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A Systematic Review and Meta-Analysis of Incontinence-Associated Dermatitis, Incontinence, and Moisture as Risk Factors for Pressure Ulcer Development

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Abstract: The aim of this analysis was to identify the association between incontinence-associated dermatitis (IAD), its most important etiologic factors (incontinence and moisture), and pressure ulcers (PUs). A systematic review and meta-analysis were performed. We searched Medline, Embase, CINAHL, Web of Science, and the Cochrane Library for relevant papers dating through March 15, 2013. Fifty-eight studies were included. Measures of relative effect at the univariate level were meta-analyzed. In most studies (86%), a significant association between variables of interest was found, with pooled odds ratios of PUs in univariate models between 1.92 (95% *CI* 1.54–2.38) for urinary incontinence and 4.99 (95% *CI* 2.62–9.50) for double incontinence ($p < .05$). This evidence indicates an association between IAD, its most important etiological factors, and PUs. Methodological issues should be considered when interpreting the results of this review.

Keywords: pressure ulcer; decubitus ulcer; skin integrity; incontinence-associated dermatitis; incontinence; systematic review; meta-analysis

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Pressure ulcers (PU) cause severe pain, physical, and psychological discomfort and restrictions in activities, and they further lead to prolonged hospitalization, utilization of the health care system and mortality (Gorecki et al., 2009; Hopkins, Dealey, Bale, Defloor, & Worboys, 2006). In addition, treatment of pressure ulcers increases costs significantly (Gorecki et al.). Pressure ulcers (PU) are localized injuries to the skin and/or underlying tissue, usually over a bony prominence (National Pressure Ulcer Advisory Panel [NPUAP] & European Pressure Ulcer Advisory Panel [EPUAP], 2009). The identification of risk factors for pressure ulcer development is essential to timely and appropriate prevention.

Pressure, shear, friction, and microclimate interact as extrinsic factors in the development of pressure ulcers (Garcia-Fernandez, Agreda, Verdu, & Pancorbo-Hidalgo, 2014; NPUAP & EPUAP, 2010). Skin surface microclimate includes temperature and moisture. Exposure to moisture can lead to moisture-associated skin damage in the sacral area as a result of inflammation of the epidermis and dermis. Often incorrectly classified as a type of pressure ulcer, moisture-associated damage includes intertrigo associated with perspiration, periwound skin damage caused by wound exudate or effluent, and incontinence-associated dermatitis (IAD) (Gray et al., 2011). The prevalence of incontinence varies between 3% and 75% (Macmillan, Merrie, Marshall, & Parry, 2004; Nitti, 2001; Offermans, Du Moulin, Hamers, Dassen, & Halfens, 2009). IAD is defined as "erythema and edema of the surface of the skin, sometimes accompanied by bullae with serous exudate, erosion or secondary infection" (Gray et al., 2012, p. 61) and has a prevalence ranging

from 5.6% to 50% and an incidence of 3.4% to 25% (Gray et al., 2007). Skin irritants from incontinence include urine, fecal and double incontinence, and liquid fecal matter (Brown, 1995). Exposure to urine and stool results in hyperhydration of the skin and a rise in skin pH, which diminish tissue tolerance. In addition, stool includes fecal enzymes, intestinal flora, and moisture, which are particularly damaging to the skin (Gray et al., 2012).

The etiologies of IAD and pressure ulcers are multifactorial and different (NPUAP & EPUAP, 2010). IAD is the result of top-down damage to the skin due to tissue intolerance (e.g., age, nutrition), an affected perineal environment (e.g., incontinence), and obstacles to effective toileting (e.g., restraints) (Brown, 1995). In contrast, pressure ulcers can be the result of both bottom-up and top-down damage, when the deeper tissue is affected by pressure or shear (Brown, 1995). Moisture from incontinence and perspiration increases the vulnerability of the skin and superficial tissue layers to pressure-induced blood flow reduction (Mayrovitz & Sims, 2001). Moisture also weakens the skin and makes it more vulnerable to the effects of pressure and shear (NPUAP & EPUAP, 2010). However, in a recent systematic review, Coleman et al. (2013) moisture and incontinence did not emerge clearly as PU risk factors. Mobility/activity, perfusion, and skin/pressure ulcer status (existing/previous PU) were risk factors for PU development, but none of these alone explained PU risk.

The aim of this systematic review and meta-analysis was to identify the associations between IAD, moisture and incontinence as its most important etiologic factors, and pressure ulcer development. The following research questions were addressed:

1. What is the association between IAD and pressure ulcer development?
2. What is the association between incontinence and pressure ulcer development?
3. What is the association between moisture and pressure ulcer development?

Methods

Search Strategy

A two-step search strategy was used to identify all relevant literature. First, five electronic databases were systematically searched: Medline (OVID) (1949 to present), Embase (1947 to present), CINAHL (EBSCO-interface) (1981 to present), Web of Science (1900 to present), and the Cochrane Library. The search consisted of a combination of index terms and free text words using Boolean operators (Fig. 1). Second, a hand search through conference proceedings (European Pressure Ulcer Advisory Panel, European Wound Management Association, Wound Ostomy

