Recommendation 1.1 Evidence Profile

Recommendation question 1: Should the use of health technologies be recommended or not for early detection and assessment of pressure injuries?

Recommendation 1.1: The expert panel suggests that nurses and health providers use subepidermal moisture detection as an adjunct to skin assessment for early detection of pressure injuries.

Population: Persons with or at risk of pressure injuries (PI)
Intervention: Health technologies used for early detection and assessment of pressure injuries
Comparison: Standard care or visual skin assessment alone
Outcomes: Incidence rate of pressure injury [critical], Accuracy of predicting pressure injury development [critical], Pressure injury precursor signs and symptoms [critical], Health provider compliance with use of health technology [critical] (not measured), Person/caregiver satisfaction [critical] (not measured)

Setting: All health-care settings, including but not limited to: community care, outpatient care, and acute care.

Bibliography: 48

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Intervention**	**Control**			
Accuracy of predicting pressure injury development (measured with sensitivity and specificity)											
4[a]	Non-randomized studies	Very serious[b]	Serious[c]	Not serious	Not serious	Not detected	N=803 (total)	NR	Mean sensitivity was 72.07±23.05%. Sensitivity scores ranged from 48.3% to 100%. Mean specificity was 51.96±20.20%. Specificity scores ranged from 24.4% to 83%.	⊕◯◯◯ Very Low	48: Moore et al., 2022
Incidence rate of pressure injury (follow-up time NR)											
1[d]	Non-randomized study	Serious[e]	Not serious	Not serious	Very serious[f]	Not detected	PI events: 2/195 Stage I (n=1) and Stage II (n=1)	PI events: 12/89 Stage I (n=4); Stage II (n=6); Stage III (n=1), and deep tissue injury (n=1).	RR (95% CI): 0.08 (0.02- 0.33) For every 100 people who receive SEM detection, 12 less people will have PI (ranges from 13 less to 9 less).	⊕◯◯◯ Very low	48: Moore et al., 2022
Pressure injury precursor signs and symptoms (measured as incidence of stage 1 pressure injury)											
1[d]	Non-randomized study	Serious[e]	Not serious	Not serious	Very serious[g]	Not detected	Stage I PI events: 1/195	Stage I PI events: 4/89	RR (95% CI): 0.11 (0.01-1.01)	⊕◯◯◯ Very low	48: Moore et al., 2022

Quality assessment							No. of participants		Effect	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
									For every 100 people who receive SEM detection, 4 less people will have a stage I PI (ranges from 4 less to no more or less).		
Health provider compliance with technology (not measured)											
N/A											
Person/caregiver satisfaction (not measured)											
N/A											

Additional Table – Individual Study Details

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
Outcome: accuracy predicting pressure injury development						
Bates-Jensen et al., 2018 Okonkwo et al, 2020 O'Brien et al., 2018 Moda Vitoriano Budri et al., 2020 (Taken from review Moore et al., 2022)	SR of non-randomized studies (prospective and observational)	USA (2 studies), Ireland (2 studies)	N=803 (total participants) Participant details: Okonkwo et al, 2020: Inpatient facilities (six acute care and three post-acute care settings (189 participants) Moda Vitoriano Budri et al., 2020: Nursing home residents (150 participants) O'Brien et al., 2018: Medical and a surgical unit (47 participants) Bates-Jensen et al., 2018: Nursing home residents (66 participants) SEM device: Bates-Jensen et al., 2018: Delfin MoistureMeter D (Delfin Technologies, LTD, Greenwich, Connecticut) dermal phase meter Okonkwo et al, 2020 and Moda Vitoriano Budri et al., 2020: Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC) O'Brien et al., 2018: SEM Scanner (Bruin Biometrics Europe, Ltd, UK)	Not reported- accuracy was not compared to other diagnostic tool.	Mean sensitivity was 72.07±23.05%. Sensitivity scores varied from 48.3% to 100%. Mean specificity was 51.96±20.20%. Specificity scores ranged from 24.4% to 83%. Okonkwo et al, 2020: Sensitivity 87.5% (95% CI: 74.8–95.3%) Specificity 32.9% (95% CI: 28.3–37.8%) Moda Vitoriano Budri et al., 2020: Sensitivity 100% Specificity 24.4% O'Brien et al., 2018: Sensitivity 100.00% (95% CI: 83.89–100.00% Specificity 83.33% (95% CI: 75.44–89.51%) Bates-Jensen et al., 2018: Sensitivity Right heel Stage 1 PU 58.6%, Left heel Stage 1 PU 60.8% • DTI right heel 49.3% • Left heel DTI 48.3% Specificity Right heel Stage 1 PU 47.2% • Left	Systematic review: LOW Individual studies: SERIOUS

