Oedema as a predictor of the incidence of new pressure injuries in adults in any care setting: A systematic review and meta-analysis

Wendy Chaboyer [1], Fiona Coyer [2], Emma Harbeck [3], Lukman Thalib [4], Sharon Latimer [3], Ching Shan Wan [5], Georgia Tobiano [6], Bronwyn R Griffin [7], Jill L Campbell [8], Rachel Walker [9], Joan J Carlini [10], Ishtar Lockwood [3], Justin Clark [11], Brigid M Gillespie [12]

1. Background

Pressure injuries are potentially preventable injuries to the skin and underlying tissues. In hospitalised patients, pressure injury prevalence is 12.8% and the incidence rate is 5.4/10,000 (Li et al., 2020). The most frequently affected anatomical locations are the sacrum (37.3%) and heel (29.5%) (Li et al., 2020). International clinical practice guidelines recommend various strategies for pressure injury prevention including the use of pressure relieving devices and support surfaces, regular repositioning and oedema measurement, also known as sub-epidermal moisture measurement, as an adjunct pressure injury prevention intervention (European Pressure Ulcer Advisory Panel et al., 2019).

Pressure injuries are caused by prolonged pressure, shear and/or friction (European Pressure Ulcer Advisory Panel et al., 2019). This injury triggers an inflammatory response with the release of mediators causing vasodilation and an increase in microvascular permeability resulting in fluid leaking from the vasculature and the formation of oedema (Gefen, 2018). This microscopic injury involves cell death which can progress to changes to the tissue pH, increased oedema and large-scale cell death (Gefen, 2018). Eventually, the injury presents macroscopically as skin discolouration, pain and heat (Gefen and Ross, 2020) with sustained tissue deformity determined to be the main cause of pressure injury (Gefen, 2018).

Visual skin assessment is the current 'gold standard' in pressure injury identification, however, its subjective nature and high inter-rater variability reduces its reliability in early detection (Edsberg et al., 2016). Several non-invasive portable devices have been developed to measure changes in epidermal oedema (Gefen and Ross, 2020) including the Delfin MoistureMeter and Bruin Biometrics Sub-epidermal moisture scanner (Qassem and Kyriacou, 2019). These devices provide quantitative data on potential underlying tissue damage (Gefen and Ross, 2020) by measuring the tissue biocapacitance or the ease to which an electrical current can pass through the cell membrane and into the intracellular space (Peko Cohen and Gefen, 2019). High extracellular oedema results in a higher biocapacitance value detected by the devices (Oliveira et al., 2017). Other devices used in dermatology such as the Nova Petite, measure skin impedance or resistance associated with skin hydration (Qassem and Kyriacou, 2019). Demonstrating their potential value in the early detection of pressure injury, the 2019 international clinical practice guidelines for the prevention and treatment of pressure injuries recommend the use of a sub-epidermal moisture/oedema measurement device as an adjunct tool to standard pressure injury risk assessment (European Pressure Ulcer Advisory Panel et al., 2019).

There is some empirical support for the association between early tissue damage and subsequent pressure injuries although several studies in the area have been undertaken in single sites and with small samples (Bates-Jensen et al., 2020; Gefen and Gershon, 2018; O'Brien et al., 2018). A review of four studies published between 2007 and 2012 showed elevated or abnormal oedema was associated with skin and tissue damage (Oliveira et al., 2017). The aim of that review was to detect the accuracy of sub-epidermal moisture [their term] to detect damage and pressure injuries. Those

authors conceptualised sub-epidermal moisture measurement as a prognostic factor but did not subsequently use published guidance for prognostic factor reviews available at that time (Hayden et al., 2013; Huguet et al., 2013; Moons et al., 2014; Riley et al., 2013) to extract data, assess the risk of bias of the studies or assess the certainty of the body of evidence. They undertook a narrative synthesis, did not plan, or conduct a meta-analysis and did not assess the overall certainty of the body of evidence. However, it is important to note that their review was conducted prior to clear guidance for undertaking reviews of prognostic factors. Finally, since their review, several studies on the topic have been published. Thus, an up-to-date prognostic factor review, following newer methods for this review type is warranted to synthesise the growing body of evidence and may help inform clinicians approaches to pressure injury prevention. Therefore, the primary objective of this systematic review was to determine the prognostic value of measuring oedema, termed sub-epidermal moisture by many authors, as a predictor of future pressure injuries in adults in any care setting. In terms of clinical impact, we proposed that oedema measurement supports critical thinking and subsequent action. That is, the identified presence of oedema 'triggers' the use of new and or additional pressure injury prevention strategies. Therefore, a secondary objective was to determine the effect of oedema measurement on the number and/or frequency of pressure injury prevention strategies, however defined by the study authors. Another secondary objective was to determine the effect of oedema measurement on pressure injury Stage 2 or greater.

2. Material and methods

This prognostic factor systematic review (Riley et al., 2019) used a modified 2-week systematic review process that incorporates automation tools from the Systematic Review Accelerator (Clark et al., 2020). Because traditional systematic reviews can take months or years to complete (Beller et al., 2018; Borah et al., 2017), they do not support the rapid transfer of evidence into practice (O'Connor et al., 2019). This has resulted in international efforts to automate parts of the process, to make it more efficient and accurate (Beller et al., 2018). The 2-week systematic review process is one result of this international effort; saving time and human resources because reviewers undertake several steps concurrently and automated tools allows the process to be much more time efficient while still ensuring high quality reviews are conducted (Beller et al., 2013; Clark et al., 2021; Clark et al., 2020; O'Connor et al., 2019). Shortening the time from conception of the review to publication has the potential to narrow the evidence-practice gap.

The population, intervention, comparator, outcome, timing, setting (PICOTS) for structuring prognostic review question was used (see Supplementary file 1 Table 1). The population was pressure injury free adults, and the intervention was oedema measurement. We restricted studies to studies that recruited patients who did not have pressure injuries because of the importance of the temporal order of effect. That is, we wanted to ensure oedema occurred prior to the development of a pressure injury and not as a result of it. The comparator was any other pressure injury prevention strategies, however defined by the authors of included studies or no comparator. In the case of no comparator prognostic factors, we compared normal to abnormal or high oedema measurements (however defined by the authors of included studies). The primary outcomes were cumulative incidence or time to pressure injury. Secondary outcomes were the use of pressure injury prevention strategies (however defined by the authors of included studies) and Stage 2 or greater pressure injuries. The timing we expected was up to 14 days and the setting was any care setting. This was a contextualised review (Huguet et al., 2013) whereby it was undertaken to aid clinicians in their decision-making about the use of oedema measurement devices. We were guided in our

reporting by the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines for reporting meta-analyses of observational studies (Stroup et al., 2000).

