The effectiveness of topical skin products in the treatment and prevention of incontinence-associated dermatitis: a systematic review protocol

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Review question/objective

This review aims to answer the following question: Is the use of topical skin protectants in patients with incontinence effective in reducing the occurrence of incontinence-associated dermatitis (IAD) or the risk of developing IAD in adult patients with fecal and/or urinary incontinence and diarrhea and if so which products are the most effective?

The quantitative objective for this review is to identify the effectiveness of the use of topical skin protection on reducing the occurrence and severity of IAD in adult patients experiencing incontinence and or diarrhea.

More specifically, the objectives are to:
Identify the efficacy of individual topical skin preparations on the IAD incident rate in adult patients who are incontinent or experience diarrhea by comparing individual skin products with other skin products, or with no intervention, or with other interventions.

Background

Incontinence associated dermatitis is an inflammation of the skin that occurs when the skin comes into contact with urine and/or fecal matter.¹ It is categorized as an inflammatory condition that presents with redness, swelling, excoriation and pain and may be complicated by opportunistic fungal infections.² The inflammation is usually confined to the skin areas that come into contact with urine and/or feces and can include the perianal and gluteal cleft, the buttocks, upper thighs, external genitalia and
suprapubic areas. It differs from pressure injuries in that it is “top down” damage where superficial skin damage occurs initially and can progress to deeper tissue damage. Pressure injury on the other hand is a “bottom up” injury where deeper tissues become affected first by decreased blood flow and then progress to the superficial tissues and the skin. Incontinence and the problems associated with it in both pediatric and adult populations has been an area that requires significant resources in terms of nursing hours and costs, and continues to be a daily challenge for healthcare professionals in all settings. Among the numerous difficulties associated with incontinence, skin complications are a priority because of the pain, skin infections, sepsis and pressure injuries that can result.

The two primary structural layers of the skin are the epidermis and the dermis which cover a subcutaneous fat layer. It has been established that skin integrity is maintained by skin pH, moisture content, friction and commensal colonization on the skin’s surface. The skin has an important moisture barrier function which is quantified by measuring the trans-epidermal water loss (TEWL). The skin loses moisture in two ways: by excretion of sweat from the sweat glands and from the surface of the stratum corneum through the epidermis.

The intercellular lipids in the stratum corneum, in intact skin, contribute to the moisture barrier function. The amount of intercellular lipids in this layer reflects the skin’s barrier and water proofing capacity. When the moisture barrier is interrupted it leads to hyperhydration of the skin and moisture associated skin damage.

The natural acidic pH of the skin ranges between 4 and 6.8 with a mean of 5.5. This pH range is referred to as the “protective acid mantle.” Prolonged exposure to moisture, urine or feces (particularly liquid fecal matter) causes the skin pH to become more alkaline. This alters the skin’s acid mantle making it more permeable to irritants and vulnerable to bacteria and fungi. Alkaline lipolytic and proteolytic enzymes (specifically lipase and protease) which are digestive enzymes present present in feces and are also produced by a number of fecal bacteria have been identified as causal agents for IAD when not removed promptly from the skin. These enzymes are inactive when present in the large bowel but become active in an alkaline environment. A study on the effects of time and temperature on excreted urine revealed that the pH of urine can increase to as high as 9 over time, thus altering the pH of the skin surface and damaging its “acid mantle.”

Skin with an impaired barrier function and abnormal TEWL measure becomes more permeable, erythematous, taut and painful, and is easily abraded and excoriated in the presence of mechanical forces, e.g. shearing associated with cleansing or friction. This results in a red or erythematous rash with or without excoriation of skin that can be classified as mild, moderate or severe IAD.