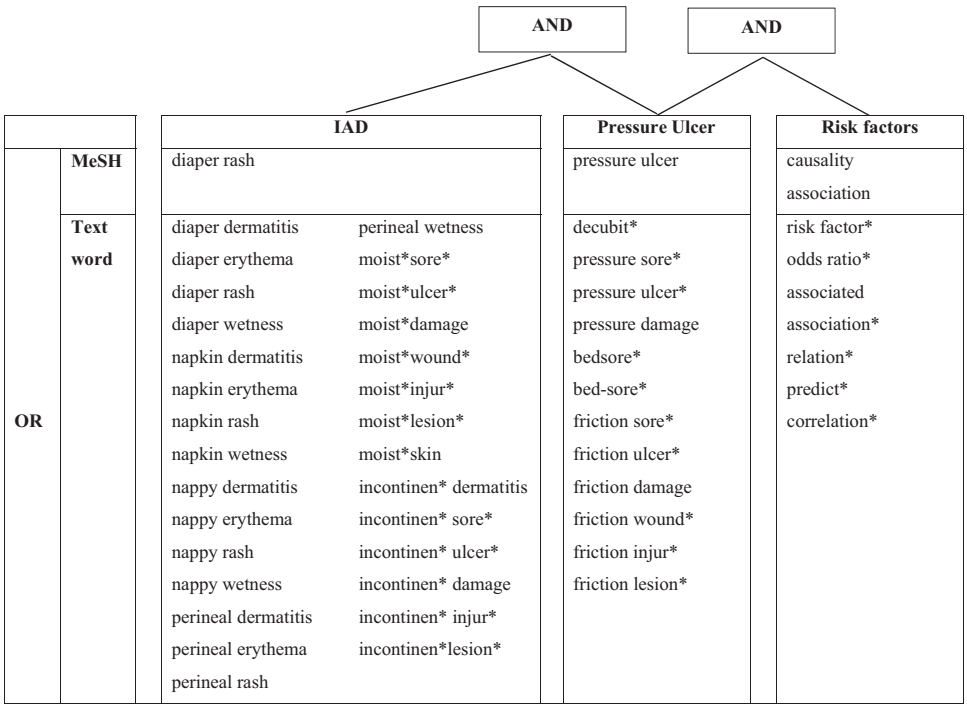

FIGURE 1. Search filter.

and Continence Nurses Society) and the reference lists of all retrieved articles was carried out to identify additional studies.

Articles were included if the following criteria were met: (1) reporting an original study, (2) having a quantitative research design, (3) studying persons ages 18 years and older, and (4) investigating an association between incontinence-associated dermatitis, incontinence, or moisture and the development of pressure ulcers. Only articles published in English, French, and Dutch were considered for inclusion. No limitation was set on the date of publication. Articles were excluded if: (1) insufficient data were available to report on an association and (2) the study reported a case study.

The titles and abstracts of the retrieved records were screened by one reviewer. The full text of all potentially relevant records was retrieved and further checked for inclusion. A quality assurance check was independently performed by a second reviewer on 10% of the retrieved records and the full texts of the potentially relevant records. Disagreements about inclusion or exclusion were discussed until consensus was reached. If necessary, advice from a third reviewer was sought. The inter-rater reliability for study selection was tested using overall percentage of agreement and Cohen's kappa.

Methodological Quality Rating

The methodological quality of the included articles was evaluated by using the Quality Assessment Tool for Quantitative Studies. This tool was developed by the Effective Public Health Practice Project (Thomas, Ciliska, Dobbins, & Micucci, 2004) and adapted by Vyncke et al. (2013). A quality assurance check was independently performed by a second reviewer on 10% of the included articles. Disagreements about quality assessment were discussed until consensus was reached. When necessary, advice from a third reviewer was sought.

Data Collection and Synthesis

Data from the included articles were extracted and tabulated using a standardized evidence table. The authors were contacted if insufficient data were available in the abstract and full text. The following data were extracted: study design, setting, sample characteristics, measures, results, and limitations. The odds ratio was either provided by the authors or computed using the raw data reported by the authors. The following formulas were used: Odds ratio $(OR) = ad/bc$ or $OR = \exp(\beta)$, Standard error $(SE) = \sqrt{(1/a + 1/b + 1/c + 1/d)}$, 95% Confidence Interval (95% CI) $= \ln(OR) \pm (1.96^{*} SE)$.

Data Pooling

Odds ratios, relative risk ratios, and hazard ratios were combined using a meta-analysis. Only univariate data were pooled because of missing information in the results from multivariate analysis in multiple studies and the use of different confounders in the multivariate models. Results from multivariate analysis including at least one confounder were reported narratively.

Data were pooled using either a fixed or a random effect model, depending on the heterogeneity of the studies. Heterogeneity was determined using the Cochran's Q test at a significance level of .10. I^2 was calculated to quantify the heterogeneity (Higgins, Thompson, Deeks, & Altman, 2003). In studies with a high heterogeneity ($I^2 \geq 75\%$), a random effect model was used (Higgins et al., 2003).

The generic inverse variance method of the software program (version 5.2.5) Review Manager (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2012) provided by the Cochrane Collaboration was used for meta-analysis (Higgins et al., 2003). The log of the relative effect and its standard error were calculated. If relative risk and hazard ratio were reported and if the outcome event (PU development) was rare, relative risks and hazard ratios were entered as odds ratios, and a sensitivity analysis was performed to assess the effect of this imputation (Cummings, 2009).

The source of heterogeneity was explored using subgroup analysis and a sensitivity analysis. Subgroups were based on design of the study and type of setting. A sensitivity analysis was performed to assess the robustness of the findings by excluding from the analysis the studies reporting relative risks and hazard ratios. Publication bias could not be assessed because insufficient studies (<10) were entered into the meta-analysis (Higgins & Green, 2009).

Results

The systematic search resulted in 13,270 records: 3,806 in Medline, 2,948 in Embase, 3,148 in CINAHL, 3,095 in Web of Science, and 273 in the Cochrane Library, of which 5,719 duplicates were removed (Fig. 2). The hand search resulted in one record from the reference lists of the retrieved articles and one record from an expert. Six records from conference proceedings were identified. The primary author was contacted, but none of the authors responded to the request for additional information.

Based on the screening of title and/or abstract, 7,262 records were excluded. The full texts of 289 records were reviewed in detail, and an additional 231 records were excluded. Reasons for exclusion are listed in Figure 2. The remaining 58 studies were included in this review and are shown in Table 1, of the study on IAD and PU development, and Tables 2 and 3, of studies on incontinence and/or moisture and PU development. There was substantial to almost perfect agreement between the reviewers for study selection. An overall agreement of 97.5% and 92.6% and a Cohen's kappa of .71 ($p < .001$) and .85 ($p < .001$) were found for selection based on title/abstract and full text, respectively.

