

Bath Oils

1. Primary literature

Reference

Loden M, Iburaczewska I, Edlund F. Irritation potential of bath and shower oils before and after use: a double-blind randomized study. Br J Dermatol. 2004; 150:1142-47.

Study Objective

The investigation of possible differences in the irritation potential of eight shower or bath oils and the investigation of whether surfactant residues may form a reservoir of irritant substance on the skin.

Methods

o Design- Randomized study. The ability of products to cause skin irritation was determined using conventional patch test techniques. Detection of potentially irritant residues was done by occlusion of the treated and rinsed skin area, followed by an evaluation of the skin response. Measurements of transepidermal water loss (TEWL) and superficial skin blood flow served as indicators of the injurious effects of the products. During the test period, subjects were allowed to wash normally but were not to use any skin care products on their arms. They were also asked not to use any body care products on their forearms for at least 3 days before the test started. The study was carried out in October and November.

o Allocation- Not applicable

o Blinding- double-blinded

o Follow-up period- Arms were visually assessed using a range of 0 to 4 according to European Society of Contact Dermatitis (ESCD) guidelines on clinical scoring of acute SLS irritant reactions. Visual assessment was conducted at 1 hour and 24 hours after application. The scale was: 0, negative (no damage); 0.5, doubtful (very weak erythema or minute scaling); 1, weak (weak erythema, slight oedema, slight scaling and/or slight roughness); 2, moderate moderate degree of erythema, oedema scaling and/or roughness; 3 strong (marked, degree of erythema, oedema, scaling, roughness); 4, very strong/caustic (same as 3, with necrotic areas). Measurements of TEWL (transepidermal water loss) and skin blood flow were then measured.

o Setting- Sweden

o Participants- 15 healthy human volunteers (11 women and 4 men, aged 23-57 years old)

o Intervention -8 different types of shower or bath oils from the European market were used. These products claimed to be suitable as shower or bath oils for dry skin. They differed in

their main surfactant. Distilled water was used as the negative control, and 1% aqueous of sodium lauryl sulphate (SLS) was used as a positive reference.

- o Outcomes- Occlusive exposure to the test products caused visible skin reactions especially in the 24 hour mark in most of the skin sites. Compared to water, the control, instrumental evaluations for TEWL and blood flow revealed that F,G and H increased both TEWL and blood flow significantly whereas A,B and C did not cause significantly higher values. No significant differences in erythema were detected between the products were detected at the 1 hour or 24 hour readings. Although there were significant differences in TEWL between the oils ($P = 0.012$), no differences were seen for skin blood flow. Oils E, G and the positive control SLS yielded significantly higher TEWL compared to water. Oil G also caused high irritation during the patch test whereas E appeared mild to the skin and did not significantly increase TEWL. The magnitude of TEWL and blood flow were almost 10 times lower after rinsing the skin with water than after ordinary patch test exposure.

- o Patient follow-up - Not applicable

Main results

Large differences between products in terms of irritant potential. Some did not irritate more than water, others demonstrated considerably damaging effects. There was still a presence of barrier-impairing residues on the skin after rinsing with water.

Conclusions

Rather than protecting the skin, some bath oil formulations may cause subclinical injuries and delay skin barrier function recovery with prolonged risk for patients with eczema.

Comments/Critical Appraisal

There were a few limitations to this study. First, it was carried out in only healthy Swedish patients and as a result, may have poor external validity and not as applicable to non-Swedish patients or to those with dermatitis. As well, the sample size was small with just 15 volunteers of 11 women and four men. The study also only used short term changes in transepidermal water loss as a surrogate marker for the severity of the skin condition when it may have been better to consider more long term changes in the skin condition. However, the study had good internal validity since during the test period, subjects were allowed to wash normally but were not to use any skin care products on their arms. They were also asked not to use any body care products on their forearms for at least 3 days before the test started. This was to ensure that there would be no confounding factors when assessing results. The study also used a within subject design where subjects acted as their own control, a design that effectively reduces the amount of error that could arise from natural variance between individuals. Overall,

this study provides little evidence and support for the first-line use of bath oils in the treatment of dermatitis.

2. Primary literature

Reference

Betzuege-Pfaff BI, Melzer A. Treating dry skin and pruritus with a bath oil containing soya oil and lauromacrogols. *Curr Med Res and Op.* 2005;21(11):1735-39.

Study Objective

Bath oils containing soya oil and anti-pruritic lauromacrogols have been shown in experimental and clinical studies to be safe and effective. The objective of this observational cohort study was to generate more efficacy and safety-related data on the day-to-day of bath oils containing these ingredients in paediatric patients.

