Does evidence suggest that the use of barrier enhancing emollient is beneficial in the care of preterm neonates?

Nosocomial infection is a frequent and serious complication of preterm infants. Preterm infants less than 34 weeks' gestation have a poorly developed epidermal barrier compared to term infants that leads to two major effects: susceptibility to nosocomial infection and high transepidermal water loss. This review was undertaken to determine whether topical emollients improve epidermal barrier function and reduce the risk of infection in preterm neonates.

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Key points

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- The skin of preterm infants less than 34 weeks' gestation has a poorly developed epidermal barrier compared to term infants.
- 2. The thinner dermis and greater surfaceto-volume ratio of the preterm infant allow for easier invasion through the skin barrier.
- 3. Topical emollients improve epidermal function and maturity of the skin.
- 4. The evidence supports the use of emollients to reduce infection in preterm infants in the developing world, but not in the developed world such as in the UK.

n the neonatal intensive care unit (NICU) environment, the skin of a premature infant is the site at which many different interventions and procedures such as peripheral and central vascular cannulation, securing of respiratory support modes and lumbar puncture take place. The thinner dermis and greater surface-to-volume ratio of the preterm infant allow for easier invasion of pathogens through the skin barrier.

Incidents of skin breakdown secondary to pressure damage from the use of nasal continuous positive airway pressure (CPAP) prongs and masks in the authors' unit led to the use of a scoring tool to document the nasal status during CPAP delivery. As part of the development of this tool, the literature on neonatal skin care was reviewed (**TABLE 1**). To encompass the moderately to seriously preterm population, the authors intended to apply an inclusion criterion of gestation <34 weeks. However, few studies were limited solely to <34 weeks and it was not always possible to disaggregate these babies from more mature preterm babies.

Traditionally, the assessment of skin integrity has been a task delegated to the nursing staff. Without guidelines or formal training in assessing the skin, the assessment is purely subjective and open to question. In 2001, skin care guidelines were published by the Association of Women's Health, Obstetrics and Neonatal Nursing and National Association of Neonatal Nurses¹. They have been validated as leading to an improvement in care practices and skin assessment during the implementation of standard care practices^{1,2}. However, 10 years after these guidelines were produced, practices have not been reviewed.

Nosocomial sepsis is a frequent and serious complication of premature infants³. A major point of entry for invasive pathogens may be the skin because of compromised barrier function^{4,5}. The skin of an infant born before 34 weeks' gestation is particularly susceptible to injury and infection leading to increased morbidity and mortality⁶.

| Inclusion criteria | Exclusion criteria |
|--|--|
| All studies from 1997 | Studies prior to 1997 |
| All types of studies in the Hierarchy of Evidence ⁷ | |
| Studies done in any country (provided they were published and written or translated in English) | Published in foreign language |
| Studies on application of emollients such as oil and/or Aquaphor ointment and/or paraffin ointment compared to no application or routine skin care | Studies on application of oils used for massage purposes |
| Outcomes: infection, skin integrity, TEWL, fluid and electrolyte balance, mortality | |

TABLE 1 Criteria for considering studies in this search.