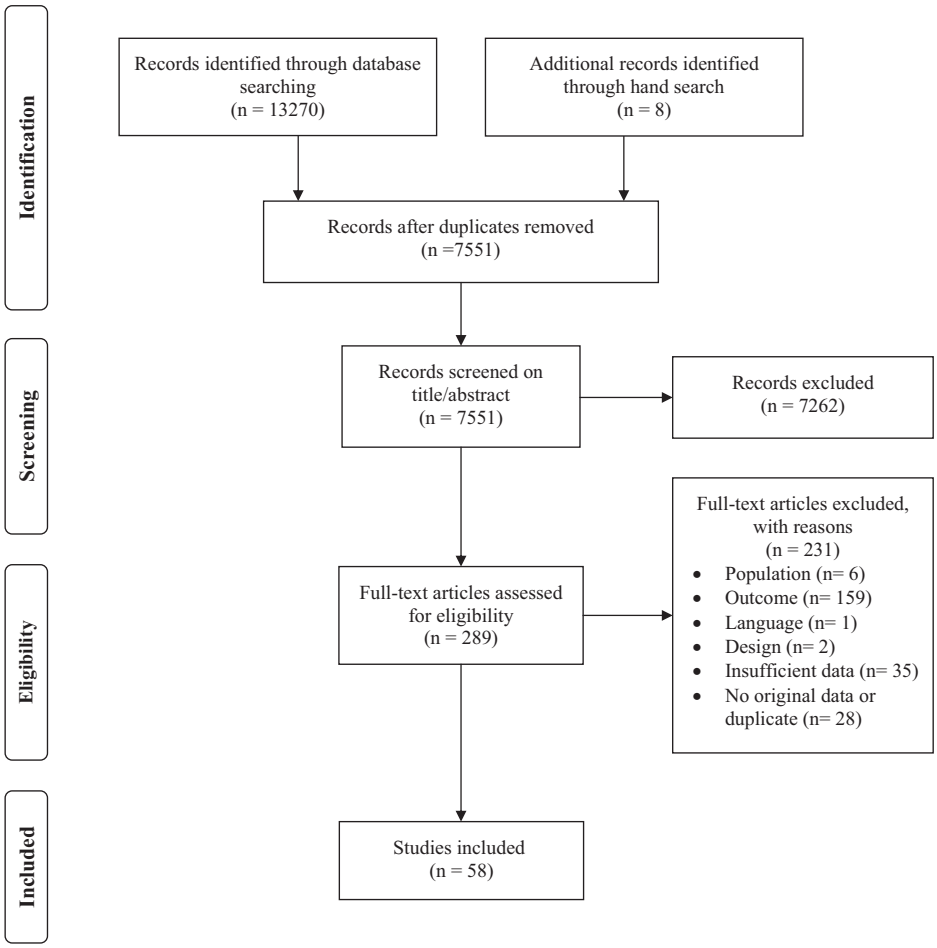

FIGURE 2. Flow-chart.

The quality of the 58 articles was assessed. No study was excluded based on low methodological quality. The most important methodological limitations of the studies were (1) selection bias ($n = 46$), (2) lack of information about the validity and/or reliability of data collection methods ($n = 28$), (3) lack of information about withdrawals and dropouts ($n = 31$), and (4) the absence of an a priori sample size calculation ($n = 52$).

IAD and Pressure Ulcer (PU) Development

One study (Table 1) was an examination of the association between IAD and PU development in at-risk patients who received standardized prevention and yielded a significant independent association between IAD and PU (*OR* 2.71; 95% *CI* 1.12–6.57) (Demarré et al., 2013).

Double Incontinence and PU Development

Overall association. All nine teams examining this association reported a significant association between double incontinence and PU development at the univariate level, as shown in Table 2 (Baumgarten et al., 2004; Henoch & Gustafsson, 2003; Isaia et al., 2010; Papanikolaou, Lyne, & Lycett, 2003; Perneger, Heliot, Rae, Borst, & Gaspoz, 2002; Salzberg et al., 1998; Scott, 1998; Tourtual et al., 1997; Watret, 1999).

In meta-analysis, an overall significant association was detected, producing a pooled odds ratio of 4.06 (95% *CI* 1.74–9.47) (Bates-Jensen, McCreath, Kono, Apeles, & Alessi, 2007; Papanikolaou et al., 2003; Perneger et al., 2002; Salzberg et al., 1998; Scott, 1998; Tourtual et al., 1997). The results of the meta-analysis are provided in Table 4.

One of the five teams (Papanikolaou et al., 2003) conducted a multivariate analysis and reported that incontinence was a significant predictor of PU incidence. Another team (Defloor & Grypdonck, 2005) tested multiple multivariate models including different confounders and found that significance of association depended on the confounders in the model. All teams used different confounders in their models.

Table 1. Study of Association Between IAD and PU Development

Authors (Year)	Study Design	Setting	Sample Size	PU Incidence	Univariate Analyses			Multivariate Analyses			
					Outcome	Predictor	Significance	Outcome	Predictor	*OR* (95% *CI*)	Significance
Demarré et al. (2013)	Prospective cohort study	Hospitals ($n = 5$)	610	20.3%	PU II+	IAD	$p < .20$	PU II+	IAD	2.71 (1.12–6.57)	$p < .05$
						Moisture	$p > .20$	PU II		3.11 (1.15–8.46)	$p < .05$
						UI	$p = .48$	PU III–IV		NR	$p > .05$
						FI	$p = .42$				
						Double incontinence	$p = .91$				

Note. PU, pressure ulcers; IAD, incontinence-associated dermatitis; UI, urinary incontinence; FI, fecal incontinence; *OR*, odds ratio; *CI*, confidence interval; NR, not reported.

Association when patients were PU-free at start of study. Two of the three groups examining this association (Table 3) reported a significant association between double incontinence and PU development at the univariate level (Bergquist & Frantz, 1999; Fife et al., 2001). In our meta-analysis of the two results, an overall significant association was detected, with a pooled odds ratio of 4.99 (95% *CI* 2.62–9.50). At the multivariate level, both teams reported that incontinence was a significant predictor of PU incidence, using different confounders in their models.