2.1. Inclusion and exclusion criteria

Eligible study designs included cohort (both prospective and retrospective), case-control, case series if relevant comparisons were reported, randomised controlled trials if the association between oedema measurement and pressure injury was reported, and registry data. Cross-sectional studies and case reports were excluded because they cannot determine the temporal relationship between the prognostic factor and outcome. Clinical audits and quality improvement projects if no ethics committee approval had been granted were excluded. If studies included participants with pressure injuries at baseline and there was no data on oedema measurement before pressure injury development, they were excluded because the temporal order between the prognostic factor and outcome could not be established. Paediatric and animal studies were also excluded. In press and published articles were included but submitted papers that had not been peer-reviewed were excluded. Conference abstracts were excluded because their brevity did not allow us to extract prognostic factor information or properly assess the risk of bias and the level of peer review of abstracts is unclear. There were no restrictions on the language of publication.

2.2. Data sources, searching and screening

Databases searched by three PhD prepared authors including one consumer (blinded for peer review) with oversight by a PhD prepared content expert included: Medical Literature Analysis and Retrieval System Online (MEDLINE) (via PubMed), The Cumulative Index to Nursing and Allied Health Literature (CINAHL), Excerpta Medica (EMBASE) and the Cochrane Library. Backward searching of the reference lists of included articles was undertaken. Filters were not used. Databases were searched from inception to 13 July 2021 with no language restrictions. Two registries (World Health Organization International Clinical Trials Registry Platform (ICTRP) and US National Institutes of Health Ongoing Trials Register) were also searched. A specialist Health Librarian assisted in refining the search strategy and a senior information specialist familiar with various automated tools assisted with the searching and screening process. The full search strategy for each database used the SRA Polyglot Search Translator (Clark et al., 2020) and is listed in Supplementary File 1.

After duplicate papers were removed using SRA Deduplicator (Clark et al., 2020), three authors independently used the selection criteria to identify potential studies by reviewing titles and abstracts using the SRA Screenatron tool (Clark et al., 2020). The SRA Disputatron tool was used to identify disagreements, which were adjudicated by the fourth reviewer. Full-text papers were then retrieved, uploaded into EndNote (Version 20), and screened by three reviewers against the inclusion and exclusion criteria. Disagreements that could not be resolved were adjudicated by a third author.

2.3. Data extraction and quality assessment

The Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies – Prognostic Factors (CHARMS-PF) (Riley et al., 2019) guided data extraction. This checklist includes information on the participants, outcomes, prognostic factors, sample size, missing data, analysis results and interpretation and discussion. In extracting data and reporting the results, we used the authors' terminology (i.e. if they referred to oedema as sub-epidermal moisture, we used their term). We pilot tested the checklist on four potential studies and revised it to make the wording reflective of our review. Data extractors underwent a training program including extracting data on two included studies. For each article, two independent authors extracted the data using

Microsoft Excel and compared their results. Disagreements that could not be resolved were adjudicated by a third author. If information was unclear or key data required for analyses were missing, authors of the primary studies were contacted.

The Quality in Prognostic Factor Studies (QUIPS) (Hayden et al., 2013) tool was used to assess the risk of bias of the individual studies. It has six domains (study participants, study attrition, prognostic factor measurement, outcome measurement, study confounding and statistical analysis and reporting) with a series of prompting items for each domain. As recommended, we pre-defined specific information for our review for each prompting item in each domain, using published exemplars as a guide (Grooten et al., 2019). The form was piloted on three reviews and prompting items were subsequently refined. According to Hayden et al. (2013), studies are categorised as high, moderate or low risk of bias in each of the domains, with low risk of bias studies reflecting those that all or most important domains are assessed as low risk of bias. A priori, we determined the domains of prognostic factor measurement, outcome measurement and statistical analysis and reporting were most important and had to be evaluated as low risk of bias to achieve an overall low risk of bias rating. Risk of bias assessors underwent a training program and assessed two included studies in this training. Two authors independently assessed each included study and if disagreements arose and could not be settled a third author adjudicated.

The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) for prognostic factors (Foroutan et al., 2020) was used to assess the certainty of the body of evidence. It provides guidance on how to apply the five grade principles (risk of bias, inconsistency, imprecision, indirectness, publication bias) and how to make decisions on rating the body of evidence as high, medium, low, or very low quality. This assessment was undertaken in GRADEpro (McMaster University, 2020) by a team of three senior researchers and checked by a fourth methodologist, all experienced in Cochrane reviewing. We used a contextualised approach where we focused on measuring oedema as a single prognostic factor that could inform decision-making about its use and did not consider other comparative factors in assessing the certainty of evidence (Foroutan et al., 2020).

2.4. Synthesis of results

Separate unadjusted and adjusted meta-analyses were planned for studies that report Risk Ratio, Odds Ratio and Hazard Ratio. Regression coefficients reported for continuous outcome data were to be pooled separately unless individual patient data were available for data categorisation. Adjustments were planned for other prognostic factors including age, gender, mobility status, pressure injury risk (as determined by a risk assessment tool) and tissue oxygenation. Random effects meta-analyses were planned because heterogeneity was expected (Riley et al., 2019). Heterogeneity was assessed using I^2 (Higgins et al., 2021). Heterogeneity was regarded as low, not important, moderate, substantial, or considerable if I^2 was less than 40%, 30% to 60%, 50% to 90%, or 75% to 100%, respectively (Higgins et al., 2021). If heterogeneity was low, a fixed-effect meta-analysis was run, but if heterogeneity was high a random-effects model was used (Higgins et al., 2021). Subgroup analyses were planned to be conducted for anatomical location of pressure injury (sacrum, heel) and for cut-offs for abnormal oedema (≥0.5 and ≥0.6) based on the Bruin Biometric sub-epidermal moisture scanner because it is commonly used (Gefen and Ross, 2020; Moore et al., 2017). Meta-regressions were planned for age, gender, and sample size. Meta-regression models used effect estimate (log risk ratio) as the outcome and these a-priori determined covariates were assessed for their potential influence on the effect of oedema on pressure injury. Sensitivity analyses were planned by restricting analyses to low risk of bias studies, Stage 2 or worse pressure injury and

Bruin Biometric scanner results. Funnel plots were planned to assess reporting bias (Sterne and Egger, 2001).

3. Results

The initial search yielded 212 citations; after duplicates and irrelevant citations were removed, 115 titles and abstracts were screened, and 26 papers (and one corrigendum) remained for full-text review. A list of the 20 excluded studies after full-text screening and reasons for exclusion is contained in Supplementary File 1 Table 2. After full-text screening, six studies (Budri et al., 2020; Gefen and Gershon, 2018; Kim et al., 2018; Lee et al., 2019a; O'Brien et al., 2018; Okonkwo et al., 2020) and one corrigendum (Lee et al., 2019b) were included in this review. A search of cited papers from included studies did not yield any new relevant studies. Trial registry searches yielded two studies; respective authors were contacted and reported one was ongoing and the second was completed but the results were confidential. Fig. 1 provides a summary of the selection process. There was 88.5% agreement between the screeners with a Cohen's Kappa of 0.653.

