

Introduction

Pressure ulcers (PUs), defined as ‘a localised area of skin and soft-tissue damage that usually occur over bony prominences, due to pressure or pressure in combination with shear’¹ are a common type of chronic wound categorised in four stages, with an additional un-stageable category and suspected deep tissue injury².

A serious form of avoidable harm to patients, PUs have widespread universal financial impacts; in 2017-18, approximately 200,000 people in the United Kingdom (UK) developed a new PU, with a daily cost of £1.4 million.³ Using data obtained from The Health Improvement Network (THIN) Database, Guest et al.⁴ estimate the costs of managing PUs in the UK as ranging from £1400 for a category 1 ulcer to in excess of £8500 for more severe types of PU. Attributable to their gravity and clinical nursing time involved in patient care, daily treatment costs of managing PUs have been estimated between £1,214 to £14,108 depending on severity.⁵ In the USA, approximately 2.5 million patients suffer hospital-acquired PUs (HAPUs) at an annual cost of almost \$26.8 billion.⁶

Pressure Ulcer Assessment and Identification

Individual patient factors (such as patient comorbidities) and external factors in the environment that have a negative effect on skin integrity can induce the development of a PU and external forces such as pressure, shear, and friction.⁷ Heat and moisture in the environment^{8,9} can increase their likelihood. Regular patient repositioning, the use of pressure relieving devices, and frequent visual and physical skin inspections, are strategies commonly used to avert pressure damage developing in at-risk patients. Identifying at-risk patients through the completion of risk assessment and identification tools, alongside a visual skin assessment to detect visible signs of tissue damage, are techniques employed in clinical practice to maintain healthy skin integrity.¹⁰ A limiting factor of such preventative methods is the reliance on individual clinical judgement to predict and assess the likelihood of emerging and

potentially non-visible tissue damage. This subjective approach, open to individual interpretation, can expose patients to unnecessary risk if such assessments are inadequate.^{11, 12} As the physical signs of tissue damage are usually only visible on the surface of the skin 3-10 days after damage has started to occur,¹³ a patient's skin health can significantly deteriorate before an effective PU intervention is adopted.

Patient outcomes and wound healing trajectory are largely dependent on the clinician's ability to accurately identify damaged skin, and the literature describes the impact that this approach to PU treatment and management can have on patient experiences of care.¹⁴ Physical changes in the skin due to pressure, including an increased inflammatory response, localised tissue oedema, and an increase in sub-epidermal moisture (SEM)¹⁵, mean that a dependence on visual assessment to detect pressure damage presents a missed opportunity to implement early interventions to prevent escalation. NICE¹¹ recommendations for PU prevention and management highlight the importance of training and education for health care practitioners (HCPs) in undertaking a visual skin assessment and employing appropriate PU prevention strategies. However, some HCPs continue to have difficulties making evidence-based decisions in the absence of objective tools to support the identification of microscopic tissue damage.¹⁶

The Pressure Ulcer Reduction Programme (PURP)

Recent advancements in SEM (sub-epidermal moisture) assessment technology have been used to reduce pressure ulcer (PU) incidence alongside standard PU care pathways as an adjunct to the current standard of care¹⁷. The Pressure Ulcer Reduction Programme (PURP) is a potential tool to reduce incidence of pressure ulceration in hospital patients by enabling clinicians to collect data on the inclusion of SEM in clinical practice. PURP programmes are designed using a pragmatic framework to replicate routine clinical practice in daily PI/PU care. The framework and implementation methodology aligns with NICE guidelines described in the Real World Evidence DSU Technical Support Document 17, 2016 and is compliant with the General Data Protection Regulation 2016/279¹⁸.

SEM uses Biocapacitance to notify clinicians that a patient has an increased risk of developing a PU before such damage is visible on the skin¹⁹. Institution- and patient-level data demonstrates the SEM has the potential to prompt appropriate interventions with associated financial benefits. For example, Padula et al.⁶ evaluated the cost-effectiveness of using SEM assessment technology in comparison to existing HAPU prevention guidelines using a Markov modelling technique and established that using the technology was associated with cost savings of \$4054 per acute care admission. Interestingly, for every 1000 hospital admissions in high-risk acute care, the technology was found to have the potential to eliminate seven HAPU related deaths and reduce patient length of hospital stay by approximately 206 days. Gefen²⁰ used probabilistic modelling to understand the financial implications of using SEM assessment in a PU prevention strategy for the early detection of a HAPU and subsequent application of early interventions. Where there was a low incidence of PUs (1.6%) the expected cost saving per patient was found to be £15.23, with estimated total savings of £0.6 million per annum and £3.3 million for a high incidence. The authors concluded that the predictive models suggest significant cost reduction through early identification of PU and supportive clinical decision making when using SEM assessment technology compared to standard care.