Prevention and treatment of IAD is focused on removing the body fluids, minimizing the length of exposure to fecal matter, redirecting the fecal matter away from the skin and applying skin protection or some form of barrier. Studies have been carried out using a number of products that range from petrolatum, zinc oxide, acrylate terpolymer and dimethicone. Currently, practices in some clinical settings appear to be based on availability of products and there is confusion and a lack of evidence that supports the efficacy of one product over another. As new products emerge on the market it can become more difficult to make choices as cost, marketing and commercialization may drive selection of one product over another. Despite increasing recognition and efforts to manage the dermatological issues and complications of incontinence, to date there is a
lack of rigorously performed research addressing the effectiveness of different skin care products to prevent and treat IAD.\textsuperscript{23,24}

The identification of a product or type of product that best mimics the skin’s barrier function, with a pH close to that of intact healthy skin, and remains on the skin as a waterproof protectant is fundamental to reducing the development of IAD.\textsuperscript{26} Products vary in formula and application method.\textsuperscript{27} They may be packaged as a liquid, emulsion, creams, spray, foam, gels, towelette, wipes or washcloths.\textsuperscript{10} Products that remain on the skin as a waterproof barrier, isolates and protects the skin from enzymes in urine and feces, and does not rub off onto bed linen and clothes appear to be most effective.\textsuperscript{13}

Limited literature reviews on comparison of effectiveness of products were retrieved during initial searching. Cost analysis studies on different products have been carried out and although they provide some comparison on products and are valuable for financial comparisons they do not shed any light on the efficacy of the products. Two reviews that focused on IAD treatment and prevention products were retrieved.\textsuperscript{25,27} These studies are literature reviews and although they provide insight into studies carried out on IAD treatment and prevention they lack the robust, comprehensive, systematic analysis and test for heterogeneity used by a systematic review design.

These studies have recognized that much more research and experimental studies are needed to identify the products that have the best results in preventing or treating IAD making a systematic review of current literature a logical starting point. An initial search of the Cochrane Library, the Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports and MEDLINE identified no other systematic reviews on this topic.

**Keywords**

nursing; critical care nursing; incontinence associated dermatitis topical skin care

**Inclusion criteria**

**Types of participants**

This review will consider studies conducted in all settings (acute care, intensive care, aged care, palliative care and community care) that included adult patients (both male and female) over the age of 18 years with urine incontinence, fecal incontinence with or without diarrhea, both urine and fecal incontinence with or without diarrhea and diarrhea by any causal factor. For the purpose of this study incontinence will be considered as “the inability to reach or use the toilet to pass urine and or feces as a result of cognitive or functional impairment”. Diarrhea will be defined using the Bristol Stool Form Scale. Both incontinence and diarrhea will be acknowledged as present as identified by the researchers in the articles reviewed.

As there are no standardized diagnostic tools currently used to diagnose IAD, patients who developed redness, inflammation, swelling, blistering or excoriation of skin in contact with urine and/ or feces (as identified by the researchers in literature reviewed) will be considered as having IAD. This includes the skin in the perineal, buttocks, genitals, suprapubic and upper thighs regions.

The review will include studies that used topical skin care products or barrier creams to prevent IAD in patients who did not have IAD but were considered at risk of developing IAD and skin care products
used to treat IAD in patients who were diagnosed with or considered to have IAD as per the criteria stipulated.

The review will exclude studies on individuals under the age of 18 in line with the definition of “adult” and the fact that the pathophysiology and etiology of pediatric or infant nappy rash is different to adult incontinence associated dermatitis.

**Types of intervention(s)/phenomena of interest**

This review will consider clinical studies that used topical applications used in liquid, emulsion, creams, spray, foam, gel, towelette, wipes or washcloths forms, and compare the effectiveness of each application method over other application methods. It will also consider the active ingredients in the commonly used products, such as petrolatum, zinc oxide, acrylate terpolymer and dimethicone, and compare the effectiveness of each product against the effectiveness of active ingredients in other products. The frequency of the applications, e.g. once daily or “application after each incontinent episode” will be reviewed for effectiveness. The once daily application frequency will be compared against the “application after each incontinent episode” frequency to establish which frequency method is most effective. Finally different care bundles or skin care regimes with or without the use of a skin care product will be analyzed for effectiveness and compared to determine more or less effectiveness by comparison.

