and 218 to the control group. This does not materially affect the validity of trial design but it would be useful to understand how this arose. The authors suggest their use of a simple randomisation technique may have been the cause, as the technique can result in imbalances in numbers recruited to each group.[24]

  Patients, carers, clinical study officers and research nurses were not blind to treatment allocation, but statisticians carrying out the analyses were. This was a pragmatic trial and the authors said it is not possible to create a credible “placebo” emollient bath additive. This is a valid argument and does not significantly compromise the validity of findings.

  Children in the intervention group were prescribed emollient bath additives (ideally one of the three most widely prescribed in the UK) and asked to use them regularly for 12 months, while children in the control group were not prescribed emollient bath additives and were asked not to use any emollient bath additives for 12 months. *Oilatum*® was used by 45% of the intervention group, *Aveeno*® by 26% and *Balneum*® by 4.5%, with 30% of children prescribed another brand of emollient bath additive. Emollient bath additives containing antimicrobials were not permitted as they may cause irritation. Both groups received written information on how to wash, including use of leave-on emollients as a soap substitute. No data presented suggested that there was any differential approach to management between the two groups.

The primary outcome was eczema severity, measured by the validated Patient Oriented Eczema Measure (POEM) score over 16 weeks. POEM is a patient/carer-reported outcome measure which consists of seven questions to provide a score of between 0 and 28; minimal clinically important difference (MCID) is 3 points. At baseline, 62 children (13%) had severe eczema, 233 (48%) had moderate eczema and 187 (39%) had mild eczema. Although baseline mean POEM scores are similar between the intervention and control groups (9.5 vs. 10.1, respectively), it would appear that more patients with mild eczema were randomised to emollient bath additives (43%) than the control group (33%) – it could be argued that this reduced the scope to achieve significant reductions in POEM score from baseline in the intervention group.

The study was adequately powered for the primary outcome to have a 90% chance of detecting a mean difference of 2.0 points on the POEM scale at $p<0.05$ level in the intention-to-treat (ITT) population, if such a difference existed. It was slightly underpowered to undertake a per-protocol (PP) analysis but only by a few patients.

Results

In the intervention group, mean POEM score over 16 weeks was 7.5 points (SD 6.0) from a baseline score of 9.5; in the control group, mean POEM score was 8.4 points (SD 6.0) from a baseline score of 10.1. There was no statistically significant difference in POEM score between the two groups over 16 weeks. After adjusting for baseline severity, confounders (including topical corticosteroid and soap substitute use), and allowing for clustering within practices and responses within participants over time, the POEM score in the control group was 0.41 points higher (95% confidence interval [CI] -0.27 to 1.1) compared with the intervention group. The upper limit of the CI (1.1 points) falls well below the MCID of 3 points, so the authors feel that this rules out the possibility of a clinically significant effect within the credible range of results seen.

These findings were reinforced in the PP analysis (which increases the likelihood of demonstrating a positive difference in that it selects the population that actually complied with the allocated treatments) in which mean difference in POEM score was a statistically insignificant difference of 0.32 (95% CI: -0.37 to 1.02).

There was no significant difference between groups according to baseline disease severity. Adjusted difference in mean POEM score was -0.07 (95% CI: -1.08 to 0.95) in the mild eczema group, 0.65 (95% CI: -0.45 to 1.74) in the moderate eczema group, and -1.16 (95% CI: -3.62 to 1.32) in the severe group.

No significant differences were observed between groups for any of the secondary outcomes. These included POEM scores measured every four weeks over 52 weeks, disease-specific quality of life at 16 weeks and one year (measured using dermatitis family impact), generic quality of life at 16 weeks and one year (measured using child health utility-9D), number of disease exacerbations requiring primary care consultation over one year, type and quantity of topical corticosteroid/topical calcineurin inhibitor prescribed over one year, resource use, adherence to treatment allocation, and adverse effects.

The authors also assessed the economic impact of using emollient bath additives and found no benefits that could be used to consider them to be cost-effective.

- Overall mean annual cost to the NHS was £180.50 in the intervention group vs. £166.12 in the control group, a non-significant difference of £14.38 (95% CI: -£33.45 to £62.21).
- For costs borne by families, there was a non-significant difference between groups, with a higher spend of £51.37 in the control group (95%CI: -£15.74 to £118.49); the adjusted difference was £47.56 (-£18.07 to £113.19).
- There was no significant difference in quality adjusted life years (QALYs) between groups, with 0.91 QALYs in the intervention group vs. 0.90 in the control group, mean difference 0.00 (-0.01 to 0.02).

Adverse events were similar across groups. Over the first 16 weeks, 35% of children in each group reported at least one adverse event, with no significant difference between groups (odds ratio 1.4, 95% CI: 0.79 to 2.47). Adverse events reported at 16 weeks across the intervention and control groups, respectively, were slipping in bath (17% vs. 25%), redness (14% vs. 23%), refusal to bathe (8% vs. 12%) and stinging (2% vs. 2%). At 52 weeks, these figures had mostly increased – slipping in bath (22% vs. 30%), redness (17% vs. 29%), refusal to bathe (12% vs. 15%) and stinging (3% vs. 2%).

