Incontinence-associated dermatitis: why do we need a core outcome set for clinical research?



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Incontinence-associated dermatitis (IAD) is a type of irritant contact dermatitis related to chemical and physical irritation of the skin barrier, triggering inflammation and subsequent skin damage. Management of IAD should essentially focus on skin cleansing to remove the irritant, debris and microorganisms; skin moisturisation to repair or augment the skin's barrier, retain and/or increase its water content, reduce transepidermal water loss and restore or improve the intercellular lipid structure; and the application of a skin barrier product to prevent skin breakdown by providing an impermeable or semi-permeable barrier on the skin. The lack of comparability between studies about efficacy and (cost-)effectiveness of products and procedures complicates standardisation of IAD management. To overcome this challenge, the development and use of a Core Outcome Set (COS) is needed. A COS is a consensus-derived minimum set of outcomes that should be measured and reported in clinical trials of a specific health condition. A 2018 international study at Ghent University concluded that erythema, erosion, maceration, IAD-related pain and patient satisfaction are core outcome domains in IAD clinical research. Identical outcomes across trials will allow comparability of results and, thus, enhance the value of evidence synthesis and reduce the risk of outcome reporting bias.

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Repeated and/or prolonged exposure of the stratum corneum to moisture, such as perspiration, wound exudate, saliva, urine or faeces, can lead to the development of associated skin damage. The skin surface is regularly exposed to urine and/or faeces in both infants and adults with incontinence. In babies and small infants, this cutaneous problem has been recognised for decades as diaper dermatitis (Folster-Holst et al, 2011; Blume-Peytavi et al, 2014). Other widely used terms for this skin condition in early childhood are perineal, diaper, or napkin dermatitis/rash. However, this cutaneous problem not only occurs in paediatric patients, but is also common in adults, which was first introduced as 'incontinence-associated dermatitis' (IAD) by Anthony et al, (1987). In 2007, the concept was promoted by an international consensus panel (Gray et al, 2007).

The panel defined IAD as a skin inflammation manifested as redness with or without blistering, erosion, or loss of skin barrier function that occurs as a consequence of chronically or repeated exposure of the skin to urine or faeces (Gray et al, 2007). Currently, IAD is considered as part of a broader group of skin conditions, referred to as moisture-associated skin damage (MASD) (Gray et al, 2011).

Prevention and treatment of IAD

The exposure of the skin to urine or faeces constitutes the primary risk factor for IAD. Therefore, the goal of any intervention for IAD prevention and treatment is to eliminate or minimise skin contact with the irritant (Bender et al, 2017). The two key strategies are to manage incontinence and to implement a structured skin care regimen to maintain or restore skin barrier, skin integrity and health (Beele et al, 2017).

Incontinence management

Incontinence management includes the

evaluation of the bladder and kidney function regarding urinary incontinence, and that of the intestine and colon in the case of faecal incontinence (Beele et al, 2017). Whenever possible, the cause of the incontinence should be identified and eliminated, and treatment options examined (Wishin et al, 2008). If treatment is not possible, it is recommended that suitable incontinence products are used and non-invasive behavioural interventions implemented.

Incontinence products, such as briefs and liners, should be chosen carefully, depending on the population. Preferably they should use smooth and breathable materials with maximum absorption capacity, as occlusive conditions between the incontinence product and the skin in combination with incontinence may exaggerate the risk and the severity of IAD (Muller and McInnis, 2013). Bed linens and occlusive faecal containment products should be changed frequently to minimise exposure to both moisture and faeces, a time-consuming process that may interfere with other important nursing tasks (Foureur et al, 2006, Wishin et al, 2008). In specific situations, indwelling urinary catheters, faecal management systems, or pouches can temporarily provide a solution in severe forms of urinary or faecal incontinence in high-risk patients (Morris, 2011; Coyer and Campbell, 2017). Behavioural interventions include nutritional and fluid management, mobility enhancement, and different toileting techniques (Wishin et al, 2008). These are relevant to all patient populations as evidence suggests that structured toileting and exercise interventions can improve incontinence and skin status in elderly nursing home residents (Bates-Jensen et al, 2003). It is recommended to reassess the type and frequency of incontinence on regular basis, to tailor incontinence management and estimate the risk for skin lesions, such as IAD.