| Study No | Author | Year | Setting | Study design | Emollients used | Participants |
|-------------|----------------------------|------|------------|--|--|---|
| 1 | Conner et al ¹⁷ | 2004 | USA | Systematic review consisting of four studies | Eucerin cream (one study) Aquaphor ointment (three small studies) | Preterm <37 weeks Total participants: 1304 Multicentre study: 1191 BW <1000g Treatment group: 602;control group:589 Three other small studies included: 113 Study 1: 34 neonates; <36 weeks Study 2: 60 preterms; <33weeks Study 3: 19 preterms; <30weeks |
| 2 | Darmstadt ¹⁸ | 2004 | Egypt | Randomised controlled trial | SSO | Preterm <34 weeks Treatment group: 51 Control group: 52 |
| 3 | Darmstadt⁵ | 2005 | Bangladesh | Randomised controlled trial | SSO and Aquaphor ointment | Preterm <33weeks Treatment group SSO: 159 Treatment group Aquaphor: 157 Control group: 181 |
| 4 | Darmstadt ²⁵ | 2007 | Bangladesh | Randomised controlled trial | SSO and Aquaphor ointment | Preterm <33 weeks Treatment group SSO: 159 Treatment group Aquaphor: 157 Control group: 181 |
| 5 | Darmstadt ²⁶ | 2008 | Bangladesh | Prospective, randomised, controlled trial | SSO and Aquaphor ointment | Preterm <33 weeks Treatment group SSO: 159 Treatment group Aquaphor: 157 Control group: 181 |
| 6 | Wananukul ²⁷ | 2001 | Thailand | Clinical trial | Vaseline: liquid paraffin (1:1) | Preterm <35 weeks No. of infants: 30 Right side of the body: treatment side Left side of the body: control side |
| 7 | Wananukul ²⁸ | 2002 | Thailand | Clinical trial | Vaseline: liquid paraffin (1:1) | Preterm <35 weeks Treatment group: 20 Control group: 20 |
| 8 | Campbell ²⁹ | 2000 | USA | Case-control study | Aquaphor ointment | Preterm <1000g Case group: 10 Control group: 30 |
| 9 | Beeram ³⁰ | 2006 | USA | Retrospective study | Aquaphor ointment | Preterm <27 weeks with BW <1000g Study infants: 18 Control infants: 36 |

TABLE 2 Brief overview of the nine studies. SSO=sunflower seed oil.

This may be due to the lack of vernix, the relative stratum corneum immaturity and overall compromised function of the skin coupled with multiple procedural interventions. Organisms that normally inhabit the skin are the major causes of sepsis in very low birthweight (VLBW) infants in developed countries⁸.

Another cause of morbidity and mortality related to the skin in preterm infants is high insensible water loss (transepidermal water loss – TEWL) due to a high ratio of skin surface area to body volume, thin immature skin, large exposed surface area and lack of subcutaneous tissue^{9,10}. Extremely preterm infants may have TEWL in excess of 100mL/kg/day with concomitant difficulties in fluid and electrolyte homeostasis.

Several strategies are available to protect the integrity and promote the hygiene of the skin, augmenting its function as a barrier to TEWL and percutaneous absorption of toxic agents¹. Rutter and Hull¹¹ showed that TEWL was reduced by 40-60% after one application of Aquaphor (petrolatum) topical ointment and Nopper et al¹² concluded that topical therapy with Aquaphor ointment decreased TEWL for six hours after one application.

This article focuses on the use of topical emollients. The term emollient is derived from the Latin meaning to soften and implies a substance that acts to smooth the skin surface¹³. Emollients are believed to restore the integrity of the epidermal barrier in two ways: First, they form an oily (occlusive) layer over the skin that prevents the evaporation of water¹⁴. The water trapped in the stratum corneum passes into the corneocytes which swell, and fissures reduce. Secondly, emollients can penetrate deep into the stratum corneum and mimic the barrier effects of lipids, which are deficient in a preterm infant's skin¹⁵. This prevents penetration of irritants and allergens that can provoke local inflammatory reactions.

Topical emollients have been shown to be effective in improving epidermal functions and maturity of the preterm infant's skin^{12,16}. However, there are reports of adverse effects of emollients, such as an increased risk of nosocomial infections¹⁷.

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This is contested by Darmstadt et al^{6,18} although their evidence is limited to developing countries. Thus a literature review was conducted to determine whether the positive results of application of emollients in developing countries are applicable to the UK population.

Literature review

In order to conduct an appropriate review of the literature, the following question was devised:

Is topical emollient therapy an effective strategy in enhancing the epidermal barrier function, thus improving skin integrity and reducing the risk of infection, in preterm neonates?

A systematic literature search was performed (**TABLE 1**). There were nine studies that addressed the research question and met the inclusion criteria. They include one systematic review, six clinical trials, one case-control study and one retrospective study (**TABLE 2**).

Findings of the studies

Infection and mortality results

There were five studies that dealt with infection as an outcome (studies 1-4 and 8) and two studies (2 and 5) that dealt with mortality as an outcome (**TABLE 3**).