Urinary Incontinence and PU Development

Overall association. Four of the seven teams examining this association (Table 2) reported significant associations between urinary incontinence and PU development at the univariate level (Bianchetti, Zanetti, Rozzini, & Trabucchi, 1993; Goldstone & Goldstone, 1982; Pase, 1994; Salzberg et al., 1996). In meta-analysis, an overall significant association was measured with a pooled odds ratio of 1.92 (95% *CI* 1.54–2.38) as shown in Table 4 (Bergquist & Gajewski, 2011; Bianchetti et al., 1993; Pase, 1994; Reed, Hepburn, Adelson, Center, & McKnight, 2003; Salzberg et al., 1996). In multivariate analyses in individual studies, no teams reported that urinary incontinence was a significant predictor of PU incidence. All teams used different confounders in their models.

Association when patients were PU-free at start of study. Four of the 10 groups examining this association (Table 3) reported a significant association between urinary incontinence and PU development at the univariate level (Bergquist & Frantz, 1999; Berlowitz & Wilking, 1989; Brandeis, Ooi, Hossain, Morris, & Lipsitz, 1994; Wilczweski et al., 2012). In meta-analysis, as seen in Table 4, an overall significant association was detected, with a pooled odds ratio of 2.05 (95% *CI* 1.62–2.60) (Bergquist & Frantz, 1999; Brandeis et al., 1994; Lepisto, Eriksson, Hietanen, Lepisto, & Lauri, 2006; Schue & Langemo, 1999; Theaker, Mannan, Ives, & Soni, 2000). In individual studies at the multivariate level, two (Berlowitz, Brandeis, Anderson et al., 2001; Berlowitz, Brandeis, Morris et al., Berlowitz et al., 2001b2001) of the teams reported that urinary incontinence was a significant predictor of PU incidence. All groups used different confounders in their models.

Fecal Incontinence and PU Development

Overall association. In five of the nine studies in which this association was examined (Table 2), a significant association between fecal incontinence and PU development at the univariate level was reported (Bergquist & Gajewski, 2011; Bianchetti et al., 1993; Porell & Caro, 1998; Poss et al., 2010; Salzberg et al., 1996). One team examined the association between diarrhea and PU development at the univariate level and reported no

Table 2. Studies of Association Between Incontinence or Moisture and PU Development in Patients With and Without PU at Start of Study

						Univariate Analysis		Multivariate Analysis	
Authors (Year)	Study Design	Setting	Sample Size	PU Incidence	Outcome	Predictor	Results	Predictor	Results
Baldwin and Ziegler (1998)	Prospective cohort	Large county hospital	36	30.6%	PU I+		NR	Moisture	*OR* 2.96 (95% *CI* 1.06–8.31; $p = .04$)
Bates-Jensen et al. (2007)	RCT (secondary analysis)	Two nursing homes	35	44.4%	PU I+	SEM	$p < .001$	SEM versus erythema/stage I	*OR* 1.002 (95% *CI* 0.99–1.005)
								SEM versus stage II+	*OR* 1.002 (95% *CI* 0.996–1.008)
Bates-Jensen et al. (2008)	RCT (secondary analysis)	Two nursing homes	31	48.4%	PU I+	Concurrent SEM	$p < .001$	Concurrent SEM versus erythema/stage I	*OR* 1.008 (95% *CI* 1.003–1.013)
								SEM versus stage II+	*OR* 1.008 (95% *CI* 1.005–1.010)
Bates-Jensen et al. (2009)	RCT (secondary analysis—pooled data)	Four nursing homes	66	24.4%	PU I+; light skin tones	SEM	$p < .001$	SEM versus erythema/stage I	*OR* 1.000 (95% *CI* 1.000–1.003)
								SEM versus stage II+	*OR* 1.010 (95% *CI* 1.001–1.010)
								SEM versus erythema/stage I	*OR* 1.010 (95% *CI* 1.001–1.012)
					PU I+; dark skin tones	SEM	$p < .001$	SEM versus stage II+	*OR* 1.020 (95% *CI* 1.007–1.024)
Batson et al. (1993)	Prospective cohort	Two teaching hospitals, one general hospital ICU	51	NR	PU I+	Diarrhea	*OR* 1.49 (95% *CI* −9.60–10.40; $p = .945$)		NR
Baumgarten et al. (2003)	Prospective cohort	59 nursing homes	2,015	10.3%	PU II+		NR	UI	*OR* 0.9 (95% *CI* 0.5–1.7)
								FI	*OR* 2.5 (95% *CI* 1.4–4.3)
								UI and FI	*OR* 1.1 (95% *CI* 0.7–1.8)
Baumgarten et al. (2004)	Prospective cohort	59 nursing homes	1,938	23.2% 0.38 per person-year	PU II+	Incontinence	$p < .001$	UI	*HR* 0.68 (95% *CI* 0.45–1.04; $p = .073$)
								FI	*HR* 1.45 (95% *CI* 0.95–2.24; $p = .094$)
								UI and FI	*HR* 1.01 (95% *CI* 0.70–1.45; $p = .948$)
Bergquist and Gajewski (2011)	Retrospective cohort	Five home health agencies	5,395	1.3%	PU I+	UI	*OR* 1.42 (95% *CI* 0.89–2.27)	UI	$p > .05$
						FI	*OR* 5.67 (95% *CI* 3.35–9.63; $p < .001$)	FI	*OR* 2.84 (95% *CI* 1.04–7.75; $p = .042$)
Berlowitz and Wilking (1989)	Prospective and retrospective cohort	Hospital rehabilitation services	299	11%	PU I+	UI	$p = .33$ $p = .25$		NR
Bianchetti et al. (1993)	Prospective cohort	One psychogeriatric hospital	148	14.2%	PU I+	UI	*OR* 4.13 (95% *CI* 1.26–13.51; $p < .01$)		NR
						FI	*OR* 9.19 (95% *CI* 3.02–27.92; $p < .001$)		
Boyle and Green (2001)	Prospective cohort	Three hospital ICUs	534	18.48 PU per 1,000 patient days	PU I+	FI	$p = .13$		NR
Cowan, Stechmiller, Rowe, and Kairalla (2012)	Retrospective cohort	One veterans hospital	213	46.9%	PU I+	Moisture	$p > .05$		NR
Cox (2011)	Retrospective cohort	One hospital ICU	347	18.7%	PU I+	Moisture	$p > .05$		NR
Defloor and Grypdonck (2005)	Prospective cohort	11 long-term care facilities	1,458	32.4% (PU II+: 11.7%)	PU I+		NR		Model 1
								Incontinence	*OR* 0.71 (95% *CI* 0.60–0.84; $p < .001$)
								Moisture	*OR* 0.82 (95% *CI* 0.69–0.96; $p = .013$)
									Model 2
								Incontinence	*OR* 0.86 (95% *CI* 0.61–1.07; $p = .18$)
								Moisture	*OR* 0.97 (95% *CI* 0.79–1.19; $p = .77$)
					PU II+		NR		Model 1
								Incontinence	*OR* 0.76 (95% *CI* 0.61–0.93; $p = .009$)
								Moisture	*OR* 0.96 (95% *CI* 0.78–1.16; $p = .65$)
									Model 2
								Incontinence	*OR* 0.89 (95% *CI* 0.68–1.15; $p = .37$)
								Moisture	*OR* 0.1.11 (95% *CI* 0.87–1.42; $p = .39$)

