

Is it time to re-evaluate the inevitability of ulcers at the end of life?

Gillian Raine

Abstract

Background: The prevention of pressure injuries/ulcers (PI/PUs) in patients at the end of life is achievable, albeit challenging. Objective diagnostic tools, such as sub-epidermal moisture (SEM) scanning, support healthcare practitioners' clinical judgment in preventing PI/PUs. **Aim:** A pragmatic study was conducted to assess the feasibility of preventing PI/PUs using SEM technology as an adjunct to routine care in a 22-bed inpatient hospice. **Methods:** Daily SEM scanning was introduced to support the device-trained practitioners' clinical judgment in detecting developing, non-visible PI/PUs. Preventive interventions were initiated by clinical judgment informed by Waterlow scores, visible, tactile skin and tissue assessments and scanner readings. **Results:** Prior to the study, the incidence of PI/PUs was 9%. The 6 month study period reported a 4.8% PI/PU incidence, 7/146 consenting patients developed a PI/PU, resulting in a 47% reduction in incidence rates. **Conclusion:** Preventing the development of PI/PUs is possible with clinical judgment aided by SEM data.

Key words: ● Pressure injury ● Pressure ulcer ● Sub-epidermal moisture ● End of life

Compromised skin integrity, alongside multiple organ failure, is a common occurrence in terminally ill patients (De Conno et al, 1991; Shannon and Lehman, 1996; Julian, 2020). The treatment and management of these end-of-life skin changes, including terminal ulcerations in patients referred to palliative and end-of-life care settings are complex (Hughes et al, 2016). A patient's organs may be compromised when they have a critical illness. This localised and, or systemic failure of the skin, the largest organ of the body, is associated with skin changes that are concomitant to pressure injury/ulcer (PI/PU) risk factors (Levine, 2017; Latimer et al, 2019; Levine, 2019). While impaired tissue perfusion seems to be the most significant risk factor, necrosis may rapidly advance towards chronic and terminal ulceration (Sibbald et al, 2010). It may be possible that skin failure shares a common aetiology with developing PI/PUs, which explains the relative PI/PU prevalence being much higher in palliative care compared to other care settings (Galvin, 2002; Artico et al, 2018). At this time, there is no gold standard in diagnosing Skin changes at life's end (SCALE). Preventive and treatment strategies adopt PI/PU wound care guidelines as the standard for patient care, such as the

Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline 2019. Additionally, the definition and classification of end-of-life skin failure, including Kennedy Terminal Ulcers (KTUs), SCALE, avoidable and unavoidable PI/PUs is poorly defined. Specifically, the terms 'Kennedy Ulcer', 'unavoidable', and 'avoidable harm' are no longer used in the NHS to categorise end-of-life PI/PUs developed due to skin failure (NHS Improvement, 2018). Understanding and differentiating the aetiology behind these wounds is incomplete in literature (Levine, 2017; Latimer et al, 2019; Levine, 2019).

The prevention of these wounds is therefore traditionally seen as more of a palliative than curative speciality and is critical to palliative and hospice philosophy. In palliative care settings, PI/PU management is largely nurse-led and is often construed as a consequence of poor nursing care or mismanagement (Carlsson and Gunningberg, 2017). Palliative patients are considered at a high risk of developing PI/PUs, due to their complex co-morbidities and concomitant risk factors. Multiple factors, including underlying diseases, malnutrition, hypoperfusion, and limited mobility, make the skin susceptible to pressure-induced damage, inevitably increasing the risk of developing PI/PUs, and further reducing the