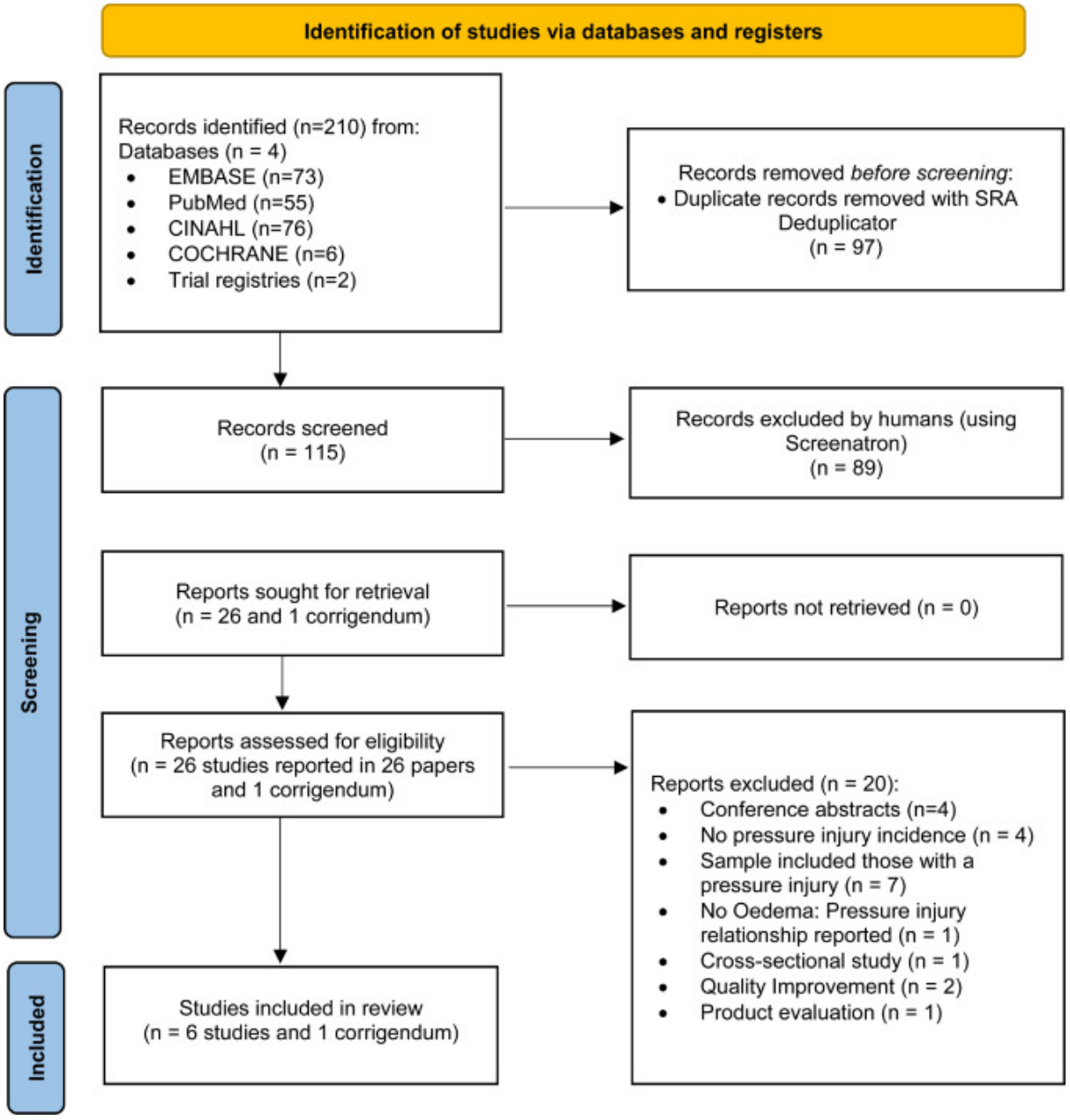

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Fig. 1. PRISMA 2020 flow diagram of included studies.

Table 1 provides a summary of the characteristics of the six included studies, all of which used the term sub-epidermal moisture (Budri et al., 2020; Gefen and Gershon, 2018; Kim et al., 2018; Lee et al., 2019a; O'Brien et al., 2018; Okonkwo et al., 2020). They were undertaken in Ireland (Budri et al., 2020; O'Brien et al., 2018), South Korea (Kim et al., 2018; Lee et al., 2019a), the United States (Gefen and Gershon, 2018) and in two countries (United Kingdom and United States) (Okonkwo et al., 2020). Two studies were set in nursing homes or aged care facilities (Budri et al., 2020; Kim et al., 2018) and four in either hospitals or post-acute facilities (Gefen and Gershon, 2018; Lee et al., 2019a; O'Brien et al., 2018; Okonkwo et al., 2020). According to Dekker et al.'s (2012) description, five studies were prospective cohorts (Budri et al., 2020; Gefen and Gershon, 2018; Kim et al., 2018; O'Brien et al., 2018; Okonkwo et al., 2020); and one was a randomised control trial (Lee et al., 2019a). No case-series with relevant comparisons were identified. The total sample size from all studies was 483 with a median of 56.5 participants (Interquartile range [IQR] 24–158; range 9–182) and follow-up periods varied widely from 3 days (Gefen and Gershon, 2018) to 12 weeks (Kim et al., 2018). Four studies were funded by an industry body (Gefen and Gershon, 2018; Lee et al., 2019a; O'Brien et al., 2018; Okonkwo et al., 2020), one by an independent funding body (Kim et al., 2018) and one by a combination of both (Budri et al., 2020).

Table 1.. Characteristics of the study, prognostic factors and PI (using the term oedema or SEM as reported by authors).