(*Continued*)

Table 2. (*Continued*)

Authors (Year)	Study Design	Setting	Sample Size	PU Incidence	Outcome	Univariate Analysis		Multivariate Analysis	
						Predictor	Results	Predictor	Results
de Souza et al. (2010)	Prospective cohort	Four long-term care facilities for elderly	94	39.4%	PU I+	Moisture	$p = .034$	NR	
Goldstone and Goldstone (1982)	Prospective cohort	One hospital	40	45%	PU I+	UI	$p < .05$	NR	
Henoch and Gustafsson (2003)	Prospective cohort	One hospice	98	20.4%	PU I+	Incontinence	$p = .03$	NR	
Isaia et al. (2010)	Prospective cohort	One hospital	387	2.5%	PU I+	Incontinence	$p < .001$	Incontinence	$p > .05$
Jiricka et al. (1995)	Prospective cohort	One hospital ICU	85	56.5%	PU I+	Moisture	$p < .01$	Moisture	*OR* 4.61 (95% *CI* 1.70–12.52)
Kwong, Pang, Aboo, and Law, (2009)	Prospective cohort	Four nursing homes	346	25.16%	PU I+	Moisture	$p > .05$		NR
Page et al. (2011)	Prospective cohort	One hospital	342	19.6%	PU II+	Moisture	*OR* 5.01 (95% *CI* 2.62–9.55; $p < .001$)		NR
Papanikolaou et al. (2003)	Cross-sectional	One hospital	498	5.02%	PU I+	Incontinence	*OR* 5.49 (95% *CI* 2.31–13.03; $p < .05$)	Incontinence (low risk)	*OR* 4.37 (95% *CI* 1.49–12.85; $p = .007$)
Pase (1994)	Prospective cohort	Hospital (n = NR)	108	25%	PU I+	UI	*OR* 2.21 (95% *CI* 0.87–5.61)		NR
Perneger et al. (2002)	Prospective cohort	One hospital	1,190	15.3%	PU I+	Incontinence	*HR* 1.6 (95% *CI* 1.3–2.0)		NR
Porell and Caro (1998)	Retrospective cohort	Nursing homes	566	NR	PU I+	FI	*OR* 2.80 (95% *CI* 2.30–3.42)		NR
Poss et al. (2010)	Retrospective cohort	Three long-term care homes	14,083	3.9%	PU I+	FI	*OR* 2.80 (95% *CI* 2.30–3.42)	FI	*OR* 1.78 (95% *CI* 1.42–2.24)
Reed et al. (2003)	Prospective cohort study	47 veterans hospitals	2,771	14.7%	PU II+	UI	*RR* 1.92 (95% *CI* 1.47–2.50)	UI	$p > .05$
						FI	*RR* 1.25 (95% *CI* 1.03–1.62)	FI	$p > .05$
Salzberg et al. (1996)	Retrospective cohort	One long-term veteran department	219	80.4%	PU I+	UI	*OR* 4.59 (95% *CI* 1.40–15.04; $p = .002$)		NR
Salzberg et al. (1998)	Cross-sectional	Eastern Paralyzed Veterans Association	800	62.4%	PU I+	UI/moisture	$p < .001$ *OR* 11.38 (95% *CI* 8.59–15.07)	UI/moisture	$p < .001$
Scott (1998)	Retrospective cohort	One hospital	314	13.7%	PU I+	Incontinence	*OR* 3.92 (95% *CI* 1.83–7.40; $p < .001$)		NR
Suttipong and Sindhu (2011)	Cross-sectional	Community	168	47.6%	PU I+	Moisture	$p < .001$	Moisture	*OR* 1.80 (95% *CI* 1.13–2.87; $p = .013$)
Tourtual et al. (1997)	Prospective cohorts ($n = 2$)	One medical center	209	Study 1 26.8% Study 2	PU I+; heel	Incontinence Moisture Incontinence moisture $p = .002$	*OR* 4.13 (95% *CI* 2.17–7.86; $p < .001$) $p = .034$ *OR* 2.83 (95% *CI* 1.60–5.01; $p < .001$)		NR
Watret (1999)	Prospective cohort	Five hospitals	1,717	1.5%	PU I+	Incontinence	$p \leq .01$		NR
Watts et al. (1998)	Prospective cohort	One trauma center	148	20.3%	PU I+	Moisture	$p > .05$		NR

Note. *CI*, confidence interval; FI, fecal incontinence; *HR*, hazard ratio; NR, not reported; *OR*, odds ratio; PU, pressure ulcers; RCT, randomized controlled trial; *RR*, risk ratio; SEM, subepidermal moisture; UI, urinary incontinence.

