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SUMMARY WITH CRITICAL APPRAISAL

Perineal Skin Cleansers for Adults with Urine Incontinence in Long-Term Care or Hospital Settings: A Review of the Clinical Effectiveness and Guidelines

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Abbreviations

AMSTAR	A MeaSurement Tool to Assess Systematic Reviews
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CRD	Centre for Reviews and Dissemination
IAD	incontinence-associated dermatitis
MASD	moisture-associated skin damage
MeSH	Medical Subject Headings
NIHR	National Institute for Health Research
PICO	Population Intervention, Comparator, Outcome
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomized controlled trial
SR	systematic review
TEWL	trans-epidermal water loss
WHO ICTRP	World Health Organization International Clinical Trials Registry Platform

Context and Policy Issues

Urinary incontinence, defined as involuntary leakage of urine, is a prevalent condition affecting approximately 3.5 million Canadians.[1,2] Though male and female incontinence may differ in terms of their etiology, clinical manifestations, and treatments, all patients with urinary incontinence can experience physical, psychological, and economic burdens as a result of their condition (e.g., reduced participation in activities, lower quality of life, purchasing incontinence-related garments).[1,3] When an individual with urinary incontinence resides in long-term care or is admitted to hospital, they may also be at an increased risk of incontinence-associated dermatitis (IAD, perineal dermatitis).[3] IAD is a type of irritant contact dermatitis seen in patients with incontinence, generally caused by prolonged exposure to moisture, and clinically presents as inflammation and/or redness of the perineal or perigenital skin; swelling and blister formation may be present in more severe cases.[4,5] IAD is particularly more prevalent for adults staying in long-term care and in hospital because patients are often older, less mobile, and may require assistance to clean soiled garments.[3]

In long-term care and hospital settings, perineal skin cleanser products may be used for patients with urine incontinence.[6] Cleanser products aim to clean the perineum area, removing skin irritants (urine, fecal matter).[7] Some skin cleansers available for purchase advertise as being pH-balanced to minimize irritation and can be a non-rinse formula with the goal of improving usability and efficiency for care staff.[6,7] Despite being used in the health care setting, it is unclear if these cleansers are more clinically effective than standard care (e.g., soap and water) for the the management for urinary incontinence. A review of the evidence is necessary to inform future purchase and policy decision-making.

Therefore, the aim of this report is to summarize the evidence regarding the clinical effectiveness of the use of perineal skin cleanser products for patients with urine incontinence in long-term care and hospital settings. Evidence-based guidelines regarding the use of perineal skin cleanser products for patients with urine incontinence in long-term care and hospital settings will also be examined.

Research Questions

1. What is the clinical effectiveness of perineal skin cleanser products for patients with urine incontinence in long-term care or hospital settings?
2. What are the evidence-based guidelines for the use of perineal skin cleansers for patients with urine incontinence in long-term care or hospital settings?

Key Findings

One systematic review was identified regarding the clinical effectiveness of perineal skin cleanser products for patients with incontinence in long-term care or hospital settings. Low-quality evidence summarized in a high-quality systematic review suggested that perineal skin cleansers may be effective at preventing incontinence associated dermatitis and maintaining skin barrier function compared to traditional soap and water. No evidence-based guidelines for the use of perineal skin cleansers for patients with urine incontinence in long-term care or hospital settings were identified. Given the limited availability and low quality of evidence, the effectiveness and use of perineal skin cleanser products for patients with urine incontinence remains uncertain.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including PubMed, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were perineal or perineum and skin cleansers. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and September 19, 2019.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Adults in long term care facilities/nursing homes/hospital wards who are urine incontinent or require incontinence products (e.g., diapers or pads)
Intervention	Perineal skin cleansing products (e.g., SproamCleanser: Coloplast [contains 0.1% benzethonium chloride]; Critic-Aid Clear: Coloplast [contains petrolatum and dimethicone]; Convatec Cleansing Foam; Sensi - Care perineal/skin cleanser; Convatec Body Wash and Shampoo; Aloe Vesta perineal/ skin cleanser)
Comparator	Q1: Alternative skin cleanser product, water, saline, no perineal skin cleanser product

