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Results from Multi-Site Longitudinal Study

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Prevalence of pressure injuries in the USA:

Over 2.5 million PIs annually

In Europe, 20% of patients in acute care settings develop a PI

In the USA, 14.8% of patients suffer from PIs

Challenges of the current standards of clinical assessment

Physical exam: it's limited! The ability of the nurse is limited by his or her experience. Therefore, an objective tool becomes even more crucial.

Important to try and improve the risk assessment tools.

We want the evaluation to be OBJECTIVE, not SUBJECTIVE.

Challenge: create an environment where we can determine the validity of a study.

Validity: the ability of a test to indicate which individuals have the condition and which do not.

Classic conundrums:

1. All of the current gold standards are imperfect

- How can you know if your tests are correct?
- What do you measure results against, for objective assessment?



2. Difficult to create a control study because medical staff has to intervene as PIs occur

- Unethical to withhold treatment if it can benefit a patient
- Intervention changes natural occurrence of condition

3. Limitations in available Clinical Study Design options

- Can't do a true randomized-controlled trial
- It's difficult to recruit patients when they know a PI will develop
- Can't ask clinicians not to intervene
- Costly

Classification of condition

How well can tests correctly classify patients of known health status, previously tested?

- **Sensitivity:** ability of a test to correctly identify those with the condition
- **Specificity:** ability of a test to correctly identify those without the condition

SEM (subepidermal moisture) Scanner correctly identified patients who did have PIs (elevated SEM reading) 91% of the time.

It identified patients who did NOT have PIs 86% of the time.

This led to a longitudinal study.

Large-scale multi-site feasibility study conducted by G O'Brien and Z Moore

Objective: to learn how well the SEM Scanner identifies PIs before they are visible to the naked eye and to evaluate the scanner as an adjunct to the naked eye.

Method of the study:

- 189 patients from 12 sites in USA and UK
- 47% female; 53% male



- White 67%; Asian 24%; Black 4%; Other 5%
- BMI: median was 26.01

- Ages 79 years old mean (female)
- Ages 73 years old mean (male)
- Most in hospital setting, skilled nursing facility or long term care facility

Recorded SEM values and did a visual skin exam

2 teams:

First were generalists (they used the SEM scanner to scan the skin on high risk areas DAILY up to 20 days)

Second team: skin/wound specialist, examine the skin daily using visual skin assessment to hopefully identify a PI as soon as it occurs

Had to be 55 or older

Had to be high risk for developing a PI

Exclusion: having an unhealed PI; broken skin; moisture lesion; other factors that make it impossible to get a SEM reading

Final data: 55 pressure injuries developed during the study

How early was the SEM scanner able to identify them?

Stage 1: 37 of them (17 sacrum; 12 left heel; 8 right heel)

Stage 2: 5 of them (5 sacrum)

Stage 3 and 4: none

Unstagnable: 2 (1 left heel; 1 right heel)



Results:

SEM Scanner Detected PIs an average of 5 days before Nurse VSA and as much as 12 days in 42 of 55 cases.

Possible complication: 92% of patients were receiving high levels of interventions throughout the study which may have been a major factor in preventing progression of PI development

What happens to patients when they receive intervention vs. when they don't?

When they were on low air loss mattresses, the SEM score was good. When removed from low air loss mattresses, the SEM score skyrocketed (not good.)

Conclusions:

- SEM scanner is a new technology that can ACCURATELY DETECT DEVELOPING PRESSURE INJURIES even when there are no visible signs of damage at the surface
- SEM can detect damage on average 5 DAYS but up to 12 days before visual assessment
- Early detection allows interventions that can reverse damage, or at least stop it from getting worse
- Current standard only detects PIs when there is visible tissue damage on the skin
- Scanner provides scientific data, giving medics objective tool to take action over subjective skin assessment
- Hospitals in US and UK are integrating SEM Scanner into clinical practice and seeing a reductions in incidence
- SEM Scanning could be the gold standard for pressure injuries the field has been seeking

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