Table 3. Studies of Association Between Incontinence or Moisture and PU Development in Patients Without PU at Start of Study

						Univariate Analysis		Multivariate Analysis	
Authors (Year)	Study Design	Setting	Sample Size	PU Incidence	Outcome	Predictor	Results	Predictor	Results
Allman et al. (1986)	Prospective cohort	One university hospital	286	12.9%	PU II+	UI	$p = .77$	FI	$p > .05$
						FI	$p = .04$		
Bergquist and Frantz (1999)	Retrospective cohort	One home health care agency	1,711	1.3%	PU I+	Incontinence	*OR* 6.69 (95% *CI* 2.97–15.04; $p < .001$)	UI	*HR* $p > .05$
						UI	*OR* 2.25 (95% *CI* 1.16–4.34; $p = .013$)	FI	*HR* 2.85 (95% *CI* 1.18–6.84; $p = .02$)
						Moisture	*OR* 7.22 (95% *CI* 3.19–16.3; $p = .003$)	Moisture	*HR* $p > .05$
Bergquist (2001)	Retrospective cohort	One home health care agency	1,684	6.3%	PU I+	Moisture	*HR* 0.38 (95% *CI* 0.31–0.48; $p < .001$)	Moisture	*HR* 0.48 (95% *CI* 0.38–0.61; $p < .001$)
Bergquist and Gajewski (2011)	Retrospective cohort	Five home health care agencies	5,116	1.3%	PU I+	UI	$p < .10$		NR
						FI	$p < .10$		
Berlowitz, Brandeis, Anderson et al. (2001)	Prospective cohort (derivation)	109 nursing homes	14,607	2.3%	PU II+	UI	$p < .05$	UI	*OR* 1.4 (95% *CI* 1.1–1.6)
Berlowitz, Brandeis, Morris et al. (2001)	Prospective cohort (validation)	108 nursing homes	13,457	2.1%	PU II+		NR	UI	*OR* 1.4 (95% *CI* 1.1–1.7)
Brandeis et al. (1994)	Prospective cohort	78 nursing homes	4,232	12.9% (range 19.3–6.5%)	PU II+; homes with high PU incidence	UI	*OR* 2.5 (95% *CI* 1.8–3.6; $p < .005$)	UI	$p > .05$
						FI	*OR* 2.3 (95% *CI* 1.8–3.0; $p < .001$)	FI	*OR* 2.5 (95% *CI* 1.6–4.0; $p < .001$)
					PU II+; homes with low PU incidence	UI	*OR* 1.7 (95% *CI* 1.1–2.6; $p < .01$)	UI	$p > .05$
						FI	*OR* 1.9 (95% *CI* 1.3–2.8; $p < .002$)	FI	$p > .05$
Carlson et al. (1999)	Prospective cohort	Three tertiary care center ICUs	136	12%	PU I+	Moisture	$p < .10$	Moisture	$p = .16$
Compton et al. (2008)	Retrospective cohort	One hospital ICU	698	17.3%	PU II+	Moist skin	*OR* 5.89 (95% *CI* 3.75–9.25; $p < .001$)	Moist skin	*OR* 2.35 ($p < .001$)
de Laat et al. (2007)	Prospective cohort	One hospital ICU	399	54 per 1,000 days	PU II+		NR	Constantly moist	$p > .05$
Fife et al. (2001)	Prospective cohort	One hospital ICU and one intermediate unit	186	12.4%	PU II+	Incontinence	*OR* 3.03 (95% *CI* 1.05–8.73; $p = .033$)		NR
Jiricka et al. (1995)	Prospective cohort	One hospital ICU	85	56.5%	PU I+	Moisture	$p < .01$	Moisture	*OR* 4.61 (95% *CI* 1.70–12.52)
Kaitani, Tokunaga, Matsui, and Sanada (2010)	Prospective cohort	One tertiary ICU, one high care unit	98	11.2%	PU I+	Moisture	$p > .05$		NR
Lepisto et al. (2006)	Prospective cohort		221	10.9%	PU I+	UI	*OR* 3.97 (95% *CI* 0.52–30.55)		NR

(*Continued*)

Table 3. (*Continued*)

Authors (Year)	Study Design	Setting	Sample Size	PU Incidence	Outcome	Univariate Analysis		Multivariate Analysis	
						Predictor	Results	Predictor	Results
Lindgren et al. (2005)	Prospective cohort	Eight long-term Two hospitals	286	14.3%	PU I+	FI Pre-operative Post-operative Moisture	*OR* 0.83 (95% *CI* 0.26–2.60) $p > .05$ $p < .01$		NR NR
Molon and Estrella (2011)	Prospective cohort	Two tertiary care hospitals	40	20%	PU II+	Moisture	*OR* 10.7 (95% *CI* 1.75–65.2; $p = .01$)	Moisture	*OR* 10.0 (95% *CI* 0.85–117)
Ooi, Morris, Brandeis, Hossain, and Lipsitz (1999)	Prospective cohort	70 nursing homes	5,518	11.4%	PU I+		NR	Incontinence	*RR* 1.56 (95% *CI* 1.24–1.96; $p < .001$)
Papanikolaou, Clark, and Lyne (2002)	Prospective cohort	Two hospitals	213	22.1%	PU I+		NR	Incontinence	*OR* 5.58 (95% *CI* 1.58–19.49; $p = .05$)
Schoonhoven et al. (2006)	Prospective cohort	Two large hospitals	1,229	9.8%	PU II+	FI	*OR* 1.81; $p = .13$		NR
Schue and Langemo (1998)	Retrospective cohort	One rehabilitation unit	170	27.1%	PU I+	Moisture	$p < .10$	Moisture	*OR* 1.90 (95% *CI* 1.07–3.37)
Schue and Langemo (1999)	Retrospective cohort	One rehabilitation unit	170	27.1%	PU I+	UI FI	*OR* 1.45 (95% *CI* 0.67–2.93) *OR* 1.53 (95% *CI* 0.64–3.52)		NR
Suriadi et al. (2007)	Prospective cohort	One hospital ICU	105	33.3%	PU I+	FI Skin moisture	*OR* 6.34 (95% *CI* 0.78–51.26; $p = .51$) *OR* 5.50 (95% *CI* 2.67–13.33; $p < .001$)	Skin moisture	*OR* 8.2 (95% *CI* 2.2–30.9; $p = .002$)
Theaker et al. (2000)	Prospective cohort	Hospital ICU and high-dependency unit (n = NR)	332	23.2%	PU I+	UI FI	*OR* 1.64 (95% *CI* 0.38–7.04; $p = .50$) *OR* 7.51 (95% *CI* 3.92–14.40; $p = .01$)	FI	*OR* 3.27 (95% *CI* 1.32–8.30; $p = .01$)
Towey and Erland (1988)	Prospective cohort	Long-term care facilities (n = NR)	60	46.7%	PU I+	Incontinence	$r = .21$; $p = .131$		NR
Wilczweski et al. (2012)	Retrospective cohort	Hospital surgical ICU (n = NR)	94	9.6%	PU I+	UI FI	$p = .009$ $p \leq .001$	UI FI	$p = .35$ $p = .19$