Gillian Raine
Lead Nurse, Marie Curie
Hospice, Newcastle upon
Tyne, UK

Correspondence to:
gillian.raine@mariecurie.
org.uk

quality of life in these patients (Carlsson and Gunningberg, 2017; Levine, 2019). However, there remains a clinical paradox in contemporary palliative PI/PU care protocols. Nurse and healthcare practitioners' (HCP) clinical judgment is confounded by hospice philosophy and patient dissent. Preventive interventions and treatment pathways like repositioning, heel elevation, etc, may increase patient suffering (Hatcliffe and Dawe, 1996; Langemo, 2006). For example, patients on ventilators or experiencing nausea may decline frequent repositioning. End-of-life patients experiencing musculoskeletal pain may prefer extended periods of immobility over physical therapy regimens. The lack of objective diagnostic tools, and the low predictive validity of current risk assessment tools (RATS), in assessing PI/PU risk further exacerbates this clinical conundrum (Chen et al, 2016; Moore and Patton, 2019). The 2019 International Clinical Practice Guidelines, provide an evolved understanding of the PI/PU aetiology and pathophysiology (European Pressure Ulcer Advisory Panel (EPUAP)/National Pressure Injury Advisory Panel (NPIAP)/Pan-Pacific Pressure Injury Alliance (PPPIA), 2019). Cell and tissue damage due to sustained pressure and tissue deformation occurs early in the damage cascade, even before visible manifestations on the skin (Gefen and Ousey, 2020). This early inflammatory phase in developing PI/PUs is characterised by a microscopic and localised accumulation of plasma in the interstitial compartments under the skin. Termed sub-epidermal moisture (SEM), this level increases with increasing, early, non-visible damage (Bates-Jensen et al, 2009; Gefen, 2018; Gershon, 2020). In the PI/PU care pathway, visual and tactile skin assessments are a subjective confirmation of a developed PI/PU. They aid in the classification and diagnosis of a PI/PU only when the damage is visible at the surface level (Baker, 2016). These assessments are more complicated in patients with dark skin tones. Likewise, risk assessment scores are based on whole-body assessments, ie anatomy-specific assessments are not possible. Regardless, a confirmed diagnosis of Stage I PI/PU, visible erythema of the skin or persistent focal oedema (World Health Organization, 2020) is indicative of damage that has already occurred and has visibly manifested at the skin surface (EPUAP/NPIAP/PPPIA, 2019). In a care pathway where timely and anatomy specific interventions are critical in keeping the skin intact, current skin tissue assessments and risk assessment tools are inadequate in providing practitioners with

objective insights into deep tissue viability and early-stage non-visible pressure induced damage. This inherent diagnostic latency in the present PI/PU standard of care in the UK and globally (SoC), the absence of reliable tools that can equip HCP's with objective, subclinical data on early-stage, non-visible skin and tissue damage, and HCP's inability to provide timely anatomically specific interventions, deters quality improvement in palliative wound care. Assessing microscopic fluctuations in SEM, a biophysical marker facilitates earlier, anatomically specific interventions (Bates-Jensen et al, 2009; Gefen, 2018; Smith, 2019; Gershon and Okonkwo, 2021), and provides HCPs with a clinically significant time advantage with considerable clinical utility for a potential reversal of damage to skin and tissue prior to the breakage of the skin's surface (Okonkwo et al, 2020).

Marie Curie Hospice

Marie Curie, established in 1948, is a charitable organisation with nine hospices across the UK, that aims to achieve a better life for people and their families living with a terminal illness. Marie Curie Hospices (MCH) provide the largest number of hospice beds outside the NHS (MCH, 2021). Preventing PI/PUs has been a quality priority for MCH since 2013. The annual quality account reports available describe implementing new PI/PU protocols, recording PI/PU incidence, increased staff awareness and training, root cause analysis and PI/PU audits (Grade III, IV) as an integral part of MCH's quality objectives (MCH, 2017). Palliative PI/PU care at MCH is patient-centred, and nursing staff are routinely trained in PI/PU prevention and management protocols to ensure HCPs, tissue viability nurses and nurse specialists are competent and capable of implementing evidence-based best practice. Ward-based training programmes, mandatory competencies, monthly strategic meetings with clinical leaders, district nurses, and tissue viability nurses, and annual updates to training programmes drive MCH's quality of care metrics (MCH, 2017). Standard of care protocols, PI/PU guidelines and policies align with NHS policies, national guidelines recommended by the National Institute for Health and Care Excellence, and EPUAP/NPIAP/PPPIA guidelines (NICE, 2014; EPUAP/NPIAP/PPPIA, 2019; NHSI, 2018). Patients are assessed during admission using Waterlow and the SSKIN bundle along with skin and tissue assessments performed by trained HCPs (Waterlow, 2005; Whitlock, 2013). The SSKIN resource pack is part of NHS' quality improvement strategy in the prevention

and care for patients at risk of PI/PUs:

- Surface ('S' right support)
- Skin inspection ('S' early detection)
- Keep patients moving ('K' mobility)
- Incontinence ('I' keep patients clean and dry)
- Nutrition ('N' healthy diet and plenty of fluids (Whitlock, 2013).