Author (Year) Country	**Study Design, start/finish dates**	**Setting**	**Sample Size**	**Follow-up time period**	**Prognostic Factors**	**Device used to measure oedema and frequency of oedema measurement**	**How was PI collected, by who and how frequently?**
Budri et al. (2020) Ireland	[a]Prospective Cohort/Jan 2016-Dec 2017	2 long term aged care facilities	*N* = 150, no LTFU	20 days	• SEM • Age • Gender • Braden PI risk score •	Daily using SEM Scanner (Bruin Biometrics Europe, Ltd. Cheshire, UK)	Daily VSA with photograph of possible PIs; PI confirmed using photographs by tissue viability nurses

Author (Year) Country	Study Design, start/finish dates	Setting	Sample Size	Follow-up time period	Prognostic Factors	Device used to measure oedema and frequency of oedema measurement	How was PI collected, by who and how frequently?
					Piezoelectric movement sensor (EarlySense)		
(Gefen and Gershon, 2018) USA	[a]Prospective Cohort/Dec 2016–Feb 2017	1 post-acute care centre	*N* = 9 (2 subgroups; at PI risk and no risk)	3–10 days depending on risk of developing a PI or DTI; at PI-risk group 3–10 days and no risk group 3 days	• SEM • Age • Gender • Braden PI risk score	Daily using SEM Scanner Point of Care 200; (Bruin Biometrics LLC, Los Angeles, CA)	Daily VSA by a wound specialist conducted
Kim et al. (2018) South Korea	[a]Prospective Cohort/June–Aug 2012	1 nursing home	*N* = 29; LTFU=4	Weekly for 12 weeks	• SEM • Age • Gender • Braden PI risk score	Weekly, 20 consecutive measures on each site using NOVA Petite (NOVA Technology Corporation, Portsmouth, NH USA) dermal phase metre	Weekly VSA by a trained wound care nurse
Lee (2018) South Korea	RCT/June 2016–Oct 2017	ICUs in 2 acute care hospitals	*N* = 66; LTFU=5 (7%)	Every 3 days during ICU stay	• SEM •	Every 3 days using Delfin MoistureMeter D (Delfin Technology,	Every 3 days by trained nurses

Author (Year) Country	Study Design, start/finish dates	Setting	Sample Size	Follow-up time period	Prognostic Factors	Device used to measure oedema and frequency of oedema measurement	How was PI collected, by who and how frequently?
					Age • • Gender • • Braden PI risk score • • SEM • • Age • • Gender • • Norton PI risk score • • Norton mobility score	Ltd, Kuopio, Finland)	
O'Brien et al. (2018) Ireland	[a]Prospective Cohort /Study dates NR	1 medical and 1 surgical unit (62 beds total) in 1 general hospital	*N* = 47; LTFU *n* = 13 (27.7%)	Daily for 4 weeks until discharged or transferred		Daily using SEM™ Scanner (Bruin Biometrics Europe, Ltd. Cheshire, UK)	Daily VSA results extracted from patient records
Okonkwo et al. (2020) USA & UK	[a]Prospective Cohort /Study dates NR	6 acute and 3 post-acute hospitals/facilities in the US and 3 acute care settings in the UK	*N* = 182; LTFU NR but reasons for 7 (3.7% of 189) patients not analysed stated	21 days; PI, discharged from the facility after at least 6 days of observation	• • SEM • • Age • • Gender • •	Daily SEM using SEM Scanner Point of Care 200; (Bruin Biometrics LLC, Los Angeles, CA)	Daily VSA by trained wound assessors blinded to SEM reading by trained wound care specialists

Author (Year) Country	Study Design, start/finish dates	Setting	Sample Size	Follow-up time period	Prognostic Factors	Device used to measure oedema and frequency of oedema measurement	How was PI collected, by who and how frequently?
					Braden PI risk score		

Note: [a]based on Dekkers et al. (2012) description. DTI= Deep tissue injury; ICU= Intensive Care Unit; ITT= Intention to treat; LTFU= Lost to follow-up; NR= Not reported; PI=Pressure injury/ulcer; RCT= Randomised control trial; SEM= Sub-epidermal moisture; VSA= Visual skin assessment.

Table 1 also reports on the measurement of oedema, comparator prognostic factors and measurement of the outcomes (pressure injury, time to pressure injury, pressure injury prevention strategies). Further study details are provided in Supplementary file 1 Table 3. While all studies measured prognostic factors in addition to oedema measurement, only two studies (Kim et al., 2018; Lee et al., 2019a) adjusted their analyses for other prognostic factors. Further, Kim et al. (2018) used pressure injury and not persons as their unit of analysis. As these two studies differed in both the unit of analysis (adjusted mean difference between two groups and adjusted odds ratio based on the number of oedema measurements) we were unable to pool them for meta-analysis. Three different oedema measurement devices were used in the six studies, with the Bruin Biometric scanner used in four studies (Budri et al., 2020; Gefen and Gershon, 2018; O'Brien et al., 2018; Okonkwo et al., 2020). For the Bruin biometric scanner device, abnormal oedema measured by a difference of ≥0.5 or ≥0.6 between the highest and lowest reading at a specific location, (termed the delta Δ value) indicates early tissue damage (Gefen and Ross, 2020; Moore et al., 2017). In the four Bruin Biometric scanner studies, abnormal oedema was defined as: a delta score (difference between the highest and lowest reading) of ≥0.06 in two studies (Gefen and Gershon, 2018; Okonkwo et al., 2020) and a delta of > 0.05 in two studies (Budri et al., 2020; O'Brien et al., 2018). Kim et al. (2018) used the Novo Petite device that has a range of values from 0 to 999 and determined that higher values indicated more oedema. Lee et al. (2019a) used the Delfin MoistureMeter D but did not report the possible range of values, instead using linear regression to determine the difference between those with and without a pressure injury. There was variable reporting of the reliability, precision, and validity of the devices. In all studies, pressure injury was defined according to clinical practice guidelines and all studies used visual skin assessment by trained staff to determine pressure injury.

Table 2 summarises the results of the included studies. Cumulative incidence of pressure injury ranged from 11.1% to 40.4%. The highest incidence was found on the sacrum of general hospital patients (O'Brien et al., 2018). The frequency and/or types of pressure injury prevention strategies used by individual patients were reported in three studies (Budri et al., 2020; Gefen and Gershon, 2018; Okonkwo et al., 2020). No studies measured the relationships between oedema measurement and the use of pressure injury prevention strategies. The Quality in Prognostic Factor Studies risk of bias assessments is in Supplementary file 1 Table 4. Based on our three a priori importance criteria, two studies were assessed to have low risk of bias (Kim et al., 2018; Okonkwo et al., 2020) and the remaining four to have moderate risk.

Table 2.. Results of the 6 included studies (using the term oedema or SEM as reported by authors).