Note. *CI*, confidence interval; FI, fecal incontinence; *HR*, hazard ratio; NR, not reported; *OR*, odds ratio; PU, pressure ulcers; *RR*, risk ratio; UI, urinary incontinence.

Table 4. Meta-Analysis of Predictors of Pressure Ulcer Development

Predictor and Additional Analyses	Subgroups	Number of Studies	Total Patients	Effect Size (Odds Ratio)	95% Confidence Interval	Cochran's Q	*p*-Value	I^2
Incontinence	All	6	3,113	4.06[a]	1.74–9.47	116.93	<.001	96%
Subgroup analysis[d]	Cross-sectional studies	2	1,298	10.61[b]	8.13–13.86	2.47	.12	60%
	Cohort studies	4	1,713	2.78[a]	1.62–4.76	14.45	.002	79%
	Hospitals	5	2,313	3.11[a]	1.83–5.26	19.45	.006	79%
Sensitivity analysis[e]		5	1,923	5.03[a]	2.64–9.58	27.22	<.001	85%
Urinary incontinence	All	5	8,641	1.92[b]	1.54–2.38	5.35	.25	25%
Sensitivity analysis[e]		4	5,870	1.91[b]	1.31–2.78	5.35	.15	44%
Faecal incontinence	All	7	23,290	2.90[a]	1.93–4.35	44.70	<.001	87%
Subgroup analysis	Hospitals	3	3,027	2.65[a]	1.24–5.65	30.06	<.001	93%
	Long-term care facilities	2	14,302	2.42[b]	1.10–5.32	.35	.55	0%
Sensitivity analysis[e]		5	20,519	2.97[a]	2.60–3.39	10.97	.05	54%
Moisture	All	3	4,303	2.05[a]	1.08–3.86	13.48	.001	85%
Incontinence	PU-free at start study	2	1,897	4.99[b]	2.62–9.50	1.36	.24	26%
Urinary incontinence	PU-free at start study	5[c]	6,666	2.05[b]	1.62–2.60	3.38	.64	0%
Fecal incontinence	PU-free at start study	6	23,290	2.31[b]	1.90–2.80	18.76	.005	68%
Subgroup analysis[d]	Hospitals	3	1,666	4.84[b]	2.88–8.13	5.97	.05	67%
Moisture	PU-free at start study	5	4,238	4.63[b]	3.29–6.52	13.09	.01	69%
Sensitivity analysis[e]		4	2,254	5.28[b]	3.72–7.50	2.36	.50	0%

[a]Random effect.

[b]Fixed effect.

[c]One article (Brandeis et al., 1994) reported two separate studies in one article.

[d]A pooled odds ratio could only be calculated if $\geq$2 studies could be included in the meta-analysis.

[e]Incontinence: sensitivity analysis was performed by excluding the study of Perneger et al. (2002) which reported hazard ratio instead of odds ratios; Urinary incontinence: sensitivity analysis was performed by excluding the study of Reed et al. (2003) which reported relative ratio instead of odds ratios; Faecal incontinence: sensitivity analysis was performed by excluding the study of Reed et al. (2003) which reported relative ratio instead of odds ratios; Moisture (PU-free at start study): sensitivity analysis was performed by excluding the study of Bergquist (2001) which reported hazard ratio instead of odds ratios.

significant association ($p = .945$) (Batson, Adam, Hall, & Quirke, 1993).

In our meta-analysis, as seen in Table 4, an overall significant association was detected, with a pooled odds ratio of 2.90 (95% *CI* 1.93–4.35) (Bergquist & Gajewski, 2011; Bianchetti et al., 1993; Pase, 1994; Porell & Caro, 1998; Poss et al., 2010; Reed et al., 2003; Salzberg et al., 1996). In multivariate analyses by individual study teams, three (Baumgarten et al., 2003; Bergquist & Gajewski, 2011; Poss et al., 2010) of the five reported that fecal incontinence was a significant predictor of PU incidence. All groups used different confounders in their models.

Association when patients were PU-free at start of study. Four of the 10 groups examining this association (Table 3) reported a significant association between fecal incontinence and PU development at the univariate level (Allman, Goode, Patrick, Burst, & Bartolucci, 1986; Brandeis et al., 1994; Theaker et al., 2000; Wilczweski et al., 2012). In meta-analysis (Table 4), an overall significant association was detected, with a pooled odds ratio of 2.31 (95% *CI* 1.90–2.80) (Brandeis et al., 1994; Lepisto et al., 2006; Schoonhoven et al., 2006; Schue & Langemo, 1999; Suriadi et al., 2007; Theaker et al., 2000). In their own analyses at the multivariate level, three of the six groups (Bergquist & Frantz, 1999; Bergquist & Gajewski, 2011; Theaker et al., 2000) reported that fecal incontinence was a significant predictor of PU incidence. One team split the reporting of their data by nursing homes with high and low PU incidence (Brandeis et al., 1994). In the nursing homes with high PU incidence, fecal incontinence was a significant predictor of PU development, whereas in nursing homes with low PU incidence, fecal incontinence was not a significant predictor of PU development. All studies used different confounders in their models.