Discussion

This is a pragmatic study conducted in primary care centres in the UK – so clearly applicable to practice, particularly in children. There may be some debate as to whether it is appropriate to extrapolate findings to adolescents, adults and patients with more severe disease who require specialist care (as only 13% had severe disease).

The open-label design of the study may have introduced bias, as parents knew which group their child was randomised to. This knowledge may have affected how they managed their child's eczema, for example the volume of soap substitute emollient used. In addition, all participants in the study received information on use of emollients as soap substitutes. However, both of these factors would be expected to improve the patients' skin in both groups. It would have been interesting to have been presented with an analysis of proportion of patients in each group that achieved a 3-point reduction in baseline POEM score – as this would have supported a more intuitive NNT-type (number needed to treat) analysis of the results.

The authors analysed the results using both ITT and PP principles. ITT is the preferred approach in superiority trials. The researchers showed no significant difference in the ITT population (which is the population that more closely reflects clinical practice). Analysis of the PP population takes account of the fact that some patients in the intervention group used additives less than 50% of the time and some patients in the control group used emollient bath additives more than 50% of the time. This potentially reduces the chances of showing a difference in favour of emollient bath additives if one exists. However, in taking the "non-compliant" patients out of the PP analysis, there was still no significant beneficial effect seen from using emollient bath additives.

There were low rates of loss to follow-up in both arms of the study – 13/265 in the intervention group and 9/218 in the control group. As no significant differences were found in terms of primary or secondary outcomes it seems unlikely that loss to follow-up significantly impacted on the results described. However, without a dichotomous outcome (such as proportion of patients that achieved a fall of 3 points or more on POEM score), it is not possible to explore this in any more detail.

In the absence of any robust evidence to contradict the findings of this RCT, this study provides sufficient assurance that there is good evidence to support not routinely using emollient bath additives in children with mild-to-moderate atopic dermatitis that are managed in primary care. It would seem appropriate to extrapolate the findings to older patients and those with other dry skin conditions, in the absence of any conflicting trial data. However, it is less clear whether it is appropriate to extrapolate the findings to patients with severe disease who may require a combination of treatment modalities.

Note: The BATHE study has also been published as a health technology assessment report.[24]

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Appendix 1: Definition of emollient preparations

NHS England requested a review of the evidence base for emollient bath and shower preparations, as defined in the BATHE study.[14] The definition is:

> "Emollients are applied in one of three ways:
> - leave-on, where emollients are directly applied to the skin;
> - soap substitutes, where emollients are used instead of soap or other wash products; and
> - bath additives, comprising oil or emulsifiers, or both designed to be added to bath water and thought to leave a film of oil over the skin.
>
> Some emollients can be used in more than one way. We therefore use the term "emollient bath additives" or "bath additives" rather than bath emollients to emphasise the differences between the three methods of application in recognition that products may have more than one method of application."

We have used the term 'emollient bath additives' when discussing bath emollients within this evidence review.

Appendix 2: Search strategy

Database	Search term	Results
EMBASE – 25/3/19	("EMOLLIENT AGENT"/ AND (BATH/ OR (bath).af OR (shower).af)) AND (exp "CONTROLLED CLINICAL TRIAL"/ OR exp REVIEW/)	88
Medline – 25/3/19	(exp EMOLLIENTS/ AND (BATHS/ OR (bath).af OR (shower).af)) [Document type Meta-analysis OR Randomized Controlled Trial OR Review]	38
CINAHL – 15/3/19	(exp EMOLLIENTS/ AND ("BATHING AND BATHS"/ OR (shower).af)) [Publication types Meta Analysis OR Randomized Controlled Trial OR Systematic Review]	5
BNI – 15/3/19	((bath).af OR (shower).af AND (emollient).af))	18
Cochrane Library via www.thecochranelibrary.com – 15/3/19	Search: Moisuturi* AND (bath* OR shower*) Emollient* AND (bath* OR shower*)	 36 53
NICE Evidence – 4/3/19	Search: bath emollient Limit to guidance and policy; remove prescribing and technical information	34
Google Scholar – 5/3/19	Advanced search: Search exact phrase = bath emollient AND Search = trial OR study OR adult OR child	143
GREAT database via www.greatdatabase.org.uk – 15/3/19	Search: (Bath [any field] OR shower [any field]) AND emollient* [any field]	24

Appendix 3: Exclusion criteria

- leave-on emollients
- soap substitutes
- healthy volunteers
- neonates
- prevention of dry skin, e.g. routine skin care in healthy infants
- tar-containing preparations
- antibiotic-containing preparations
- antiseptic-containing preparations
- studies evaluating cellular or biochemical responses, or blood tests
- conference abstracts