Preventive interventions primarily include intermittent repositioning, pressure-distribution support surfaces and elevation of the patient's heels. Classification of PI/PUs follows the EPUAP classification system (EPUAP/NPIAP/PPPIA, 2014). All diagnosed PI/PUs are reported to a central safety incident reporting database (MCH, 2017). Despite improving SoC protocols, incorporating trained tissue viability nurses, improved PI/PU awareness training, and taking part in the national React to Red Skin campaign (UHCW, 2014), preventing PI/PUs was not fully realised. An increase in PI/PU incidence was recorded in eight of nine hospices between 2016–2017 (MCH, 2017). In 2017, MCH leadership identified SEM Scanning as a potential test to indicate the risk of developing early stage PI/PUs. A clinical outcome study was developed

Table 1. Impact of SEM data in health practitioners' clinical decision making and subsequent anatomically specific interventions	
Health practitioners' change in clinical decision making from sub-epidermal moisture assessments	58/145 patients (40%)
Increased turning or mobilisation	37/58 (64%)
Introducing a specialist surface	24/58 (41%)
Introducing heel support or elevation of heels	33/58 (57%)

and implemented one of the MCH sites (the Newcastle Hospice, a 22-bed unit), to evaluate SEM scanning as an adjunct to SoC when assessing palliative patients.

Objective

To assess the feasibility of preventing PI/PUs in palliative care using SEM technology as an adjunct to SoC in assessing patients at increased risk for PI/PUs.