Moisture and PU Development

Overall association. Five of the nine teams examining this association (Table 2) reported a significant association between moisture and PU development at the univariate level (Page, Barker, & Kamar, 2011; Reed et al., 2003; Suttipong & Sindhu, 2011; Tourtual et al., 1997). In meta-analysis, an overall significant association was detected with a pooled odds ratio of 2.05 (95% *CI* 1.08–3.86) as seen in Table 4 (Page et al., 2011; Perneger et al., 2002; Reed et al., 2003). In their own analyses at the multivariate level, two of the four author teams (Baldwin & Ziegler, 1998; Suttipong & Sindhu, 2011) reported that moisture was a significant predictor of PU incidence. One group used multiple multivariate models including different confounders and found contrasting results (Defloor & Grypdonck, 2005). All groups used different confounders in their models.

Three studies were conducted by one group on the association between subepidermal moisture and PU development (Bates-Jensen et al., 2007; Bates-Jensen, McCreath, Pongquan, & Apeles, 2008; Bates-Jensen, McCreath, & Pongquan, 2009). All analyses yielded a significant association at the univariate level ($p < .001$), but the association did not remain significant at the multivariate level.

One team examined the association between urinary incontinence and moisture and PU development at the uni- and multivariate levels (Salzberg et al., 1998). A significant association was found at both levels ($p < .001$).

Association when patients were PU-free at start of study. Eight of the 12 groups examining this association (Table 3) reported a significant association between moisture and PU development at the univariate level (Bergquist, 2001; Bergquist & Frantz, 1999; Compton et al., 2008; de Souza, de Gouveia Santos, de Souza, & de Gouveia Santos, 2010; Jiricka, Ryan, Carvalho, & Bukvich, 1995; Lindgren, Unosson, Krantz, & Ek, 2005; Molon & Estrella, 2011; Suriadi et al., 2007). In our meta-analysis (Table 4), an overall significant association was found, with a pooled odds ratio of 4.63 (95% *CI* 3.29–6.52) (Bergquist, 2001; Bergquist & Frantz, 1999; Compton et al., 2008; Molon & Estrella, 2011; Suriadi et al., 2007). In their own analyses at the multivariate level, five of the eight groups (Bergquist, 2001; Compton et al., 2008; Jiricka et al., 1995; Schue & Langemo, 1998; Suriadi et al., 2007) reported that moisture was a significant predictor of PU incidence. All studies used different confounders in their models.

Discussion

Even when the methodological issues and heterogeneity of the results are taken into consideration, the evidence reported here supports IAD as a predictor of PU development in one prospective study (Demarré et al., 2013) and does, as proposed, link its most important etiological factors (double incontinence, urinary incontinence, fecal incontinence, and moisture) to the development of PUs (Garcia-Fernandez et al., 2014; NPUAP & EPUAP, 2010). These findings reinforce the importance of including incontinence and moisture in pressure ulcer risk assessment scales (Garcia-Fernandez, Pancorbo-Hidalgo, & Agreda, 2014).

In the recent systematic review performed by Coleman et al. (2013), moisture (including incontinence) was not always associated with PU development. In our review, although an association was found at the univariate level, we also had mixed results regarding incontinence and moisture in multivariate analysis. All studies used different confounders in multivariate models, which made comparison impossible, and suggests that other factors add to the effect of incontinence or moisture in the development of PU.

The results need to be interpreted with caution for a number of reasons. The studies included had methodological limitations, of which selection bias and lack of information about the validity and/or reliability of data collection methods were the most important. For example, IAD may have been incorrectly classified as PU. Only Demarré et al.

(2013) made a distinction between IAD and PUs. Furthermore, our meta-analysis was limited by missing odds ratios because some studies did not report them or gave insufficient information to calculate them. The results may therefore be a biased representation. We reported the association based on *p*-values to provide a broader picture, which in the majority of cases revealed a significant association.

Moreover, observational studies do not always allow a determination of causality, because rival hypotheses are more difficult to rule out (Mann, 2003). Nevertheless, high-quality cohort studies can determine a causal relationship if performed adequately. The next step in research is to examine whether the associations found in this systematic review are causal relationships. Cohort studies including only PU-free patients and using sacral PUs as an outcome measure are needed.

In addition, caution is needed because heterogeneity was present. In a meta-analysis, it is important to examine the variability between studies (Walker, Hernandez, & Kattan, 2008). We made a distinction between studies including and excluding patients with PUs at start of the studies and found low to moderate heterogeneity in the studies only including patients free of PUs at the start and by performing subgroup and sensitivity analyses. Nevertheless, heterogeneity was not always explained, which makes an overall justification of the results more difficult.

The association found in this systematic review implies that IAD, incontinence and moisture may be considered key factors in the risk assessment of PUs in daily practice. Published guidelines on the prevention of PUs advise a structured approach for risk assessment, such as clinical judgment based on key risk factors, to identify patients at risk of PU development (Beeckman et al., 2012; National Pressure Ulcer Advisory Panel & European Pressure Ulcer Advisory Panel, 2009). However, a recent meta-analysis demonstrated high predictive capacity of the risk assessment scales that including incontinence/moisture and recommended that PU risk assessment should not be based solely on clinical judgment due to its poor predictive ability (Garcia-Fernandez et al., 2014).

In patients at risk of both IAD and PU, an individualized prevention plan should be implemented, including repositioning and use of pressure redistributing devices, and our work indicates that attention also should be given to exposure to moisture (Beeckman et al., 2012). For the prevention of IAD, structured perineal skin care, including gentle cleansing with a product with a balanced pH, and use of a skin protectant following each major incontinence episode or skin protectants that do not require application after every incontinence episode, is suggested (Beeckman, Schoonhoven, Verhaeghe, Heyneman, & Defloor, 2009; Gray et al., 2012). However, more high-quality randomized controlled trials on the effectiveness of prevention and treatment of IAD as part of PU care are needed in order to formulate more conclusive recommendations.

Conclusion

Despite the methodological variation in available studies and the heterogeneity of their results, our analysis indicates a likely association between IAD, its most important etiological factors, and the development of PUs. Well-designed cohort studies are needed to determine a causal relationship between the variables.

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