The evidence suggests that the PURP can reduce PU incidence in hospitalised at risk patients by providing an objective measure of a patient's tissue health to drive real-time decision-making and appropriate interventions. Smith²¹ found that when the SEM was used on the heels and sacrum of hospitalised patients considered at risk of developing a PU (Waterlow score >10) once a day from admission over a two-month period, no patients developed a PU during their inpatient stay, despite recording a delta reading of ≥ 0.6 (indicative of the early signs of pressure damage), although one patient was found to develop a PU within seven days of discharge. In the UK, Littlefield and Kellett²² found a 95% reduction in grade 2-4 HAPUs when using the PURP on 234 inpatients; Raine²³ found a 46.8% reduction in HAPU when the PURP was used in an palliative care setting; and Ore et al.²⁴ also found a reduction in HAPUs in the community setting in a sample of 17 palliative care patients, with the majority of staff reporting that the tool had made a significant impact on their clinical decision

making. Okonkwo et al¹⁹ evaluated the sensitivity and specificity of the SEM when used by 'generalists' with no specific training in PU visual assessment, compared to 'specialists', using a blinded, longitudinal prospective design involving patients across 12 acute and post-acute hospital sites across the UK (3 acute care settings; n=42) and USA (six acute care, three post-acute settings; n=147). The SEM Scanner was found to have a sensitivity of 87.5% in identifying PUs and the device produced a positive finding 4.74 days (SD 2.39 days) earlier. Specificity was lower at 32.9% (95% CI 28.3% to 37.8%), although achieving high sensitivity may be considered to be of higher priority. Hence the scanner can be considered to be a conservative diagnostic tool; although a certain fraction of false positive cases will be recorded, very few genuine cases will be missed.

In addition, Raizman et al.¹⁷ undertook a two-phase clinical comparison of the SEM Scanner to evaluate the clinical utility of the device in patients at-risk (using the Braden risk assessment tool) of developing HAPU in Canada at one of the three hospitals within the network. Patients (n=89) were assessed and scanned five times per week for one month or until discharge, receiving standard of care clinical risk assessment by trained practical nurses, but in only the second phase of the study were SEM readings used in clinical decision making to determine appropriate interventions. Results showed a significant difference in the observed PU incidence between phases, with a 93% reduction in HAPU incidence when patient assessments and care planning incorporated SEM delta values. More specifically, 12 out of 89 patients (13.5%) in Phase 1 developed visible PUs, compared to 1.0% in Phase 2, despite these patients being more clinically unwell.

There are obvious clinical benefits of the utilising SEM scanning technology in clinical practice to reduce the incidence of PU in at risk patients and the literature points to the positive impact that this approach has on clinical practice, nurse decision making and the associated financial benefits.

The aim of this paper is to assess the effectiveness of the PURP in reduction of Category 2 or above pressure ulceration by conducting a meta-analysis to compare incidence pre- and post-

implementation in patients in a variety of settings across several countries in a multisite study. A subsidiary aim includes the investigation of differential effects across setting types.

Methods

Data collection

Anonymized data was obtained from 28 institutions in the United Kingdom, Belgium, Canada, Spain and Ireland. The setting of each institution was categorised as Category A or Category B. Category A settings included: elderly/long-term care, orthopaedic/trauma, rehabilitation/stroke/neurology, medium-to-long-term stay medical, and community settings. Category B settings included: general medical, ICU, mixed surgical, renal, vascular, orthopaedic/short stay trauma, diabetes and palliative settings. In each setting, the number of patients admitted (recorded admissions) and the number of patients with one or more pressure ulcers (PUs) of Category 2 or above during a pre-PURP implementation period starting between November 2017 and July 2018 was recorded. From this information, the proportion of patients reported with one or more pressure ulcers (PUs) of Category 2 or above during the implementation period was extracted. The duration of this period was not recorded for all institutions but was given as 12 months in all institutions in which the duration was recorded.

The proportion of patients scanned at the sacrum and heels who were observed to have one or more pressure ulcers (PUs) of Category 2 or above during a post-PURP implementation period starting between November 2018 and July 2019 was determined, again evaluated from recordings of the number of patients scanned and the number of patients with one or more pressure ulcers (PUs) of Category 2 or above. This implementation period generally commenced within a few days of the end of the corresponding pre-PURP implementation period for that ward. The duration of this period was not recorded for all institutions but was given as between 2 weeks and 6 months in the institutions in which the duration was recorded.

Statistical analysis

The sample was summarised descriptively by implementation period. Z-tests for the comparison of two proportions was conducted on each institution, comparing the proportion of patients who were observed to have one or more pressure ulcers (PUs) of Category 2 or above, pre- and post-PURP implementation. An analysis of covariance was conducted to assess the relationship between the outcome PU incidence (post-PURP implementation) and institution category, controlling for PU incidence (pre-PURP implementation).

A random effects meta-analysis, using the DerSimonian and Laird method, was conducted on the data, to obtain an overall estimate of the effect of the PURP; comparing the relative risk (RR) of PU incidence at each included institution individually pre- and post-PURP implementation. RR was calculated as

$$RR = \frac{\text{Incidence of PU (post PURP)}}{\text{Incidence of PU (pre PURP)}}$$

with a correction factor of 0.5 applied in cases of zero events, following common practice.