Author (Year) Country	Oedema results	Other prognostic factor results (PI risk, mobility)	PI cumulative incidence	Oedema to PI time	Worse stage of PI	PI location	PIP strategies used (n)	Unadjusted/ Adjusted Results
Budri et al. (2020)	Abnormal SEM (Delta Δ ≥0.5) *n* = 118 (78.7%)	Braden; week 1 (baseline): 14.5 ± 3.4 Week 2: 14.5 ± 3.3 Week 3: 14.5 ± 3.3 Week 4: 14.4 ± 3.4 Movement score 121.1 ± 143.5 movements/ hour Median 59.4 movements/ hour	19/150 (12.7%)	Number of days from abnormal SEM to visual PI 8.2 ± 6.3 days Mean time difference from abnormal SEM to visual PI −6.2 days (95% CI: −10.1 days to −2.4 days)	Stage 1 = 19 (100%)	VSA: sacrum *n* = 11 (57.9%) Right heels *n* = 8 (42.1%)	Reposition 2 hourly *n* = 2 (1.3%), 4 hourly *n* = 45 (30%), 6 hourly *n* = 9 (6%); No repositioning: *n* = 94 (62.7%) Type of mattress used: alternating pressure air mattress *n* = 108 (72%) High standard foam mattress *n* = 42 (28%)	OR 25.4 (95% CI: 13.7–47.3). Adjusted NR
Gefen and Gershon 2018	NR	Braden score at PI-risk and no risk subgroups groups combined12.2 ± 5.3	1/9 (11.1%)	2 days	1 SDTI	Left heel	5 strategies applied as usual care for those at risk, 1 patient from group 1	NR

Author (Year) Country	Oedema results	Other prognostic factor results (PI risk, mobility)	PI cumulative incidence	Oedema to PI time	Worse stage of PI	PI location	PIP strategies used (n)	Unadjusted/ Adjusted Results
							was noted to receive a specialised mattress	
Kim et al. (2018)	Mean SEM values: Normal skin 216, Blanching erythema 232 Stage 1 PI 388 (no SD)	Braden 18.3 ± 2.7 *n* = 19/29 (65.5%) had score > 19	6/29 (20.7%)	1 week (OR 1.03 95% CI 1.001–1.006)	NR by patient	NR by patient	NR	Concurrent SEM OR 1.007 (95% CI 1.001–1.014) Covariates of SEM at 1-week prior, anatomical sites, Braden score, age, sex, diabetes mellitus, cardiovascular accident, hypertension, and dementia
Lee (2018)	With PI SEM value 71.8 ± 13.6, Normal skin SEM value 4.4 ± 8.92	Braden 14.3 ± 2.5 Intervention 13.4 ± 2.0 Control 15.29 ± 2.69 Absolute bed rest *n* = 61 (92.4%)	10/66 (15.2%) Control group = 9/31 (29.0%), Intervention = 1/35 (2.6%)	NR	Intervention group: *n* = 1 Stage I; Control group: *n* = 9 Stage I (11 had blancha	Anatomical location only stated: coccyx, sacrum, and both buttocks	Dressing applied every 3 days for intervention participants *n* = 35/66 (53.0%) Standard	Difference of SEM value -15.49 (p-value = 0.024); Adjusted by patients' body mass

Author (Year) Country	Oedema results	Other prognostic factor results (PI risk, mobility)	PI cumulative incidence	Oedema to PI time	Worse stage of PI	PI location	PIP strategies used (n)	Unadjusted/ Adjusted Results
					ble erythema)		PIP strategies not specified	index, albumin level, Braden Scale score, and continence
O'Brien et al. (2018)	*N* = 31 (66%) Abnormal SEM (Delta Δ ≥0.5 for ≥3 days)	Norton score *M* = 12 (range 8–17) no SD reported. Mobility: 39% slightly limited, 25% very limited, 36% immobile Activity: 43% walks with help, 36% chair, 21% bedfast	*n* = 19/47 (40.4%) (per VSA)	Abnormal SEM 1.5 days (±1.4) PI occurred at 5.5 days (±2.5) (i.e. abnormal SEM 4 days prior to PI)	Stage 1 *n* = 19 (100%)	21 PIs in 19 patients: Sacrum (81% *n* = 17), left heel (14%; *n* = 3) right heel (5%; *n* = 1)	NR	NR
Okonkwo et al. (2020)	SEM delta Δ ≥ 0.6 = 42 /182 SEM Δ <0.6 6/182	Braden *n* = 166: very high risk *n* = 15 (90.4%), high risk *n* = 50 (30.1%) Waterlow: *n* = 16 Very high risk *n* = 5 (31.3%);	*n* = 48 of 182 pts (26.4%)	True positives: 4.7 (± 2.4) days	Stage 1 *n* = 32 (66.7%), Stage 2 *n* = 3 (6.3%), No Stage 3 or 4 Unstageable *n* = 2	Heel 32 (66.6%) Sacrum 16 (33.3%)	NR	NR

Author (Year) Country	Oedema results	Other prognostic factor results (PI risk, mobility)	PI cumulative incidence	Oedema to PI time	Worse stage of PI	PI location	PIP strategies used (n)	Unadjusted/ Adjusted Results
		high risk *n* = 3 (18.8%)			(4.2%), SDTI *n* = 11 (22.9%)			

Note: CI= Confidence interval; delta Δ = Delta difference between the highest and lowest value; *M* = Mean; NR = Not reported; OR = Odds Ratio; PI = Pressure injury; RRR = Relative Risk Ratio; SD = Standard deviation; SDTI = Suspected deep tissue injury; SEM= Sub-epidermal moisture; TDC = Tissue dielectric constant; VSA = Visual skin assessment.

Fig. 2 shows the forest plot for the relationship between oedema and cumulative incidence of pressure injuries. As only four studies provided data for this meta-analysis and all used the Bruin Biometrics sub-epidermal moisture scanner, this forest plot includes the overall pooled results and the results for the two Bruin Biometrics cut-offs of ≥0.5 and ≥0.6. Using a fixed-effects model because of low heterogeneity (I^2 = 0%), the risk ratio was very large and statistically significant for all three analyses (all studies RR 18.87, 95% CI 9.30–38.29; cut-off ≥0.5 RR 15.03, 95%CI 2.13–106.01; cut-off ≥0.6 RR 19.53, 95% 9.14–41.72). While the risk ratio was slightly higher for the cut-off of ≥0.6, the difference between it and ≥0.5 was not statistically significant.