The Cochrane systematic review (study 1) considered three small RCTs and one multicentre study set in the USA. Dominated by the results of the multicentre study, the review concluded that daily prophylactic application of a topical ointment in premature infants in developed countries increases the relative risks of coagulase negative Staphylococcus(CONS) infection by 31% and the relative risk of any nosocomial infection by 20%.

Study 8, also undertaken in a developed country (USA), showed an increased risk of systemic candidiasis after Aquaphor (OR 11, 95% CI:1.0-6.3), although study 1 showed no significant difference in the risk of fungal infection.

By contrast, two studies in the developing world with sunflower seed oil (SSO) (studies 2 and 3) found a highly significant reduction in the incidence of nosocomial infections (adjusted incidence ratio, 0.46-0.59, p=0.007-0.03), despite the limitation in the power of the studies resulting from the high mortality rate (60%) in study 2. Death due to sepsis was not significantly different in either group (adjusted odds ratio 0.72; 95% CI 0.39-1.34; p=0.30), but no further details of the cause of death are mentioned. It was not clearly stated why the mortality rate was high. In study 3, there was a non-significant reduction in the risk of infection with Aquaphor (0.60, CI 0.35-1.03, p>0.05.). Study 5, also in a developing country, showed that treatment with SSO resulted in a statistically significant 26% reduction in mortality rates, compared with infants not receiving topical emollient therapy. It also found that Aquaphor therapy significantly reduced mortality rates by 32%.

| Study No | Emollients used | Infection | Mortality |
|----------|---|---|--|
| 1 | Aquaphor ointment Eucerin | Increases the relative risk of coagulase-negative Staphylococcal infection by 31% and increases the relative risk of any nosocomial infection (including bacterial and fungal organisms) by 20% in treated infants. Increased trend in the risk of any bacterial infections in infants treated with prophylactic application of topical ointment. | |
| 2 | Sunflower seed oil | Highly significant reduction in the incidence of nosocomial infections (adjusted incidence ratio, 0.46; 95% Cl, 0.26- 0.81; p=0.007) compared with infants not receiving topical prophylaxis (n=52). | High overall mortality rate (64 of 103 – 60%). Death beyond the first two days of life due to sepsis was not significantly different in the two groups (adjusted odds ratio, 0.72: 95% Cl 0.39-1.34; p=0.30). |
| 3 | Aquaphor ointment/ Sunflower seed oil versus no application | Infants treated with SSO were 41% less likely to develop nosocomial infections than controls (adjusted incidence rate ratio IRR 0.59, 95% CI 0.37-0.96, p=0.032). Aquaphor did not significantly reduce the risk of infection (0.60, CI 0.35-1.03, p=0.065). | |
| 4 | Aquaphor ointment/ Sunflower seed oil versus no application | The SSO group showed a 72% elevated odds of having a false-positive skin culture associated with a negative blood culture (ie skin flora blocked from entry into the blood) compared with the control group. | |
| 5 | Aquaphor ointment/ Sunflower seed oil versus no application | | The neonatal mortality rate was significantly reduced (p=0.042) by 26% in infants treated with SSO (hazard adjusted ratio: 0.74: 95% CI: 0.55-0.99). Treatment with Aquaphor also significantly reduced mortality rates by 32% (hazard adjusted ratio: 0.67; 95% CI: 0.51- 0.92: p=0.013). |
| 8 | Aquaphor ointment | The odds ratio for skin care with Aquaphor in case infants versus control infants was 11 (95% CI: 1.9-63). Skin care with Aquaphor was discontinued and the incidence of systemic candidiasis decreased to baseline. | |

TABLE 3 Infection and mortality results. SSO=sunflower seed oil.

The contrast in these results may perhaps be explained by the different conditions in baby units in the developed and developing countries, rather than indicating a contradictory effect of emollients. In developing countries, survival is lower, care practices differ, and the range of agents of infection is markedly different. This is emphasised by the lack of CONS and group B Streptococcal sepsis and a predominance of gram-negative sepsis, particularly *Klebsiella pneumoniae*, in developing countries¹⁹.