**Types of outcomes**

This review will consider studies that include the following primary outcome measures:

- The absence or non-development of IAD (redness, inflammation, swelling, blistering or excoriation of skin in contact with urine and or feces in the perineal, buttocks, genitals, suprapubic and upper thighs regions) as a result of the use of a topical skin care product.
- A reduction or the resolution of IAD directly related to the use of a topical skin care product.
- New development of or increase in the occurrence of IAD directly related to the use of a skin care regimen or skin protection product.
- An increase in the severity of IAD symptoms related to the use of a topical skin care product.
- The number of days from commencement of application of skin protectants to resolution of IAD symptoms for products used that demonstrated a restorative effect on skin diagnosed with IAD.

Secondary outcome measures of interest are:

- Adverse effects caused by or associated with topical skin care products used to treat or prevent the development of IAD.

**Types of studies**

This review will consider randomized controlled trials, non-randomized controlled trials, quasi-experimental studies, before and after studies, prospective and retrospective cohort studies and case control studies that measure the effect of skin preparations or products in the development, prevention or resolution of IAD in adult patients. Studies with a clear scientific method will be considered but those based on opinion without a scientific framework will be excluded.
Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE will be undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all included databases (Appendix I). Thirdly, the reference lists of all identified reports and articles will be searched for additional studies. Studies published in English will be considered for inclusion in this review. Studies in languages other than English will be excluded as resources for translation are limited. Studies published from 1990 to 2014 will be considered for inclusion in this review as there are limited studies that focus on the efficacy of different products for the prevention and treatment of IAD and this appears to be the period when initial literature on the subject of IAD was published.

The databases to be searched include:

- PubMed
- CINAHL
- Scopus
- Cochrane CENTRAL
- Clinicaltrials.gov
- Australian New Zealand Clinical Trials Registry
- International Clinical Trials Registry Platform
- PsycINFO
- Embase
- Web of Science

The search for unpublished studies will include:

- ProQuest Dissertations and Theses
- Open Access Thesis and Dissertations
- MedNar

Initial keywords to be used will be:

Incontinence associated dermatitis, perineal dermatitis, incontinence dermatitis, perineal rash, nappy rash treatment.
Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix II). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data extraction

Data will be extracted from papers included in the review using the standardized data extraction tool JBI-MAStARI (Appendix III). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.

Data synthesis

Exploration of the effectiveness of the products used for protection against and treatment of IAD will be undertaken. Studies will be assessed for methodological quality and statistical significance will be used to determine validity and generalizability of study results.

Quantitative data will, where possible, be pooled in statistical meta-analysis using RevMan 5.2 software. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis.

Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs included in this review. If possible, subgroup analysis will also be undertaken to compare different types of products, such as creams versus sprays or wipes. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

There are no conflicts of interest to be reported.

Acknowledgements

The Nursing Research Centre Mater Health Services for the support and guidance provided in conducting this systematic review.
References


Appendix I: Search terms

diaper dermatitis OR diaper erythema OR diaper rash
napkin dermatitis OR napkin erythema OR napkin rash
nappy dermatitis OR nappy erythema OR nappy rash
perineal dermatitis OR perineal erythema OR perineal rash
moist* sore* OR moist* ulcer* OR moist* damage OR moist* wound* OR moist* injur* OR moist* lesion*
incontinen* dermatitis OR incontinen* sore* OR incontinen* ulcer* OR incontinen* damage OR incontinen* injur* OR incontinen* lesion*
(MH "Skin Care+")
skin care OR skin care regimen
zinc oxide OR dimethicone OR petrolatum OR dermashield OR uniderm OR dermafilm OR cavilon OR aqueous cream OR sudocrem OR silver sulfadiazine OR lanolin
topical treatment OR skin barrier OR skin protectant OR barrier cream OR emolient OR moisturiser OR ointment OR lotion OR cream OR barrier film OR moisture barrier OR humectant
Appendix II: Appraisal instruments