	Q2: Not applicable
Outcomes	Q1: Clinical effectiveness (benefit/harm, skin irritation and breakdown, dermatitis, pain, burning, intact skin) Q2: Evidence-based guidelines
Study Designs	Q1: Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized controlled trials Q2: Guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, were duplicate publications, were already captured in an included systematic review (SR) or were published prior to 2009. Guidelines with unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included SR was critically appraised by one reviewer using A MeaSurement Tool to Assess systematic Reviews (AMSTAR) II.[8] Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 365 citations were identified in the literature search. Following screening of titles and abstracts, 345 citations were excluded and 20 potentially relevant reports from the electronic search were retrieved for full-text review. Six potentially relevant publications were retrieved from the grey literature search for full-text review. Of these 26 potentially relevant articles, 25 publications were excluded for various reasons, and one SR met the inclusion criteria and was included in this report. Appendix 1 presents the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[9] flowchart of the study selection. Additional references of potential interest are provided in Appendix

Summary of Study Characteristics

Additional details regarding the characteristics of included publications are provided in Appendix 2.

Study Design

One Cochrane SR, published in 2016, was identified regarding the clinical effectiveness of perineal skin cleanser products for patients with incontinence.[10] This review searched for literature published from inception to September 28, 2016. Two of the 13 studies included in the SR were relevant to this report; both studies were conducted using a non-randomized study design (cluster design published in 2011 and cross-over design without a washout period between treatments published in 1995).[10]

Country of Origin

The included SR was conducted in Belgium.[10]

Patient Population

Relevant to this report, the two relevant studies included in the SR comprised adult patients with incontinence (urinary, fecal or both) and at risk of or affected by IAD in hospital or long-term care settings.[10] The authors of the SR defined IAD as erythema (redness) and edema (swelling) of the surface of the skin, sometimes accompanied by bullae with serous exudates (blisters with serous fluid), erosion, or secondary cutaneous (skin) infection.

Interventions and Comparators

The included SR investigated topical skin care products aiming to prevent or treat IAD.[10] The two studies included in the SR that are relevant to this report examined non-rinse skin cleansers for the prevention of IAD. The comparator for both included studies of the SR was soap and water.[10]

Outcomes

The two studies included in the SR that are relevant to this report investigated the prevention of IAD by examining the number of participants with new cases of IAD.[10] One study included in the SR examined skin barrier function via trans-epidermal water loss (TEWL). Details surrounding the meaning of the numerical values reported or the unit of measurement (e.g., g/m^2 per hour) were not provided.[10] For this review, it is assumed that a lower TEWL is associated with a higher skin barrier function.[11]

Summary of Critical Appraisal

Additional details regarding the strengths and limitations of included publications are provided in Appendix 3.

Systematic Reviews

The AMSTAR II checklist[8] was used to assess the quality of the SR included in this report[10] and the quality was high. Strengths of the SR included: a clear description of research questions and eligibility criteria were provided, multiple databases and grey literature were searched, reference lists of included studies were searched to find additional potentially relevant studies, full search strategy provided in appendix, and data selection and extraction performed independently and in duplicate. Five authors independently assessed the risk of bias of the included studies using a validated tool. The authors graded the two relevant studies as low-quality with risk of bias assessments ranging from low to high risk of bias, depending on the type of bias assessed (e.g., selection bias versus performance bias). In addition, the authors developed a protocol a priori and the final review had a dedicated section describing differences between the protocol and review. In their protocol, the review authors developed a plan a priori for how results would be analyzed if a meta-analysis was appropriate. Due to the heterogeneity in participant population, skin care products, skin care procedures, outcomes, and measurement tools, the investigators correctly decided to not conduct a meta-analysis. For transparency, the study authors disclosed their funding sources and reported that the authors had no conflicts of interest.[10] These strengths increase the reproducibility of the findings.

Though the authors provided a list of excluded studies as well as the reason for exclusion, the authors did not provide a rationale for including randomized controlled trials (RCTs) and quasi-RCTs and no other study designs.[10] The lack of rationale for excluding specific study designs leaves the reader uncertain of whether the decision was justified (based on the landscape of the literature) or unwarranted (if decision was made without adequate

discussion with content and methodological experts). In addition, the SR did not provide context regarding the meaning of the numerical values reported or the unit of measurement used to measure TEWL.[10] This prevents the reader from truly understanding the significance of the reported results for the skin barrier function outcome.

Summary of Findings

Appendix 4: presents a table of the main study findings and authors' conclusions.