In developed countries, a frequent portal of entry for CONS in preterm neonates is the site of instrumentation²⁰, which is unlikely to be amenable to topical emollient therapy. On the other hand, in developing countries, indwelling intravascular devices are less frequently available. Furthermore degrees of malnutrition and environmental contamination and infectious challenge to the skin barrier are much higher²¹. In such cases, infections are more likely to be due to skin barrier compromise and the study intervention compensates for this compromise.

Study 4 provided evidence of a barrier mechanism of protection by SSO. A possible mechanism for an increased rate of infection with these treatments in infants in developed countries, is contamination that may have occurred during application of the treatment.

Skin integrity results

Skin condition was addressed in studies 1-4 and 8 (**TABLE 4**). There was improvement in skin condition in all of the studies, although this was only briefly mentioned. Only studies 2 and 4 presented statistical evidence.

TEWL and fluid balance results

Transepidermal water loss was addressed in studies 4, 6, 7 and 9 (**TABLE 5**). Studies 6 and 7 showed that TEWL was reduced in preterm babies under phototherapy after application of topical ointment. In study 4, TEWL could not be measured although it was mentioned as an aim.

Study 9 showed that the application of topical emollient was beneficial in terms of reduced fluid intake, better urine output, lower serum potassium and bilirubin levels. These suggest overall improved fluid balance, which is attributable to reduced TEWL. In none of these studies was it stated whether

| Study No | Study design/setting | Emollients used | Skin condition results |
|-------------|--|---------------------|--|
| 1 | Systematic review Developed countries | Aquaphor Eucerin | Improved skin condition |
| 2 | RCT Egypt | SSO | Improved skin condition (p=0.037) |
| 3 | RCT Bangladesh | SSO Aquaphor | No reports of adverse events – such as skin reactions, injuries or infections, or phototherapy burns after use of either emollient |
| 4 | RCT Bangladesh | SSO Aquaphor | Although mean skin score gradually worsened in all groups, patients treated with SSO or Aquaphor had better skin scores (better skin condition) at day 3 and day 28 compared to the control group. |
| 8 | Case study USA | Aquaphor | Lack of any toxic or local reactions. Problems with cardiac monitor electrodes and temperature probe placement |

TABLE 4 Skin condition - results of reviewed studies. SSO=sunflower seed oil.

| Study No | Emollients used | TEWL |
|-------------|--|---|
| 4 | Aquaphor ointment/Sunflower seed oil versus no application | Studied but no definitive data |
| 6 | Vaseline and paraffin (1:1 preparation) | Reduced by 29% (p<0.002) and 26% (p<0.011) at 30 minutes and 4-6 hours after the application of clear ointment. |
| 7 | Vaseline and paraffin (1:1 preparation) | Evaporation rate (ER) was increased by 8% (p=0.01) in the control group and decreased by 19.2% (p<0.001) in the treatment group at 30 minutes during phototherapy. ER was increased by 14.5% (p<0.001) and decreased by 13.2% (p<0.003) respectively after five hours of phototherapy |
| 9 | Aquaphor ointment | Fluid intake was lower and urine output was significantly better in Aquaphor treated infants during the first two weeks of life. Peak serum potassium and bilirubin values were lower in the study infants |

TABLE 5 Findings for TEWL and fluid balance.

incubators were humidified. Ambient temperature and humidity were only shown in studies 6 and 7, and there were no significant differences between the treatment and non-treatment groups.

Applying the evidence

The decision whether to implement research evidence depends on the quality of the research, the degree of the uncertainty of the findings, relevance to the clinical setting, whether the benefits to the patient outweigh any adverse effects, and whether the overall benefits justify the cost when competing priorities and available resources are taken into account²².

Although all the reviewed studies met all

the inclusion criteria and did not violate any of the exclusion criteria, there are broad differences from the UK experience, in particular in the setting of the study, healthcare facilities, type of patient population, intervention used, and care management.