Implementation of a structured skin care regimen

The second key strategy is the implementation of a structured skin care regimen, which comprises a thorough skin assessment, correct differential diagnosis, gentle cleansing, and the application of a leave-on product (Gray et al, 2012). Skin assessment includes the clinical observation of signs of IAD via visual inspection of the skin areas that are being exposed to urine and/or faeces (Gray et al, 2011; Abrams et al, 2017). It is recommended to assess the skin of all patients with urinary and/or faecal incontinence on a daily basis. In certain circumstances, such as diarrhoea or frequent episodes of incontinence, frequency of skin assessment should be increased (Beeckman et al, 2015).

To date, one risk assessment tool for IAD has been developed but with only limited use in research studies (Nix, 2002). Moreover, the usefulness in clinical practice has not been established (Nix and Haugen, 2010). Quantifying risk with risk assessment scales is not advised for clinical practice as the predictive value of such risk scales varies per setting (Defloor and Grypdonck, 2005). Therefore, it is recommended to perform skin assessments in every patient with urinary and/or faecal incontinence. Nevertheless, the assessment and management of potential risk factors, such as nutritional status, are important (Beele et al, 2017). If symptoms of IAD are observed, a correct differential diagnosis is crucial for appropriate treatment, accurate documentation and quality reporting (Junkin and Selekof, 2008).

A recent Cochrane review on skin care interventions in the prevention and treatment of IAD in adults included 13 trials with 1,316 participants incontinent for urine, faeces or both in a qualitative synthesis (Beeckman et al, 2016). The overall quality of the trials was low, with small sample sizes and short follow-up periods. More recently, a Joanna Briggs Institute (JBI) systematic review on the effectiveness of topical skin products in the treatment and prevention of IAD was performed (Pather et al, 2017). Of the 10 studies included in this review, five focused on both cost-effectiveness and clinical effectiveness while the other studies focused solely on clinical benefits. A total of 804 participants across all studies were included in the final review. In both systematic reviews, meta-analysis of the extracted results was not possible due to the heterogeneity of the measurement tools, outcomes, time points and interventions (Beeckman et al, 2016, Pather et al, 2017). Current recommendations about IAD management including gentle cleansing and the application of a leave-on product are based on a limited number of clinical trials and best practices recommendations. Strict distinctions between IAD prevention and treatment have not been made so far.

Skin cleansing

Effective cleansers remove organic matter rapidly and thoroughly from the surface, and reduce odour (Nix, 2000). During cleansing, there is a complex interaction between the cleanser, the moisture skin barrier and skin

pH. Traditional washing with water and soap should be avoided as it will change the barrier and increase skin pH (Kuehl et al, 2003; Beele et al, 2017). As the product itself can become an irritant to the skin surface, skin cleansers containing non-ionic surfactants reflecting the pH-range of the acid mantle of healthy skin are preferred because of their gentleness (Nix, 2000; Kuehl et al, 2003).

Although there is insufficient evidence showing the superiority of certain cleansing products, cleansers and washcloths consisting of low-irritating surfactants, emollients and/or dimethicone are skin barrier protective in contrast to standard care (Beeckman et al, 2016). The process of cleansing itself is detrimental to the skin barrier (Voegeli, 2008; Ananthapadmanabhan et al, 2013). Excessive cleansing can cause skin dryness and skin irritation, but also influence the pH and, hence, the bacterial flora (Beele et al, 2017). Drying the skin by rubbing causes additional friction and should be avoided (Voegeli, 2008). An optimal balance must be found between removing irritants and preventing additional irritation due to frequent cleansing. Therefore, it is recommended to cleanse daily and after every episode of faecal incontinence (Kottner and Beeckman, 2015). It is recommended to use pH balanced no-rinse cleansers, such as soft, disposable non-woven cloths, that also may simplify care, improve efficiency and patient comfort (Gray et al, 2012; Kottner et al, 2013; Beeckman et al, 2016).