Clinical Effectiveness of Perineal Skin Cleansers

One SR examined the clinical effectiveness of perineal skin cleanser products for patients with incontinence in long-term care or hospital settings.[10]

Prevention of IAD

IAD prevention was assessed in the included SR.[10] For this outcome, two studies met eligibility criteria of the current report, but their findings were not pooled in a meta-analysis. One study suggested the use of a skin cleanser is significantly more effective than the use of soap and water (low quality evidence) for the prevention of IAD. The second study found no evidence of skin breakdown (i.e., IAD developing) in any patient, including the group using no-rinse skin cleansers, but no statistical findings were presented. This may have represented a secondary or exploratory outcome of the study (low quality evidence).[10]

Skin barrier function

Skin barrier function was reported in the included SR by means of TEWL (n = 1 study).[10] This study found a significant difference in TEWL in favour of the skin cleanser group when compared to the soap and water group (P = 0.02; low quality evidence).[10]

Guidelines

No relevant guidelines for the use of perineal skin cleansers for patients with urine incontinence in long-term care or hospital settings were identified; therefore, no summary can be provided.

Limitations

Certain limitations are noteworthy when reviewing the report.

Limited evidence from one high-quality SR was identified regarding the clinical effectiveness of perineal skin cleansers for patients with urinary incontinence. Even though the literature search of this report aimed to identify studies published within the last ten years, only one relevant SR was retrieved. Moreover, the two primary studies within the SR that were relevant for this report were published in 1995 and 2001 and were of low quality. This may suggest that there is not a lot of research available for this field of inquiry or there is not a lot of recently published work in this field.

The two studies included in the SR explored the outcome IAD prevention and one study examined skin barrier function for patients with incontinence. With a limited number of studies exploring two outcomes, the clinical effectiveness of perineal skin cleansers is still unclear. Moreover, the two primary studies included in the SR comprised patients with urinary and/or fecal incontinence. Future work would benefit from exploring additional pertinent outcomes, including pain and safety (e.g., adverse reactions to skin cleaners) for patients with urinary incontinence alone. In addition, both studies compared no-rinse

perineal skin cleansers to soap and water. Future studies may consider comparing perineal skin cleansers to other comparators, such as an alternative skin cleanser product.

No relevant guidelines were identified which further suggests it is unclear if or how perineal skin cleansers should be used in a hospital setting for patients with urinary incontinence.

Finally, the study included in this report was conducted in Belgium and the two relevant studies included in the report were conducted outside of Canada.[10] Therefore, it is unclear how generalizable the results are to the Canadian context (e.g., available cleanser products, patient characteristics). These limitations warrant the use of caution when interpreting the findings of this report.

Conclusions and Implications for Decision or Policy Making

This report identified limited evidence about the clinical effectiveness of perineal skin cleansers for adult patients with incontinence. No evidence was identified in the form of guidelines regarding the use of perineal skin cleansers for adult patients with urine incontinence in long-term care or hospital settings.

Regarding clinical effectiveness of perineal skin cleansers, one relevant SR[10] was identified from the search. The SR included two relevant outcomes, IAD prevention and skin barrier function (TEWL), for patients in long-term care or hospital settings with incontinence. This review suggests non-rinse perineal cleansers may be effective at preventing IAD and maintaining skin barrier function relative to soap and water[10] Despite these encouraging findings, it is premature to draw conclusions about the clinical effectiveness of perineal skin cleansers given the paucity of clinical evidence, the limited number of clinical outcomes examined, the inclusion of patients with fecal incontinence, and inherent low quality of the included studies summarized by the SR. Additional studies of high methodological quality may further aid in making definitive conclusions about the clinical effectiveness of perineal skin cleansers, particularly in comparison with alternative cleansers for patients with urinary incontinence alone. Finally, evidence-based clinical guidelines are needed to discern if and how perineal skin cleansers should be used for patients with urinary incontinence in long-term care and hospital settings.