Methods

- o Design—A post-marketing surveillance study (observational cohort study) on over 3500 patients with the vast majority aged 0-4 years.
- o Allocation-- Not applicable
- o Blinding-- Not applicable
- o Follow-up period – Not applicable
- o Setting—Not applicable
- o Participants— There was a total of 3566 patients involved in the study. The age distribution of participants ranged from under 1 to over 20 years of age; however, a vast majority of patients (61.4%) were 0-4 years of age. Patients had dry, itchy dermatoses and were recruited by physicians in paediatric surgeries throughout Germany and GP surgeries with a strong paediatric focus. Atopic eczema was diagnosed in 86.4% of the patients.
- o Intervention – Patients were treated with the bath oil containing soya oil and lauromacrogols. There were no special instructions for physicians in terms of the treatment regimen, application frequency and duration due to the nature of this study. Physicians were advised to take into account the information given in the product summary. Approximately 13% of patients used the bath oil daily, 38% three times per week, 42% twice a week and 7% once a week. Based on the summary of product characteristics, the recommended use is every 2-3 days.
- o Outcomes—Four criteria were assessed by the attending physician and these determined clinical improvement. These criteria were skin dryness, itching, flaking and excoriation. A reduction in the mean sum score, which reflects the overall change in extent of all four observed criteria, was the measured outcome.

o Patient follow-up—the duration of treatment with the medical bath oil as 42 days. A further interim observation during the treatment period was performed in 1813 patients after an average of 26 days.

Main results

The sum score of symptoms decreased during the treatment period from a mean of 7.21 to 2.71 score points. Physicians also assessed the global efficacy in 89.4% of the cases as ‘very good’ or ‘good’. The local tolerability was also stated to be ‘good’ or very ‘good’ in 96.8% of the patients. In total, only 10 out of the 3566 patients experienced discomfort secondary to the bath oil.

Conclusions

The results indicate that a recommended usage frequency of 2-3 times a week leads to good results that allow for flexibility of treatment during the day and makes combined therapy routines less time consuming. Anti-pruritic bath oil is both well-tolerated and effective in treating dry and itchy skin diseases. Physicians estimated that the bath oil therapy helped to reduce the use of steroids in nearly 60% of patients. The potential to reduce use of external steroids and other specific therapeutics is of particular relevance from a pharmacoeconomic point of view.

Comments/critical appraisal

This is an observational cohort study and not a randomized control trial. Such studies are non-blinded and without specific inclusion criteria. As well, before taking part in this study, a total of 2397 patients had been treated with other topical preparations such as basic emollients, urea preparations, corticosteroids, and anti-histamines which may have confounded the study’s results. The results were also generated based on the largest age group population of children aged 0-4 years old, meaning it has weaker external validity to older children and adults. However, the children did have a variety of dermatitis conditions, although the majority of them had atopic eczema, which may also reduce the external validity. In addition, the duration of the study was only 42 days and could have been longer. Having physicians themselves assess the global efficacy in the cases may introduce an element of bias as well as make the assessment more subjective than objective. However, an advantage is that the nature of this study provides a true reflection of the use of bath oils in daily practice.

3. Textbook

Reference

Sibbald D. Atopic, Contact and Stasis Dermatitis. In: Repchinsky C, Hutsul J, Jovaisas B, Lewis G, Perrier H, Riachi M, Ross A, editors. *Patient Self-Care*. Ottawa, ON: Canadian Pharmacists Association; 2010: 510-533.

Source description

The source is *Patient Self-Care*, a text book that is referenced by healthcare professionals and is peer-reviewed by other healthcare professionals. The text covers the pathophysiology, goals of therapy, patient assessment, nonpharmacological therapy, pharmacological therapy, and monitoring of therapy for various self-care topics.

Summary

Bath oils are usually applied at the end of the bath or after the bath while the skin is still damp. It acts as a barrier to reduce water loss as well as soothe irritated skin. It also has a fast onset and is effective until it is removed from the skin. However, they are less effective than lotions or creams applied directly to wet skin since they are diluted in water, in contact with skin for a short time, and most of it is wiped off when the skin is dried with a towel. To be more effective, they should be added near the end of the bath to trap water in the skin. However, they give the patient a false sense of lubrication and can make the bathtub slippery. Bath oils containing fragrances and lanolin should be avoided. Concentrations of surfactants (e.g. sodium lauryl sulfate) above 4% reduce the affinity of oil for the skin.

There are different types of bath oils. Ones that are oil as a single ingredient, bath oil capsules which enclose small amounts of oil that dissolve in hot water but they may require a higher water temperature than desirable, as well as contain a higher percentage of fragrance.