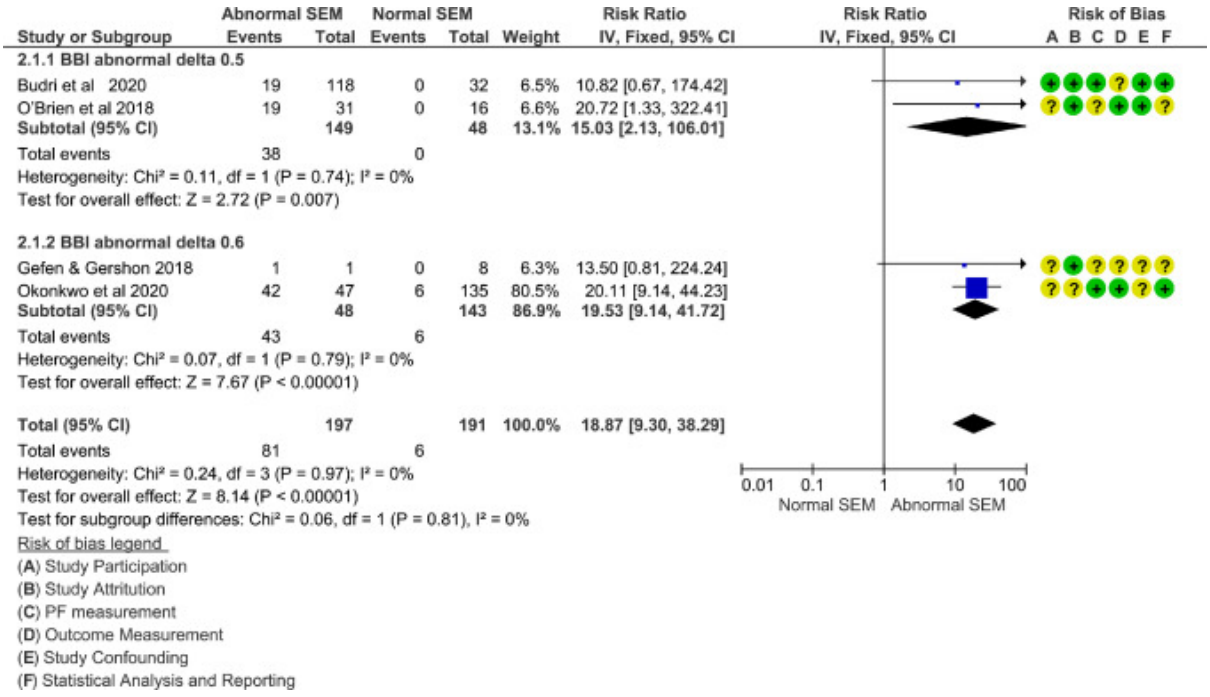

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Fig. 2. Forest plot for the relationship between oedema and cumulative incidence of PI.

Fig. 3 shows the forest plot for the pooled time to pressure injury outcome in the four studies that reported daily oedema measurement. A random-effects model was used because of high heterogeneity (I^2 = 99%. The pooled time to pressure injury was 4.08 days (95% CI 1.09–7.08). Supplementary file 1 Figs. 1 and 2 shows the forest plots for the relationships between oedema and cumulative incidence of sacral (RR 4.21, 95% CI 1.51–11.72, fixed effects model) and heel pressure injury (RR 24.54, 95% CI 9.67–61.81, random-effects model), respectively. Data were not available to undertake a meta-analysis for Stage ≥2. Three studies reported only Stage 1 pressure injuries occurred, while one study reported a single suspected deep tissue injury. However, while another study did report pressure injuries Stage ≥2 (Okonkwo et al., 2020), its risk ratio could not be calculated as patients with oedema could not be determined, despite contacting the authors (Table 2). Due to the small number of studies, no funnel plots were generated for any meta-analyses but given all studies showed a positive effect of measuring oedema, publication bias could not be ruled out.

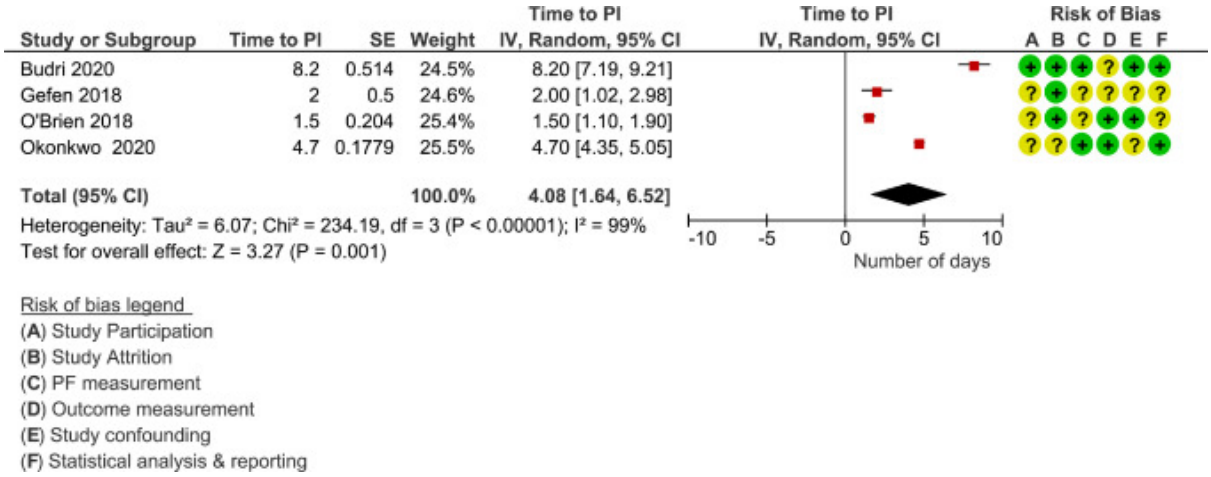

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Fig. 3. Forest plot for the pooled time to pressure injury **(**all studies measuring oedema daily).

Our meta-regression evaluated if the risk of pressure injury outcomes were associated with other a-priori variables on the estimated effect of oedema on cumulative incidence (mean age p = 0.77;% female p = 0.66; and sample sizes p = 0.83), where results indicated the strength of these associations to be very weak. Supplementary file 1 Figs. 3–5 show the meta-regression plots assessing the effect of each of these variables.

There was low certainty of evidence for the predictive value of measuring oedema for pressure injury cumulative incidence, time to pressure injury, and both sacral and heel pressure injuries. There was insufficient data to assess the certainty of the body of evidence of the value of measuring oedema in predicting the number or frequency of pressure injury prevention strategies (Table 3).

Table 3. Summary of findings and certainty of the body of evidence using GRADE (using the term oedema or SEM as reported by authors).

Abnormal sub-epidermal moisture compared to Normal sub-epidermal moisture for Pressure Injury Cumulative Incidence

Patient or population: Pressure Injury Cumulative Incidence
Setting: Any care setting
Intervention: Abnormal sub-epidermal moisture
Comparison: Normal sub-epidermal moisture