MAStARI appraisal instrument

### JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

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<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
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<tbody>
<tr>
<td>1.</td>
<td>Was the assignment to treatment groups truly random?</td>
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<td>Were participants blinded to treatment allocation?</td>
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<td>3.</td>
<td>Was allocation to treatment groups concealed from the allocator?</td>
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<td>4.</td>
<td>Were the outcomes of people who withdrew described and included in the analysis?</td>
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<td>5.</td>
<td>Were those assessing outcomes blind to the treatment allocation?</td>
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<td>6.</td>
<td>Were the control and treatment groups comparable at entry?</td>
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<td>Were groups treated identically other than for the named interventions?</td>
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<td>8.</td>
<td>Were outcomes measured in the same way for all groups?</td>
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<td>9.</td>
<td>Were outcomes measured in a reliable way?</td>
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<td>10.</td>
<td>Was appropriate statistical analysis used?</td>
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Overall appraisal: Include □ Exclude □ Seek further info. □

Comments (Including reason for exclusion)
________________________________________________________________________
________________________________________________________________________

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer __________________________ Date __________________________

Author __________________________ Year _____ Record Number _____

1. Was study based on a random or pseudo-random sample? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

2. Were the criteria for inclusion in the sample clearly defined? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

3. Were confounding factors identified and strategies to deal with them stated? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

4. Were outcomes assessed using objective criteria? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

5. If comparisons are being made, was there sufficient descriptions of the groups? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

6. Was follow up carried out over a sufficient time period? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

7. Were the outcomes of people who withdraw described and included in the analysis? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

8. Were outcomes measured in a reliable way? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

9. Was appropriate statistical analysis used? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

Overall appraisal: [ ] Include [ ] Exclude [ ] Seek further info

Comments (Including reason for exclusion)
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________________________________________________________________________
**JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control**

Reviewer: ___________________________ Date: ___________________________

Author: ___________________________ Year: _______ Record Number: _______

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<td>Is sample representative of patients in the population as a whole?</td>
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<td>2.</td>
<td>Are the patients at a similar point in the course of their condition/illness?</td>
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<td>Has bias been minimised in relation to selection of cases and controls?</td>
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<td>4.</td>
<td>Are confounding factors identified and strategies to deal with them stated?</td>
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<td>5.</td>
<td>Are outcomes assessed using objective criteria?</td>
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<td>Was follow up carried out over a sufficient time period?</td>
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<td>Were the outcomes of people who withdrew described and included in the analysis?</td>
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Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

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Appendix III: Data extraction instruments

MAStARI data extraction instrument

**JBI Data Extraction Form for Experimental / Observational Studies**

Reviewer ..................................... Date ........................................

Author ...................................... Year ........................................

Journal ..................................... Record Number ......................

**Study Method**

- RCT [ ]
- Quasi-RCT [ ]
- Longitudinal [ ]
- Retrospective [ ]
- Observational [ ]
- Other [ ]

**Participants**

Setting

Population

**Sample size**

Group A __________________ Group B __________________

**Interventions**

Intervention A

Intervention B

**Authors Conclusions:**

__________________________

__________________________

**Reviewers Conclusions:**

__________________________

__________________________
Study results

Dichotomous data

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Continuous data

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QARI data extraction instrument

**JBI QARI Data Extraction Form for Interpretive & Critical Research**

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**Study Description**

**Methodology**


**Method**


**Phenomena of interest**


**Setting**


**Geographical**


**Cultural**


**Participants**


**Data analysis**


**Authors Conclusions**


**Comments**


Select whether the form is complete:

- **Yes □**
- **No □**
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Extraction of findings complete: Yes [ ] No [ ]
Clinical Effectiveness Results

Study design

Year range of primary studies

Analysis used

Clinical outcome results

Economic Effectiveness results

Date/s of economic data

Modeling used

Measure of benefits used in economic evaluation

Direct costs

Indirect costs

Currency

Statistical analysis

Estimated benefits used in EE

Cost results

Synthesis of costs and results

Outcome category

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