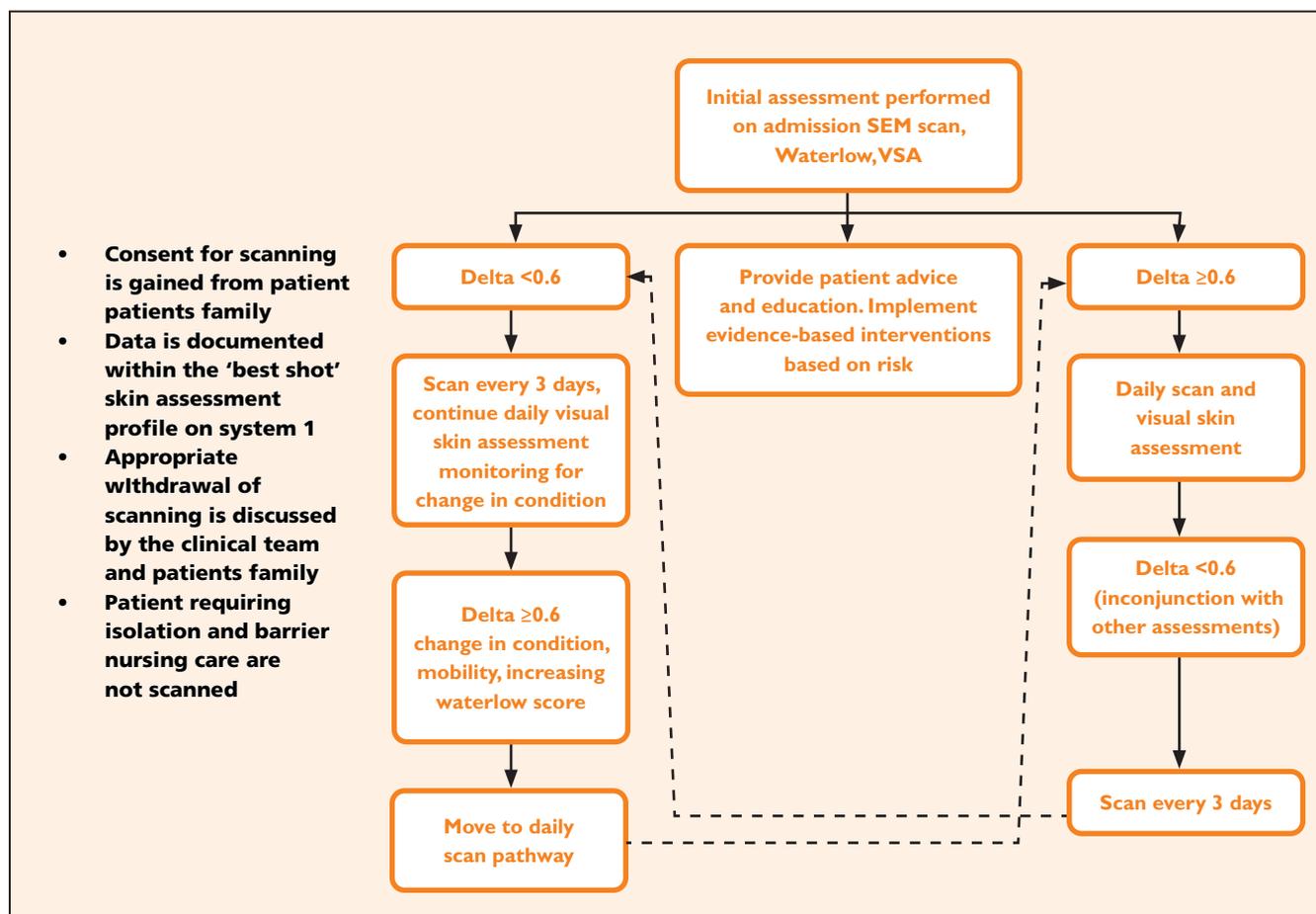


Figure 1: Marie Curie Hospitals' clinical decision-making algorithm

Table 2. Feedback in percentage of ‘yes’ responses from nursing staff (n=26) who completed the post-study survey in adopting the SEM Scanner to the patient pressure injury/ulcers care pathway

Question	Percentage of ‘yes’ responses
In my experience, it was easy to learn to use and operate the device	92% (24/26)
Scanning each patient was quick and I was able to scan each patient easily	88% (23/26)
Finding patients with a deviation (delta) of ≥ 0.6 alerted me to take appropriate clinical action	100% (26/26)
The device provides additional information to support my decision making about my patient’s PU care	100% (26/26)
Did the device provide clinically meaningful data about tissue damage (Y)?	100% (26/26)

Materials and methods

SEM Scanner

The device is a CE marked, FDA authorised (FDA.gov, DEN170021, 2017) (CE class IIa) portable, wireless, non-invasive, non-significant risk, hand-held device, intended to be used as an adjunct to current SoC for the detection of deep and early-stage PI/PUs by HCPs. The device’s sensor technology objectively alerts clinicians to specific anatomical areas of a patient’s body at risk of PI/PU. It assesses fluctuations of SEM, indicative of early, non-visible, pressure-induced cell and tissue damage (Gefen, 2018). Readings taken at and contiguous to the bony prominences assess the fluctuations of SEM within a specific anatomy. A delta value (Δ), the difference between the highest and lowest readings, is used to assess skin and tissue health (Okonkwo, 2021).

Study methodology

The study was designed to align with NHS’ quality improvement PDSA cycles tool where a problem is identified (PLAN), a small change introduced (DO) and measured (STUDY) then implemented into the care pathway (ACT) (NHS-PDSA 2018). The study focussed on improving the assessment at any time during the study. Patient-specific anonymised data sheets recorded risk assessment scores, age range, PI/PU incidence by grade, SEM delta readings at individual anatomical sites, and interventions provided. Hands-on device training and clinical orientation on the role of SEM in assessing risk for PI/PUs were provided to ward staff by the device company’s clinical implementation team. Initial assessments including SEM scans, Waterlow, and STAs were performed at patient admission. While all patients were considered at-risk of developing a PI/PU due to the long-term hospice setting, subsequent assessments were performed as described in a detailed care pathway, introducing SEM scanning into routine practice (Figure 1). A positive SEM