					heel Stage 1 PU 47.5% • DTI right heel 65% • Left heel DTI 63.4%	
Outcome: incidence rate of pressure injury						
Raizman et al, 2018 (Taken from review Moore et al., 2022)	Evaluation study (pre-post)	Canada	Phase 2: this phase is the same as Phase 1 except the resulting SEM scores were used in conjunction with risk assessment scores to determine appropriate interventions and care planning. SEM device: Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC, US))	Phase 1: patients were provided standard-of-care risk assessment and interventions and were scanned with the SEM scanner, but the resulting SEM scores were not used to determine interventions. This gave a baseline PI incidence rate.	In Phase 1, 12 of the 89 subjects or 13.5% developed visible PIs: Stage I (n=4); Stage II (n=6); Stage III (n=1), and deep tissue injury (n=1). In Phase 2, two of the 195 subjects or 1.0% developed visible PIs: Stage I (n=1) and 1 Stage II (n=1).	Systematic review: LOW Individual study: SERIOUS
Outcome: precursor signs and symptoms (measure with incidence of stage 1 pressure injury)						
Raizman et al, 2018 (Taken from review Moore et al., 2022)	Evaluation study (pre-post)	Canada	Phase 2: this phase is the same as Phase 1 except the resulting SEM scores were used in conjunction with risk assessment scores to determine appropriate interventions and care planning SEM device: Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC, US))	Phase 1: patients were provided standard-of-care risk assessment and interventions and were scanned with the SEM scanner, but the resulting SEM scores were not used to determine interventions. This gave a baseline PI incidence rate	In Phase 1, 4 of the 89 subjects developed stage1 PIs. In Phase 2, one of the 195 subjects developed stage 1 PIs.	Systematic review: LOW Individual study: SERIOUS

Acronyms:
CI: confidence interval
DTI: deep tissue injury
EBL: Evidence-based Librarianship
HAPI: Hospital Acquired Pressure Injury
NA: not applicable
NR: Not reported
PI: pressure injury
RR: relative risk
SEM: subepidermal moisture
SR: systematic review

Reference

Moore Z, McEvoy NL, Avsar P, Byrne S, Vitoriano Budri AM, Nugent L, et al. Measuring subepidermal moisture to detect early pressure ulcer development: a systematic review. J Wound Care. 2022 Aug 2;31(8):634–47.

Explanations

[a] Four non-randomized studies were included from a systematic review (Moore et al., 2022) that reported on specificity and sensitivity.
[b] SR was rated as low risk of bias based on ROBIS. Authors quality appraised observational studies using EBL checklist (studies rated 36%- 95%). Additionally, there was no comparison group. We downgraded by 2.
[c] High heterogeneity between study results (some studies report high sensitivity and specificity whereas others report low sensitivity and specificity), technology used and outcome measurement (how accuracy/validity is measured). We downgraded by 1.
[d] One non-randomized study (Raizman et al.) was included from a systematic review (Moore et al., 2023).
[e] SR was rated as low risk of bias based on ROBIS. Review authors reported that the non-randomized study was rated 73% with the EBL checklist. Reasons for concern on inclusion/exclusion criteria and data collection. We downgraded by 1.
[f] Very low number of events less than the optimal 300 (n=14). We downgraded by 2.
[g] Very low number of events less than the optimal 300 (n= 5) and corresponding wide confidence interval. We downgraded by 2.