Comments/Critical Appraisal

This is a textbook source which gives general information for the treatment of dermatological conditions within the general population. As a result, the internal and external validity of the studies behind the textbook information are not clearly defined. As well, the textbook gave a general, rather than in –depth, discussion of the pharmacological treatments for various kinds of dermatitis. The sources referenced in this chapter were based extensively on randomized clinical trials, studies and other clinical textbook sources which provides good internal validity. Various forms of dermatitis were discussed including atopic, contact and stasis, and many pharmacological options were covered. making this a great source for a quick overview of the pathology and available treatments for dermatitis.

4. Systematic reviews and meta-analyses

Reference

Tarr A, Iheanacho I. Should we use bath emollients for atopic eczema? *BMJ*. 2009;339:b4273.

Study Objective

The objective is to conduct a systematic review on the best available research on the use of bath emollients for atopic eczema.

Scope

The scope of the searched studies included patients with atopic eczema and the use of bath emollients for treatment of their atopic eczema. The outcome the authors of the article looked for was a clinical benefit of the use of bath emollients.

Methods

A search of PubMed, the *Cochrane Library*, *Clinical Evidence*, and the Current Clinical Trials database was conducted to identify published and ongoing randomised controlled trials and systematic reviews that have assessed the efficacy of bath emollients in patients with atopic eczema.

Main Results

No published randomised controlled trials specifically assessed the clinical efficacy of bath emollients in atopic eczema. The authors of the article were also not aware of any long-term clinical benefits of bath emollients that matched that for directly applied emollients. The amount of emollient applied on the skin during bathing are also likely to be far lower than the amount directly applied to the skin. Both these points do not strongly support the use of bath emollients in the treatment of atopic eczema. There were also no published evidence that ‘complete emollient therapy’, a combination of creams, ointments, bath emollients, and soap substitutes, provides ‘maximal effect’. In addition, the unproved concept of ‘complete emollient therapy’ has fostered the assumption that each of the individual components of the therapy are useful when used alone, despite the fact that they lack confirmatory data.

Conclusions

Based on current evidence, bath emollients could be offering little of no benefit.

Comments/Critical Appraisal

There was no mention of the use of MeSH terms in the search strategy. However, the risk of missing trials for this systematic review is low since the search criteria of atopic dermatitis and the use of bath emollients were more specific than general. The systematic review did not find any published randomised controlled trials on the efficacy of bath emollients in atopic dermatitis; however, the search was limited to only randomized controlled trials as well as systematic reviews. Thus, other types of sources such as meta-analysis, expert opinions, and evidence-based guidelines to treatment were excluded. Since this systematic review did not find randomised controlled trials that have specifically assessed the clinical efficacy of bath emollients in atopic eczema, bath emollients would not be considered as first line therapy. This review also only looked at atopic dermatitis which reduces the external validity of the study for patients presenting with other forms of dermatitis.

5. Clinical practice guidelines

Reference

Holden C, English J, Hoare C, Jordan A, Kownacki S, Turnbull R, et al. Advised best practice for the use of emollients in eczema and other dry skin conditions. *J Dermatol Treat.* 2002; 13:103-106.

Study Objective

The authors' aim of this review is to provide evidence-based guidelines for emollient therapy in eczema care to improve day-to-day management by health professionals in the community and to promote consistent practices by patients.

Scope

N/A

Methods

No search strategy was disclosed to explain the authors' proposals; however, the recommendations included in this paper are based on randomized control trials and meta-analysis.

Main results

Emollients, which can be in the form of creams, ointments, soap substitutes, or bath oils, are commonly recommended to improve lipid barrier function and to relieve feelings of dryness and pruritis. Despite the relative lack of clinical evidence supporting the efficacy of emollient

therapy in eczematous conditions, it is generally believed that emollients assist in barrier function.

Conclusions

Emollients are most effective when applied after bathing, when the skin has high water content, and should ideally be re-applied regularly throughout the day. However, the use of emollients alone is unlikely to provide efficacy in inflammation control and so topical corticosteroids should be used if required. To be effective, it is essential that bath emollients be supplied in sufficient quantities based on a usage of 150 mL per week for bath oils.

Comments/Critical Appraisal

The guidelines proposed in this article have been accredited by the British Skin Foundation and form the ABC (Avoid soap, Benefit from emollients, and Control inflammation) dry skin and eczema management programme supported by the National Eczema Society. The article also looked at populations with eczema as well as other dry skin conditions. However, a limitation to the article is that it is not based on a single trial but is rather based on the results and recommendations of other studies. The studies though, were appropriately referenced and supported the guidelines proposed in this article. The guidelines in this article have good external validity and can be applied to patients presenting with various forms of dermatitis. Overall, the article supported the use of bath emollients (bath oils) to help relieve dryness and itchiness for eczema and other dry skin conditions when applied continuously in sufficient quantities.