Application of a leave-on product

The authors of the Cochrane review defined a leave-on product as "moisturisers, skin protectants/barriers, and other functions, whether combined or not into one product" (Beeckman et al, 2016). Leave-on products are used for both prevention, as a barrier between the stratum corneum and any moisture or irritant, and treatment, to promote healing and allow the skin barrier to recover (Beeckman et al, 2016). Skin moisturisers aim to repair or augment the skin's barrier, retain and/or increase its water content, reduce trans epidermal water loss (TEWL), and restore or improve the intercellular lipid structure (Beeckman, 2017).

A skin barrier product aims to prevent skin breakdown by providing an impermeable or semi-permeable barrier on the skin (Beeckman et al, 2009; Kottner and Beeckman, 2015; Beeckman et al, 2016). Four main types of skin protectant ingredients can be distinguished: (1) petrolatum, which is occlusive and transparent, (2) zinc oxide, which is difficult and uncomfortable to remove, (3) dimethicone, which is silicone-based and transparent, and (4) acrylate terpolymer — a transparent film that allows skin inspection.

These ingredients are incorporated in a wide range of products, such as creams (emulsions of lipid substances and water), ointments (semi-solid, too greasy and too occlusive), pastes (a mixture of absorbent material and ointments, and more difficult to rub off), lotions (liquids that contain a suspension of inert or active ingredients), and films (liquids that contain a polymer dissolved in a solvent, transparent protective coating on the skin) (Beeckman 2017, Beele et al, 2017). As the concentration of active ingredients and the total formulation vary, determining the relative performance of an individual product is difficult (Doughty et al, 2012; Beeckman et al, 2016).

Both systematic reviews concluded that the application of leave-on products (moisturisers, skin protectants, or a combination) seem to be more effective than water and soap (Beeckman et al, 2016; Pather et al, 2017). However, with current data available, there is no proven evidence that indicates superior outcomes of any one product. The performance of leave-on products depends on the combination of ingredients, the overall formulation and the usage (e.g. amount applied) (Beeckman et al, 2016). As evidence is limited, some general recommendations are made. Skin protectants should be applied regularly and by patting in a gentle way to avoid friction, in the appropriate quantity to avoid softening of the skin, ideally before the exposure, and applied to all skin areas coming into contact with urine and/or faeces (Kottner and Beeckman, 2015; Beele et al, 2017).

When an IAD lesion is present and the skin barrier is compromised, IAD treatment should reduce inflammation, promote healing and reepithelialisation. All above interventions including incontinence management and preventive measures are applicable for treatment. A leave-on product should also be used to treat mild irritant contact dermatitis, but in severe IAD cases, dressings may be used temporally to promote healing (Kottner and Beeckman, 2015). When secondary skin infection is present, such as a Candida albicans infection, an antimicrobial (antifungal) treatment should be used as a first-line therapy (Gray et al, 2012). It is recommended to treat the infection if present. The superimposed infection may alter the loco-regional clinical picture depending on the type of microorganism (bacteria, fungus or yeasts).

Wound swabs and blood samples are indicated to confirm the infection and/or identify the micro-organism involved to target the treatment (Beele et al, 2017).

Conclusion: why do we need a core outcome set for IAD clinical research?

The previously described lack of comparability between studies about efficacy and (cost-) effectiveness of products and procedures complicates standardisation of IAD management (Beeckman et al, 2016). To overcome this challenge, the development and use of a Core Outcome Set (COS) is needed. A COS is a consensus-derived minimum set of outcomes that should be measured and reported in clinical trials of a specific health condition (Williamson et al, 2017). However, a COS does not limit researchers to choose additional outcomes and measurements (Schmitt et al, 2014). Using identical outcomes across trials allows comparability of results, enhancing the value of evidence synthesis and reducing the risk of outcome reporting bias (Williamson et al, 2012).

In 2017, Van den Bussche et al published the outcomes of their COS development study. The authors extracted 1,852 outcomes from 244 articles. After refinement, 57 panellists from 17 countries rated a list of 58 outcome domains. The final list of outcome domains includes erythema, erosion, maceration, IAD-related pain, and patient satisfaction. The authors concluded that using identical outcomes across trials will allow comparability of results enhancing the value of evidence synthesis and reducing the risk of outcome reporting bias. WINT

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