Outcome № of participants (studies)	**Relative effect (95% CI)**	**Anticipated absolute effects (95% CI)**			**Certainty**	**What happens**
Empty Cell	Empty Cell	Empty Cell	Empty Cell	**Difference**	Empty Cell	Empty Cell
sub-epidermal moisture and PI № of participants: 388 (4 observational studies)	**RR 18.87** (9.30 to 38.29)	3.1%	**59.3%** (29.2 to 100)	**56.1% more** (26.1 more to 117.1 more)	⨁⨁◯◯ LOW [a,b,c,d]	The evidence suggests that an abnormal sub-epidermal moisture results in a large increase in the risk of PI cumulative incidence.
sub-epidermal moisture and PI - BBI 0.5 № of participants: 197 (2 observational studies)	**RR 15.03** (2.13 to 106.01)	0.0%	**0.0%** (0 to 0)	**0.0% fewer** (0 fewer to 0 fewer)	⨁⨁◯◯ LOW [c,e,f]	The evidence suggests that an abnormal BBI sub-epidermal moisture scanner (delta value of 0.5+) results in a large increase in the risk of PI cumulative incidence.
sub-epidermal moisture and PI - BBI 0.6 № of participants: 191 (2 observational studies)	**RR 19.53** (9.14 to 41.72)	4.2%	**81.9%** (38.3 to 100)	**77.7% more** (34.2 more to 170.9 more)	⨁⨁◯◯ LOW [c,f,g,h]	The evidence suggests that an abnormal BBI sub-epidermal moisture scanner (delta value of 0.6+) results in a large increase in the risk of PI cumulative incidence.
Time from abnormal sub-epidermal moisture to PI № of participants: 388 (4 observational studies)	-		-	mean **4.08 days higher** (1.64 higher to 6.52 higher)	⨁⨁◯◯ LOW [a,c,i]	The mean 4.08 days higher reflects a time from abnormal sub-epidermal moisture to PI (via visual skin assessment; VSA), indicating that an abnormal sub-epidermal moisture can identify tissue damage leading to a potential PI forming approximately 4 days before VSA confirmation. The effect size was considered large.

Abnormal sub-epidermal moisture compared to Normal sub-epidermal moisture for Pressure Injury Cumulative Incidence

Patient or population: Pressure Injury Cumulative Incidence
Setting: Any care setting
Intervention: Abnormal sub-epidermal moisture
Comparison: Normal sub-epidermal moisture

Outcome № of participants (studies)	**Relative effect (95% CI)**	**Anticipated absolute effects (95% CI)**			**Certainty**	**What happens**
Empty Cell	Empty Cell	Empty Cell	Empty Cell	**Difference**	Empty Cell	Empty Cell
sub-epidermal moisture and PI-sacral location № of participants: 315 (3 observational studies)	**RR 4.21** (1.51 to 11.72)	2.5%	**10.4%** (3.7 to 28.8)	**7.9% more** (1.3 more to 26.4 more)	⨁⨁◯◯ LOW [c,i]	The evidence suggests that an abnormal sub-epidermal moisture results in a large increase in the risk of PI cumulative incidence for the sacral location.
sub-epidermal moisture and PI-heel location № of participants: 365 (4 observational studies)	**RR 24.45** (9.67 to 61.81)	1.4%	**33.0%** (13.1 to 83.5)	**31.7% more** (11.7 more to 82.2 more)	⨁⨁◯◯ LOW [c,k,l]	The evidence suggests that an abnormal sub-epidermal moisture results in a very large increase in the risk of PI cumulative incidence for the heel location.
Number of PIP strategies - not measured	Only one study (Budri et al., 2020) reports on patient-level data for the number of PIP strategies. Other studies report usual PIP practices at the study sites.				-	Insufficient data to assess outcome.

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio.

GRADE Working Group grades of evidence.

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Explanations.

a

For three studies, study participation was rated as moderate risk, including study weighted at 80%. For the study that was weighted at 80%, attrition and study confounding was moderate. Bias was present in half of the studies for PF and outcome measurement, as well as statistical analysis and reporting.

b

Overall, there was a small pooled sample size (*N* = 388). Only 81 total events, confidence intervals were also wide, indicating high imprecision, although the risk ratio suggests an important effect.

c

Huguet et al. (2013) recommend downgrading for publication bias unless the value of the risk/protective factor in the outcome has been repeatedly investigated by Phase 2 and Phase 3 studies (these are their phases and not the phases in a trial). As all of our studies were phase 2 according to their levels of studies for PF research, we have scored this criterion as 'strongly suspected'.

d

Only 4 studies, all phase 2 were included in the meta-analysis. No studies adjusted for other prognostic factors.

e

Overall, there was a small pooled sample size (*N* = 197). Only 38 total events, confidence intervals were excessively wide (2.13–106.01), indicating high imprecision, although the risk ratio suggests an important effect.

f

Only 2 studies, both phase 2 were included in the meta-analysis. No studies adjusted for other prognostic factors.

g

Study participant and study confounding were moderate risk of bias for both studies. PF and outcome measurement, as well as statistical analysis and reporting, had a moderate risk of bias for one study. The larger study was at moderate risk of bias for study attrition.

h

Overall, there was a small pooled sample size (*N* = 191). Only 43 total events, confidence intervals were also wide, indicating high imprecision, although the risk ratio suggests an important effect.

i

High I-square; Confidence intervals only overlap for 2 of 4 studies.

j

For 2 of 3 studies, study participation was rated as moderate risk, including the study weighted at 73%. For the study that was weighted at 73%, attrition and study confounding was also moderate. Bias was present in 1 of 3 studies for PF measurement (O'Brien) and outcome measurement (Budri) as well as statistical analysis and reporting (O'Brien).

k

For three studies, study participation was rated as moderate risk, including study weighted at 80%. For the study that was weighted at 80%, attrition and study confounding was moderate. Bias was present in half of the studies for PF and outcome measurement as well as statistical analysis and reporting.

l

Overall, there was a small pooled sample size (*n* = 365). Only 48 total events; the pooled 96% confidence intervals were wide indicating some imprecision although the risk ratio suggests an important effect.

4. Discussion

This prognostic factor systematic review of six studies found a strong association between oedema and the cumulative incidence of pressure injury (including in the subgroups of sacral and heel pressure injury) using one type of measuring device, Bruin Biometrics. This relationship remained strong irrespective of the cut-off value used to determine oedema. But the certainty of evidence was low for both cumulative incidence of pressure injuries and time to pressure injury. We found no effect of age, gender, and study sample size on the findings; however, data were not available to consider the effect of other prognostic factors. Our findings are consistent with Oliveira et al. (2017) earlier review, although two studies in our review had much larger samples and none of the oedema measurement devices in their review were made by Bruin Biometrics. Oedema as measured by the Bruin Biometrics device was a strong predictor of a pressure injury occurring on an average of four days later. Thus, while our goal was to provide evidence to guide clinicians' decisions, we can only say that using devices that measure oedema 'may' help clinicians to identify patients at risk of future pressure injury. Researchers have shown that some devices measuring oedema are easy to use (Gefen and Gershon, 2018; Moore et al., 2017), and have good interrater reliability. However, our review findings align with a previous National Institute for Health and Care Excellence recommendation (National Institute for Health and Care Excellence, 2020) that suggests integrating oedema measurement into clinical practice still requires good quality evidence on effectiveness to support its use and justify its expense. An economic evaluation suggests the use of oedema measurement on all patients may be cost-effective, and good value for money (Padula et al., 2020), although this conclusion was based on United States of America data using simulated models. And, while one study showed oedema measurement has high specificity (O'Brien et al., 2018), this has not been supported in other research (Okonkwo et al., 2020). In the situation where specificity is low, it is possible resources will be wasted if all patients with abnormal oedema measurements receive additional pressure injury prevention strategies. Therefore, high-quality randomised control trial evidence is needed to assess the cost effectiveness of oedema measurement.

