

# Randomized, Controlled Trial Evaluating a Baby Wash Product on Skin Barrier Function in Healthy, Term Neonates

Tina Lavender, Carol Bedwell, Stephen A. Roberts, Anna Hart, Mark A. Turner, Lesley-Anne Carter, and Michael J. Cork

## Correspondence

Tina Lavender, DBE, PhD, MSC, RM, RGN, School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK.  
Tina.lavender@manchester.ac.uk

## Keywords

randomized  
term neonates  
wash product  
neonatal skin care  
transepidermal water loss  
noninferiority trial

## ABSTRACT

**Objectives:** To examine the hypothesis that the use of a wash product formulated for newborn (<1 month of age) bathing is not inferior (no worse) to bathing with water only.

**Design:** Assessor-blinded, randomized, controlled, noninferiority trial.

**Setting:** A teaching hospital in the Northwest of England and in participants' homes.

**Participants:** Three-hundred-and-seven healthy, term infants recruited within 48 hours of birth.

**Method:** We compared bathing with a wash product ( $n = 159$ ) to bathing with water alone ( $n = 148$ ). The primary outcome was transepidermal water loss (TEWL) at 14 days postbirth; the predefined difference deemed to be unimportant was 1.2. Secondary outcomes comprised changes in stratum corneum hydration, skin surface pH, clinical observations of the skin, and maternal views.

**Results:** Complete TEWL data were obtained for 242 (78.8%) infants. Wash was noninferior to water alone in terms of TEWL (intention-to-treat analysis: 95% confidence interval [CI] for difference [wash–water, adjusted for family history of eczema, neonate state, and baseline]  $-1.24, 1.07$ ; per protocol analysis: 95% CI  $-1.42, 1.09$ ). No significant differences were found in secondary outcomes.

**Conclusion:** We were unable to detect any differences between the newborn wash product and water. These findings provide reassurance to parents who choose to use the test newborn wash product or other technically equivalent cleansers and provide the evidence for health care professionals to support parental choice.

JOGNN, 42, 203-214; 2013. DOI: 10.1111/1552-6909.12015

Accepted November 2012

Tina Lavender, DBE, PhD, MSC, RM, RGN, is a professor of midwifery and director for the Midwifery Research Group, School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK.

(Continued)

Funded by Johnson & Johnson Consumer Companies, Inc.



Infant skin has several important functions, including prevention of infection, maintenance of a stable water content level, and reduction of the penetration of allergens and irritants (Holbrook, 2000). These functions depend on the maintenance of an effective skin barrier with an optimum pH (Cork et al., 2008). A neonate's skin remains immature for some time following birth; it has been demonstrated that the stratum corneum continues to develop until at least age 12 months (Nikolovski, Stamatas, Kollias, & Wiegand, 2008). The normal skin pH at the surface of the stratum corneum after the first year of life is around 5.5. This low pH is important for maintaining low protease activity and enhancing the synthesis of the lipid lamellae, which are central to the maintenance of a normal skin barrier (Danby & Cork, 2011).

The most common skin diseases during this first year of life are napkin/diaper dermatitis, skin infections, and atopic dermatitis (AD) (Atherton & Mills, 2004). Atopic dermatitis occurs as a result of gene–environment interactions leading to skin barrier breakdown (Cork et al., 2009). Soap and harsh surfactants play an important role in facilitating skin barrier deterioration and triggering AD onset (Danby & Cork, 2011). The optimal wash product for a neonate should have a pH around 5.5 and some buffering capacity to maintain skin pH around this level. This was the pH of the wash product used in this trial. At the other end of the spectrum, a soap bar can raise the pH of the skin above 8.0. This leads to enhanced protease activity and inhibits the synthesis of the lipid lamellae, resulting in breakdown of the skin barrier (Cork

et al.; Danby & Cork). When oils are reacted with a solution of sodium hydroxide, they break down to form glycerol and the sodium salts of their fatty acids. These salts are used as soap, which are an example of an anionic surfactant. Surfactants have varying effects on skin barrier integrity (Goffin, Paye, & Piérard, 1995). Surfactants with a negative charge (e.g., sodium dodecyl [lauryl] sulphate) have greater skin irritation potential compared with glycosylated surfactants (Ananthapadmanabhan, Moore, Subramanyan, Misra, & Meyer, 2004), the latter of which were used in the study wash product.