Studies from the developing world (2-7) favour the use of emollients with considerable benefit from the intervention and low rates of adverse effects. By contrast, in developed countries (1, 8 and 9) benefits have been marginal along with a serious concern about nosocomial infection. The difference may be explained by less frequently available indwelling intravascular devices and much higher

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| Study No | Internal validity | External validity | Reliability |
|-------------|---|---|--|
| 1 | Dubious because of possible contamination | Similar sample population, settings and management of care to UK. | Reliable |
| 2 | Dubious because of high mortality | The sample population of the study was older and less sick than that generally found in a UK medical unit and the mortality was higher – so not comparable to the UK. | Questionable as the description of the intervention is too brief to allow reproduction. |
| 3,4,5 | Dubious because of discharge before the study period was complete. However, the results were analysed on intention to treat basis | The sample population of the study was comparable to the heavier section of the UK population (>1200 grams). | Reliable |
| 6 | Unblinded – potential for bias | The sample population of the study was older (<35 weeks' gestation) and less sick compared to the UK. This study can be applied to UK less immature babies. | Unreliable because of the lack of blinding |
| 7 | No problems | The sample population of the study was older (<35 weeks gestation) and less sick compared to the UK; however the results could be applicable to UK infants of the same gestation. | Reliable |
| 8 | Because of its retrospective design, baseline skin condition was not recorded (broken skin could be a portal of entry for infection) | Confounding variables: The petrolatum used did not contain preservatives that would inhibit the growth of micro-organisms: this is high risk especially in lipid-containing environment such as topical petrolatum ointment ²⁹ . More case infants were male and born vaginally. Due to the small sample size, it could not be determined if the factors were significantly different. | Questionable for lack of detail: How was the petrolatum applied? Were strict guidelines followed? Retrospective study design Record of the skin condition was not determined due to the lack of standard scoring system. It is possible that with larger sample size and multivariate analysis, factors such as vaginal delivery and prolonged intubation might be co-variables for systemic candidiasis, although they were not significant in this study. |
| 9 | Dubious because it depended on medical records or recollection of past events | Comparable to UK population. | Questionable as the control infants were born up to two years before the case infants. |

TABLE 6 Validity and reliability data.

degrees of malnutrition and environmental contamination and infectious challenge to the skin barrier in developing countries²¹. In such cases, infections are more likely to be due to skin barrier compromise resulting from subclinical injury, maturational or nutritional underdevelopment²³.

Compared with the developing countries, the patient populations studied in the developed countries were generally lighter in weight, sicker and required more invasive procedures such as intubation and insertion of percutaneous long lines, umbilical arterial and venous lines, all of which could be a portal of entry for CONS.

Only the patient populations of studies

1, 8 and 9 are similar to the UK. The increased rate of CONS infections and nosocomial infections are of concern. However, modern infection control practices are likely to reduce these complications. For example, in the authors' neonatal unit, the use of fluconazole has been introduced to reduce the incidence of invasive candidiasis in ELBW infants²⁴, and very strict sanitation procedures have been instigated. Furthermore UK infants more than 30 weeks' gestation have fewer invasive management procedures (CPAP, peripheral IV cannula and percutaneous central venous catheters), which may make them more comparable with the study population in the developing countries.

In summary, the positive results in studies 2-5 regarding infection rate and mortality, all involving patients in the developing world, do not warrant the use of topical therapy for ELBW infants in the UK.

Validity and reliability of reviewed studies

TABLE 6 summarises the validity andreliability data.

Implications for practice

Emollients provide clear benefit to certain populations of preterm infants. The literature supports their use in the developing world. However, there are concerns from comparable populations in the developed world that the risks of topical emollient treatment may increase nosocomial infection with consequent morbidity/mortality and little benefit. Changes in infection control practice since publication of the studies reviewed mean that these risks may have reduced or disappeared. There is a place for further research of the effect of topical emollient treatment on infection rates in ELBW infants under carefully controlled conditions in the UK. Research needs to compare the effects of olive oil and SSO in preterm neonates, including riskbenefit analysis.

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