Scanner indication was defined as a patient having SEM delta (Δ) ≥ 0.6 in three consecutive SEM assessments at a specific area of their anatomy. Preventive interventions prompted by SEM data included increased repositioning, a change to the pressure-redistribution support surfaces and heel elevation. All other care procedures continued as per SoC and any new PI/PU were recorded and reported as per facility protocols. Pre-study PI/PU incidence data in the preceding 12-month period were obtained through MCH’s central database. All newly diagnosed PI/PUs were recorded during the study. The following exclusion criteria were applied to all study data:

- PI/PU acquired prior to admission
- PI/PU acquired within 72 hours of admission
- PI/PU not occurring on the sacrum, heels, buttocks or coccyx
- PI/PU reported >7 days after the date of last SEM assessment.

Incidence rates were calculated as a percentage of patients developing new PI/PUs over a specific period of time. Descriptive statistics were produced by an independent biostatistician in SAS 9.4 (SAS Institute, Cary, NC) to assess preventive interventions prompted by the device’s delta reading and the change in nurse clinical decision making as alerted by the device.

Post-study staff survey

A limited, unsupervised post-study survey questionnaire was provided to all nursing staff involved in the study, who performed SEM scans on patients. Six questions (Table 2) and their responses capturing HCP experience in introducing SEM scanning into existing SoC and routine clinical practice were recorded.

Results

Prior study PI/PU incidence results

All reported sacral and heel PI/PUs for a period of 12 months preceding the study (November 2016 to October 2017) were reviewed. During

this period, a total of 377 patients were admitted to this hospice. Sacral and heel PI/PUs, 36 in total, were reported in 34 patients resulting in a pre-study incidence rate of 9% (34/377).

Study results

During the 6-month study period (Nov 2017–Apr 2018), 146 patients were scanned using the device (mean 5.6 days, range 1–27 days). This study reports results for 145 patients; one patient's data was excluded due to a scan-date error. One re-admitted patient was treated as two separate patients. In these 145 patients, at least one area of anatomy was scanned per patient during the study; the left heel was scanned in 143 patients, the right heel in 144 patients, and the sacrum in 128 patients resulting in a total of 415 patient assessments. An SEM delta (Δ) ≥ 0.6 (at any time) was recorded in 90% of assessments ($n=375/415$). SEM assessments were performed for 3 days or longer in 101 patients for the left and right heel, and in 93 patients for the sacrum.

In these patients, a positive SEM detection (as defined in the study methodology) was recorded in 91% of patients at the left and right heels ($n=92/101$), and in 78% of patients at the sacrum ($n=73/93$). Additional interventions prompted by the overall assessments, including SEM data, were reported in 48% of patients ($n=70/145$). HCPs' clinical decision-making impacted by SEM assessments alone was reported in 40% of patients ($n=58/145$). For example, increased repositioning or heel support was provided to the patient as a direct result of SEM assessments; interventions provided to patients are detailed in *Table 1*.

Post-hoc study results

In the 146 patients scanned, PI/PU incidence was reported in 13 patients (15 PI/PUs). Readers must note that a suspected norovirus outbreak in the facility paused all study procedures and no scanning was performed for 5 days in early March of 2018; this suspected outbreak was later disproven. Applying inclusion/exclusion criteria to study data, the resulting PI/PU incidence was 4.8% (7/146 patients). Prior to the study, PI/PU incidence was 9% (34/377 patients). Post-hoc analysis of incidence proportions at the 95% confidence interval (95% CI: -1.09, 8.47) resulted in a 47% PI/PU incidence reduction during the study period. Post-study survey questionnaires were completed by 26 nurses involved in the daily scanning of the patients. All nurses (100%) reported that an SEM delta (Δ) ≥ 0.6 alerted them to take additional actions on patient care. Results from the survey are detailed in *Table 1*.

Post study, full implementation results

SEM Scanners ($n=3$) were deployed in the facility for MCH tissue viability nurses and the executive leads to create tools and guidelines for a full-scale implementation of SEM scanning into routine clinical practice. Data from patient safety incident reports indicated a consistently decreasing PI/PU incidence rate after fully implementing the device into routine clinical practice. Facility nurses reported a 69% PI/PU incidence reduction in the first year of implementing SEM assessments in routine clinical care—15 months post-study completion.