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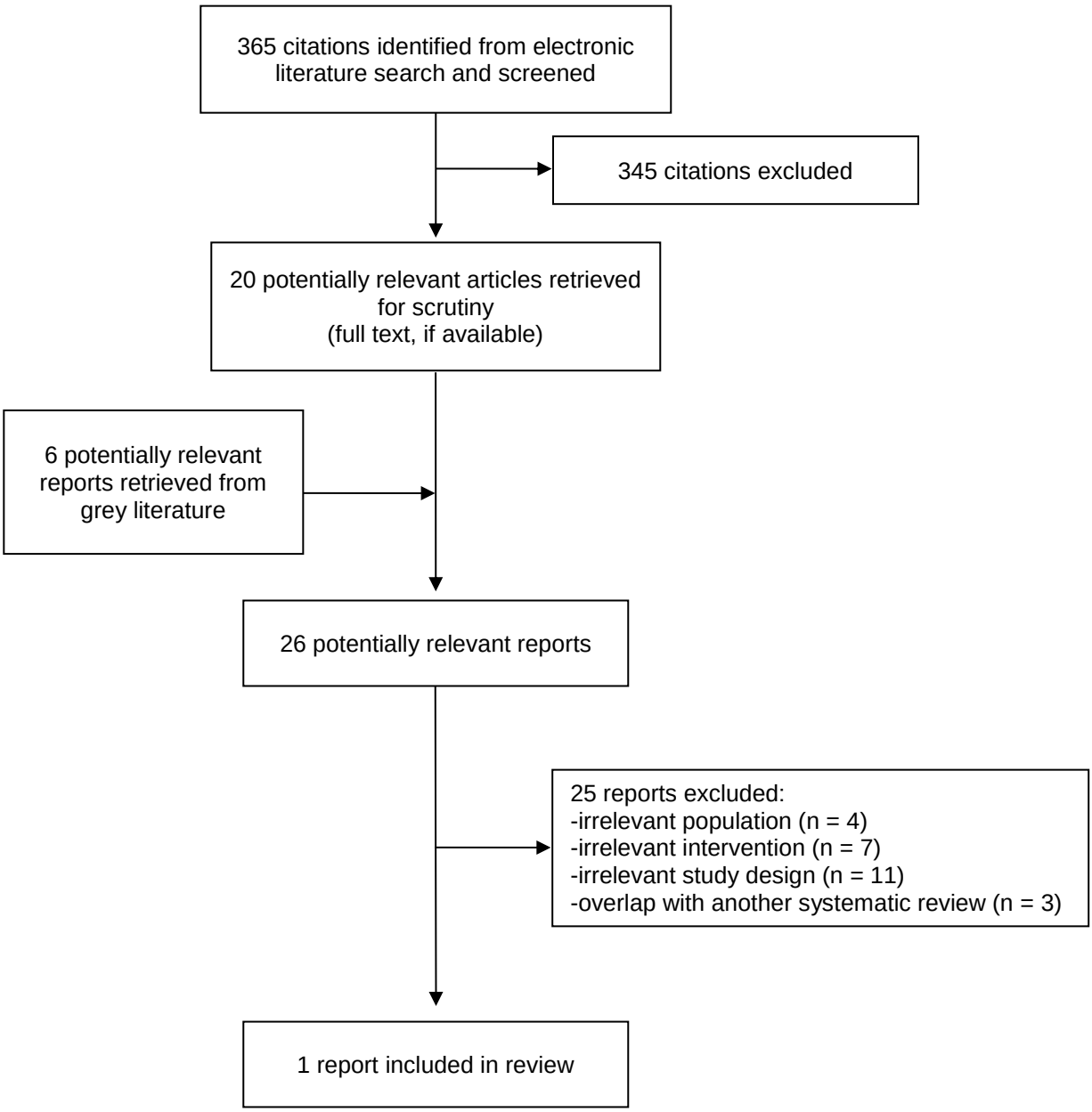
Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Systematic Review

First Author, Publication Year, Country	Study Designs and Numbers of Primary Studies Included	Population Characteristics	Intervention and Comparator(s)	Clinical Outcomes, Length of Follow-Up
Beeckman, 2016[10] Belgium	2 relevant studies (n = 1 cluster design; n = 1 cross-over design without a washout period between treatments) of the 13 included studies	Relevant to report, adult patients (over 18 years of age) with urinary and/or fecal incontinence at risk of or affected by IAD in hospital or long-term care settings	Intervention: topical skin care products (i.e., skin cleanser) aiming to prevent or treat IAD Comparator: soap and water	Prevention of IAD (number of cases of new IAD) Skin barrier function (TEWL; method and units of measurement not described) Follow-up: unclear

IAD = incontinence-associated dermatitis; TEWL = trans-epidermal water loss.