Interestingly, oedema measurement is emerging as routine practice clinical settings with evaluations reporting positive results (Musa et al., 2021; Nightingale and Musa, 2021). Other research that did not meet our inclusion criteria supports the claim that incorporating oedema measurement into clinical practice may have beneficial effects (Bates-Jensen et al., 2018, 2017; Gershon, 2020; Gershon and Okonkwo, 2021; Raizman et al., 2018). But, the international program, Choosing Wisely

(Levinson et al., 2015) has emerged because of the recognition that some clinical practices may be unnecessary or even harmful (Linder, 2018), and represent low value. Low value care has been described as 'care that is unlikely to benefit the patient given the harms, costs available alternatives, or preferences of the patients (Verkerk et al., 2018). The extent to which oedema measurement reflects an evidence-based innovation to improve practice or low value care is not yet known.

Using automated tools to help identify all relevant studies for this review was particularly beneficial as this step in prognostic factor reviews is particularly time-consuming (Dretzke et al., 2014). A typical systematic review can take up to 2-years to complete (Beller et al., 2018). Automated tools that improve efficiency and speed across systematic review tasks yet still adhere to rigorous reporting are essential. Our review used the Systematic Review Accelerator (SRA) (Clark et al., 2020; Rathbone et al., 2015) tools to facilitate literature retrieval, screening and identify screening disagreements (Clark et al., 2020). The tools designed to build our search strategy (WordFreq, SearchRefiner, Polyglot Search Translator) assisted us in formulating a search strategy quickly. In particular, the SearchRefiner allowed us to visualise whether our search strategy retrieved relevant articles and helped us quickly edit the search strategy by removing one word at a time. Further benefits of these tools were the ease of collaboration amongst reviewers and the provision of outputs of each step undertaken. This enabled clear process mapping thus facilitating swift, streamlined processes that ensured eligible studies were moved promptly and smoothly to data extraction.

Our review highlights several recommendations for future research. First, undertaking research in pressure injury free populations and including other prognostic factors will help to better understand the prognostic value of oedema measurement because the temporal order, with oedema occurring prior to the development of a pressure injury will be clear. Second, given oedema indicates early tissue damage, it seems reasonable to suggest this should trigger the use of additional prevention strategies, yet we found no studies examining this relationship. Therefore, we suggest the potential utility of oedema measurement as a point-of care-decision aid to enhance pressure injury prevention strategies should be investigated. Third, oedema measurement has been suggested to be especially beneficial in identifying pressure injury in people with darker skin tones (European Pressure Ulcer Advisory Panel et al., 2019). We only identified two papers that considered skin tone (Bates-Jensen et al., 2009; Park et al., 2018) but neither fulfilled our inclusion criteria, thus there is a need for work to be done in this area. Fourth, the extent to which oedema measurement may be beneficial in a range of populations such as intensive care should be explored. We did identify a pilot study focused on patients with spinal cord injuries, but all had a pressure injury at the time of the oedema measurement (Harrow and Mayrovitz, 2014), thus it was excluded from our review. Fifth, there is also a need to better understand the extent to which oedema measurement may be influenced by other factors including pressure injury preventions such as the use of skin barrier products, special support surfaces, prophylactic dressings, and frequency of repositioning. Finally, how the relationship between oedema measurement and pressure injury may be affected by other skin conditions such as incontinence-associated dermatitis requires investigation.

4.1. Strengths and limitations

Strengths of this review include the systematic approach we used, which followed the recommended processes for prognostic factor reviews (Riley et al., 2019). We also used recognised tools specific to prognostic factor reviews to inform our data extraction, risk of bias assessment, and evaluation of the certainty of evidence. Further, three studies in our review used prospective cohorts, viewed as the strongest level of evidence for prognostic factors research (Foroutan et al., 2020). There are limitations both in terms of the review itself and the primary studies reviewed.

First, the population in our review was pressure injury free adults, therefore our results cannot be generalised to other groups such as children or adults who have pressure injuries. Many potential studies were excluded because the sample included participants with a pressure injury at baseline or they did not report their results at the patient level or respond to our requests for this information. However, these studies were excluded at the full-text review as they did not provide data about oedema measurement prior to the pressure injury. Second, while we had planned to undertake a series of unadjusted and adjusted meta-analyses, some were not possible because of a lack of primary data, and only some authors responded to our requests for further information. Third, we had to calculate the negative predictive value and other data for the cumulative incidence of heel pressure injury for one study (Okonkwo et al., 2020), however, we used a conservative approach so that any error would favour 'no effect'. Fourth, all but one study was funded by industry, and we were unable to determine if the funding body had any influence over the studies. Additionally, due to the low number of studies in this review we were unable to assess for publication bias and acknowledge this to be a limitation of our review, especially given the funding sources of the included studies. Further, there were only six studies in our review, most were small, at moderate risk of bias and the included studies in our meta-analyses did not adjust their analysis for other prognostic factors. Due to this, our pooled risk estimates are likely overestimated. Additionally, we only had a small number of studies into the meta-regression, therefore the effect of heterogeneity could not be explored further. Finally, the two studies that did adjust for other prognostic factors could not be pooled because of measurement issues (Kim et al., 2018; Lee et al., 2019a). Though devices that measure oedema have been reported for some time, further high-quality and independently funded research is needed.

5. Conclusions

Our review of six studies showed that oedema measurement may be a useful tool to inform clinicians' approaches to pressure injury prevention, but the evidence base for its use is uncertain. Several unanswered questions remain regarding the use of oedema measurement, such as how it may be affected by changing body positions, other skin conditions and treatments such as creams and lotions. But, if future rigorous research confirms the utility of oedema measurement, it could be a game-changer; oedema measurement may become comparable to the routine monitoring of heart rate, blood pressure, temperature and oxygen saturation commonly used in contemporary health care contexts.

Declaration of Competing Interest

Author (blinded for peer review) has held a consultancy with Molnlycke; Author (blinded for peer review) has held consultancies with 3M and Hartmann. No companies had any influence on this study and no companies are associated with the equipment cited in this paper.

Acknowledgments

The authors would like to thank Leanne Stockwell, a Health Librarian, for her assistance in developing a search strategy.

Funding

Authors (blinded for peer review) salaries were funded by the NHMRC Centre of Research Excellence in Wiser Wound Care.

Appendix. Supplementary materials

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