Post-hoc estimation of the difference in proportions between the prior study data and post-study data resulted in a statistically significant absolute PI/PU reduction of 6.26% at the 95% confidence interval (95% CI: 3.18, 9.81, $p<0.001$) with SEM assessments as the only addition to routine clinical practice. During a period of 6 months in 2020 (year two), a 100% PI/PU incidence reduction was demonstrated for several months.

Discussion

Clinical practical guidelines describe PI/PUs as localised damage to the skin and underlying tissues over a bony prominence (EPUAP/NPIAP/PPPIA 2019). Definitions of category 1 PI/PU and deep tissue injuries in these guidelines are confusing for HCPs; category 1 PI/PU may be 'painful, firm, soft, warmer or cooler as compared to adjacent tissue'. Category I PI/PUs are described as a region of 'persistent focal oedema' in the international classification of diseases, ICD-10 Code L89 (World Health, 2019). Risk assessment scores (eg, Waterlow) and diagnostic tools like STAs lack predictive validity for timely diagnosis (Moore, 2019). Moreover, darker skin pigmentation may mask early signs of skin failure, including visual discoloration and localised erythema (Bates-Jensen et al, 2009; Baker, 2016). In the absence of an objective test, the reliability of these guidelines and tools is limited in keeping the skin intact. This ambiguity in objectively diagnosing localised and, or systemic skin failure in addition to the ethical dilemma in prioritising hospice philosophy and patient comfort over established wound care prevention and treatment strategies is the primary reason for the concept of 'unavoidable pressure ulcers/injuries' being more prevalent in end-of-life care (Carlsson and Gunningberg, 2017; Black and Hotaling, 2018; Ayello et al, 2019; Ferris et al, 2019; Latimer et al, 2019). Results from this study seem to provide an alternative narrative to this concept.

Introducing SEM data about skin and tissue integrity from the device into routine clinical practice, even in the absence of visible and tactile signs of damage, contemporaneously informed clinical decision making for specific patient anatomies. This singular change resulted in a 47% reduction in PI/PU incidence during the study period, demonstrating the clinical utility of SEM as a test of local and anatomically specific early tissue damage in high-risk hospice patients. Results from this study align with other study results where incorporating SEM assessments into standard patient care and routine assessments resulted in a clinically significant decrease in PI/PU incidence (Raizman et al, 2018; Smith, 2019; Ore, 2020).

The reported PI/PU study incidence of 4.8% compares favourably to previously published data. Ferris et al (2019) cited an incidence, under the current SoC, of 11.7% in palliative care patients developing PIs, while 10% of hospice patients (range 0.8% to 22%) were reported to have developed a new PI/PU in the UK during 2019 (NHS-ST, 2018; Ferris et al, 2019). Specifically, post this study, facility tissue viability nurses have reported a consistent reduction in PI/PU incidence year on year in adopting SEM assessments into routine clinical practice. Year 1 reported a 69% reduction in PI/PU incidence (15 months post-study), while a 100% reduction was demonstrated for several months during a period of 6 months in 2020; until the advent of COVID-19. These results suggest an extended use of the test of SEM in facilitating improvements in end of life preventive skin measures in critically and terminally ill patients.

Early-stage skin and tissue damage at the microscopic level and the associated damage cascade is common to both localised and systemic skin failure irrespective of the wound outcome (PI/PUs grade I-IV, DTIs, KTUs). At the cellular level, early inflammation, localised

build-up in oedema, fluctuations in SEM, and the subsequent tissue deformation are highly likely to be reversible with timely preventive measures. Once this damage threshold reaches the macroscopic level ie, erythema of the skin, visual discoloration, etc, the damage has already occurred and is unlikely to be reversible (Levy et al, 2017; Gefen and Ousey, 2020). This understanding of early-stage tissue damage and PI/PU development forms the main context in the Aetiology chapter of the Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline 2019 (EPUAP/NPIAP/PPPIA, 2019). The SEM test is an objective assessment of these early-stage microscopic fluctuations of interstitial fluids, and provides a clinically significant time advantage in identifying early and deep tissue damage incidence rates in acute care settings (Wood and Lawrence, 2020).