Appendix 3: Critical Appraisal of Included Publication

Table 3: Strengths and Limitations of Systematic Review using AMSTAR II[8]

Strengths	Limitations
Beeckman 2016[10]	
- Study authors devised a protocol a priori; authors have dedicated section in the publication for describing differences between the protocol and review - Research question clear and inclusion criteria for the review included the components of PICO - Multiple databases searched, handsearching of journals and conference proceedings searched, reference lists of included studies reviewed to find additional literature - Cochrane Incontinence Group Specialized Trials Register searched, *"which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, CINAHL, ClinicalTrials.gov, WHO ICTRP."* (p. I) - Broad keywords from search strategy provided and full search strategy provided (i.e., search syntax) in appendices - Data selection and extraction performed independently and in duplicate - Risk of bias assessed independently and in duplicate using the Cochrane Risk of Bias tool - Appropriate meta-analysis plan included; due to the heterogeneity in participant population, skin care products, skin care procedures, outcomes, and measurement tools, the investigators correctly decided to not conduct a meta-analysis. - A list of excluded studies as well as the reason for exclusion provided - Study authors discussed financial support, "*This project was supported by the NIHR, via Cochrane Infrastructure, Cochrane Programme Grant or Cochrane Incentive funding to the Incontinence Group."* (p.78) - Study authors declared no conflicts of interest (found online but not in main report)	- Study authors did not provide a rationale for including RCTs and quasi-RCTs and not other study designs - Study authors graded the two studies relevant to this report as low-quality with a low to high risk of bias for individual bias assessments

CINAHL = Cumulative Index to Nursing and Allied Health Literature; NIHR = National Institute for Health Research; PICO = Population Intervention, Comparator, Outcome; RCT = randomized controlled trial; WHO ICTRP = World Health Organization International Clinical Trials Registry Platform.

Appendix 4: Main Study Findings and Authors' Conclusions

Table 4: Summary of Findings Included Systematic Review

Main Study Findings	Authors' Conclusion
Beeckman 2016[10]	
Prevention of incontinence-associated dermatitis Risk ratio (95% confidence interval) = 0.39 (0.17 to 0.87), suggesting the use of a no-rinse skin cleanser is significantly more effective than the use of soap and water (low quality evidence; n = 1 study) No evidence of skin breakdown (IAD developing) in any patient (p.46), including a group using no-rinse skin cleanser (low quality evidence; n = 1 study; no numerical data provided) **Skin barrier function** Significant difference in TEWL favour of skin cleanser group when compared to soap and water group (12.1 vs. 15.7, respectively; *P* = 0.02; n = 1 study)[a]	"Little evidence, of very low to moderate quality, exists on the effects of interventions for preventing and treating IAD in adults. Soap and water performed poorly in the prevention and treatment of IAD…High quality confirmatory trials using standardised, and comparable prevention and treatment regimens in different settings/regions are required. Furthermore, to increase the comparability of trial results, we recommend the development of a core outcome set, including validated measurement tools. The evidence in this review is current up to 28 September 2016." p. 2 "The trials included in this review tested skin care products, procedures and frequencies of using a skin care product. Very limited evidence exists on the effects of interventions for preventing and treating IAD in adults. Larger, long-term and well performed trials are required. Furthermore, we recommend the development of a list of outcomes which are important for patients and will guide researchers in their study. This list should include well developed tools to measure the items in order to obtain accurate results." (p.4)

[a] The unit of analysis and direction of effect not reported in SR; it is assumed a higher TEWL is associated with skin barrier impairments.

IAD = incontinence-associated dermatitis; SR = systematic review; TEWL = trans-epidermal water loss.

Appendix 5: Additional References of Potential Interest

Guidelines/recommendations with unclear methodology

British Columbia Provincial Nursing Skin & Wound Committee. Guideline: assessment, prevention and treatment of moisture-associated skin damage (MASD) in adults & children; 2019 Jul: https://www.clwk.ca/buddydrive/file/guideline-masd-2017-february/. Accessed 2019 Oct 7.

Beeckman D, Campbell J, Campbell K et al. Proceedings of the Global IAD Expert Panel. Incontinence-associated dermatitis: moving prevention forward. London (GB): Wounds International; 2015: https://multimedia.3m.com/mws/media/1048834O/incontinence-associated-dermatitis-best-practice-principles.pdf. Accessed 2019 Oct 7.