Atopic dermatitis is a significant health care burden and impairs the quality of life of infants (Lewis-Jones, Finlay, & Dykes, 2001) and their parents (Lawson, Lewis-Jones, Finlay, Reid, & Owens, 1998). Such problems highlight the need for suitable skin care regimens. As a result, water alone has been suggested as the least harmful method for newborn cleansing in many countries (National Institute for Health and Clinical Excellence [NICE], 2006). However, the buffering capacity of water has been questioned, as it may increase the skin surface pH from 5.5 to 7.5 (Tsai & Maibach, 1999). A pH of 7.5 is likely to increase skin protease activity and inhibit the synthesis of the lipid lamellae, leading to a breakdown of the skin barrier (Tsai & Maibach). Water alone has been identified as an ineffective cleanser, as it fails to remove fat-soluble substances such as feces and sebum (Gelmetti, 2001). This is an issue highlighted as particularly important by mothers (Lavender et al., 2009).

Although guidelines exist for the treatment of atopic eczema (NICE, 2007), there are no guidelines for primary prevention of atopic eczema. Within the United Kingdom, national postnatal care guidelines recommend bathing with water alone in the early postnatal period (NICE, 2006). However, neonatal skin care guidelines in the United States (Lund et al., 2007) recommend the use of warm tap water for bathing with the option to use a mild cleanser that has a neutral pH (5.5 to 7.0). The absence and inconsistencies in guidelines are likely to be the result of a dearth of robust evidence from which to inform practice. [Correction added after online publication 19 Feb 2013: In the previous two paragraphs, the NICE references were erroneously listed as "NIHCE." This has been corrected here and in the reference list.]

In a recent systematic review (Crozier & Macdonald, 2010) of newborn cleansing products versus

water, of nine studies identified, only two were eligible for inclusion. A meta-analysis was not carried out because of the heterogeneity of trial protocols. The first study by Garcia Bartels et al. (2010) included 64 full-term newborns in Berlin and aimed to test the hypothesis that twice-weekly bathing with a commercially available wash gel and additional cream would not harm the natural adaptation of the skin barrier in healthy newborns. Participants were randomized to one of the four following trial arms: bathing twice weekly with commercially available wash gel product; bathing twice weekly with clear water, then applying a commercially available body cream; bathing with wash gel and applying cream after bathing; and bathing with clear water only. The second study included in the systematic review (Dizon, Galzote, Estanislao, Mathew, & Sarkar, 2010) was a three-armed trial conducted in the Philippines, which compared two different liquid cleansers with water alone; 60 infants were randomized in each arm. Authors of both studies concluded that neonatal skin barrier function was not harmed by the tested skin care regimens in healthy, full-term infants. However, neither provided an a priori primary outcome or sample size, nor did they follow the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Begg et al., 1996) for reporting. Thus, the authors of the systematic review concluded that there is currently insufficient evidence on which to base practice.

The absence of adequately powered randomized trials led us to develop a research program to examine whether a bathing product formulated for infants is appropriate for newborn bathing. First, a qualitative study exploring the views of women and health professionals on bathing regimens, in one U.K. setting, was conducted (Lavender et al., 2009). This study confirmed the inconsistencies in bathing practices and the readiness of women to use bathing products. We then conducted a pilot randomized, controlled trial (Lavender et al., 2011) comparing a newborn bathing product with water alone. The aim of the pilot study was to inform decisions for the main trial design and to optimize the robustness of trial processes. The pilot study confirmed that the primary outcome measure (transepidermal water loss [TEWL]) was feasible. However, no trends in the data were found in any direction or on any site of the body. Therefore, we have proceeded with a noninferiority trial to test the hypothesis that the use of a wash product formulated for newborn (<1 month of age) bathing is not inferior (no worse) to bathing with water only.

Carol Bedwell, RGN, RM, LLB (Hons), is a lecturer of midwifery in the School of Nursing, Midwifery and Social Work, The University of Manchester, Manchester, UK.

Stephen A. Roberts, BSc, PhD, is an applied biostatistician and senior lecturer in biostatistics in the School of Medicine, The University of Manchester, Manchester, UK.

Anna Hart, BA (Cantab), MSc, is a statistician in the Lancaster Medical School, The University of Lancaster, Lancaster, UK.

Mark A. Turner, BSc, MBChB, is a consultant neonatologist in the Institute of Translational Medicine, University of Liverpool/Liverpool Women's Hospital, Liverpool, UK.

Lesley-Anne Carter, BSc, MSc, is a postgraduate student in the School of Medicine, The University of Manchester, Manchester, UK.

Michael J. Cork, BSc, MB, PhD, FRCP, is professor and head of academic dermatology research and honorary consultant dermatologist for Sheffield Children's Hospital NHS Foundation Trust and Sheffield Teaching Hospitals NHS Foundation Trust, The University of Sheffield, Sheffield, UK.

Download English Version:

<https://daneshyari.com/en/article/5866061>

Download Persian Version:

<https://daneshyari.com/article/5866061>

[Daneshyari.com](https://daneshyari.com)