Limitations

The authors acknowledge limitations to this pragmatic study approach. MCH's primary aim was to evaluate implementing SEM scanning into routine assessments as a pilot approach. The study was designed to assess a quality and practice improvement focused on measurable changes in the incidence of PI/PUs (Category 2–4). The study was not designed to be able to measure correlations between SEM measurements and interventions guided by PI/PU risk categorisations. Risk assessment scores and patient demographic correlation to SEM data was not evaluated, to limit evaluations to a non-research clinical outcome. SEM data in combination with clinical judgment enabling early preventive interventions resulted in a reduction in PI/PU incidence in these at-risk patients.

The study design acknowledged the potential confounding effects of the Hawthorne Effect-increased awareness/attention to patient care due to being observed (Leonard and Masatu, 2006; Abraham et al, 2018). However, MCH provides periodic training in educating and increasing awareness in HCPs and tissue viability nurses to preventing PI/PUs as part of their quality improvement efforts (MCH, 2017). The authors note that these routine quality initiatives by the trust's towards patient care had made an impact, even before the introduction of the device. Besides, all study personnel were trained in using the device and its clinical interpretation before the study. As such the confounding effects of this observer effect on the study results ie, PI/PU incidence reduction as a result of increased staff awareness/attention to patient care alone, are minimal.

Key points

- Palliative care patients are considered at a high risk of developing PI/PUs due to their complex co-morbidities and concomitant risk factors
- Risk assessment tools and skin and tissue assessments lack predictive validity for timely diagnosis
- SEM assessment provides objective, anatomically specific data to support early PI/PU preventive interventions
- Data from patient safety incident reports indicated a consistently decreasing PI/PU incidence rate after fully implementing the device into routine clinical practice.

Continuing professional development: reflective questions

- What is the role of early diagnostic technology in pressure injuries (PI)/pressure ulcer (PU) prevention?
- What are the risk factors that make palliative care patients vulnerable to PI/PUs?
- What are the challenges reported in the literature of the present standard of care for PI/PU prevention such as risk assessment tools and skin tissue assessments?

Conclusion

The lack of objective diagnostic tools, the inability to provide early, individual, holistic interventions, and the ethical dilemma in hospice philosophy vs clinical care has contributed to loosely classifying end-of-life PI/PUs as 'unavoidable' (Carlsson and Gunningberg, 2017; Levine, 2017; Olshansky, 2017; Ayello et al, 2019; Julian, 2020). While NHS guidelines recommend discontinuing the terms 'avoidable/unavoidable' (NHSI, 2018), preventing PI/PUs following end-of-life skin failure is complex and challenging, specifically in conjunction with palliative and hospice philosophy. Furthermore, the conflictual definition of early-stage skin and tissue damage in current wound care guidelines is uniquely ill-suited for a differential diagnosis between avoidable, unavoidable, and non-specific PI/PUs. Results from this study seem to provide an alternative clinical approach, the test of SEM, to aid in preventing these challenging PI/PUs. In other words, although skin compromise in end of life patients is inevitable, incorporating SEM assessments into routine hospice care practice appears to provide a new window of opportunity, where early preventive interventions at specific anatomies are likely to reverse tissue deformation at the cellular level.

The ability to act on the device's objective data and providing personalised, targeted interventions is likely to prevent over treating patients, thereby providing much needed comfort to terminally ill and palliative care patients without completely compromising on clinical care. HCPs equipped with an objective diagnostic tool, the SEM test, where an elevated SEM delta indicates the presence of early skin and tissue damage, seem to have a clinically significant advantage in providing improved preventive strategies and reducing the risk of developing new PI/PUs, that until now have been considered unavoidable.

Clearly, the early, objective, and anatomically specific data provided by SEM assessments is critical in facilitating personalised preventive strategies, specifically in challenging care settings, such as hospice and palliative care. Nevertheless,

more research and pragmatic applications of the SEM test, as it applies to palliative and hospice wound care, may potentially help in redefining the course of end-of-life clinical care. *IJPN*

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