A sensitivity analysis was conducted by omitting each included study in turn and using a meta-analysis to estimate the effect of interest from the remaining studies. These estimates with their confidence intervals were plotted on an influence plot. Excessive influence of any individual study may be indicated by the point estimate of its omitted analysis lies outside the confidence interval of the combined analysis; or if its omitted MA estimate differed in significance relative to the estimate of the combined analysis.

The assessment of small-study (i.e. ward) effects was facilitated using a funnel plot (a scatterplot of measures of study precision against study-specific effect sizes).

A L'Abbé plot of the PU incidence post-PURP implementation against PU incidence pre-PURP implementation was also constructed, which illustrates variation in observed results as an aid to exploring the heterogeneity of effect estimates.

All analyses were conducted using Stata statistical software, version 14.0 I/C ²⁵.

Results

The institutions featured, their settings and classifications, are summarised in Table 1 below.

Table 1: summary of featured institutions, setting and categorisation

Institution	Country	Pre-PURP setting	Category
Site 01	UK	Medical	B
Site 02	UK	Elderly Care	A
Site 03	UK	Orthopaedic trauma	A
Site 04	UK	Orthopaedic trauma	A
Site 05	Canada	Medical	B
Site 06	UK	ICU	B
Site 07	Spain	Elderly Care	A
Site 08	UK	Rehabilitation & Stroke	A
Site 09	UK	Orthopaedic trauma	A
Site 10	UK	Mixed surgical	B
Site 11	UK	Renal	A
Site 12	Belgium	Vascular surgery	B
Site 13	Belgium	Rehabilitation	A
Site 14	Ireland	Orthopaedic	B
Site 15	Belgium	Elderly Care	A
Site 16	Belgium	Elderly Care	A
Site 17	Belgium	Elderly & Long-term Care	A
Site 18	UK	Trauma & Orthopaedics	A
Site 19	UK	Stroke & Neurology Rehabilitation	A
Site 20	UK	Medical	B
Site 21	UK	Orthopaedic trauma	A
Site 22	Spain	Trauma – short stay	B
Site 23	Spain	ICU	B
Site 24	Spain	Medical – medium/long stay	A
Site 25	Spain	Medical – medium/long stay	A
Site 26	UK	Medical – diabetes speciality	B
Site 27	UK	Palliative setting	B
Site 28	UK	Community setting	B

Category A: elderly/long-term care, orthopaedic/trauma, rehabilitation/stroke/neurology, medium-to-long-term stay

medical, and community settings

Category B: general medical, ICU, mixed surgical, renal, vascular, orthopaedic/short stay trauma, diabetes and palliative settings

The proportion of patients who were observed to have one or more pressure ulcers (PUs) of

Category 2 or above pre-and post-PURP implementation is summarised in Table 2 below, including Z-

statistics and p -values. Pre-post differences which were statistically significant at the 5% significant level are starred.

Table 2: comparison of pre- and post-PURP PU proportions of observed patients with PUs (individual institutions)

Site	Pre-PURP			Post-PURP			Z-statistic	p-value
	Cat 2+ PU observations	Patients Admitted	Proportion of patients with PU	Cat 2+ PU observations	Patients scanned	Proportion of patients with PU		
Site 01	23	1,642	1.40%	0	35	0.00%	0.705	0.481
Site 02	25	495	5.05%	2	234	0.85%	2.801	0.005*
Site 03	10	308	3.25%	0	99	0.00%	1.815	0.069
Site 04	16	384	4.17%	0	34	0.00%	1.214	0.225
Site 05	12	89	13.48%	2	195	1.03%	4.498	<0.001*
Site 06	1	12	8.33%	0	12	0.00%	1.022	0.307
Site 07	3	20	15.00%	0	20	0.00%	1.801	0.072
Site 08	13	383	3.39%	1	40	2.50%	0.301	0.764
Site 09	27	3,089	0.87%	0	59	0.00%	0.721	0.471
Site 10	14	1,242	1.13%	0	64	0.00%	0.854	0.393
Site 11	21	1,120	1.88%	0	41	0.00%	0.885	0.376
Site 12	1	868	0.12%	0	105	0.00%	0.348	0.728
Site 13	5	795	0.63%	0	45	0.00%	0.534	0.594
Site 14	40	328	12.20%	0	31	0.00%	2.063	0.039*
Site 15	29	134	21.64%	1	34	2.94%	2.543	0.011*
Site 16	13	37	35.14%	1	30	3.33%	3.184	0.001*
Site 17	2	32	6.25%	1	22	4.55%	0.269	0.788
Site 18	5	892	0.56%	0	194	0.00%	1.045	0.296
Site 19	9	206	4.37%	0	155	0.00%	2.635	0.008*
Site 20	12	1,123	1.07%	0	212	0.00%	1.512	0.131
Site 21	16	625	2.56%	2	136	1.47%	0.758	0.449
Site 22	20	1,235	1.62%	0	26	0.00%	0.654	0.513
Site 23	4	657	0.61%	0	23	0.00%	0.375	0.707
Site 24	55	1,490	3.69%	0	25	0.00%	0.979	0.328
Site 25	70	627	11.16%	0	20	0.00%	1.582	0.114
Site 26	14	838	1.67%	0	61	0.00%	1.017	0.309

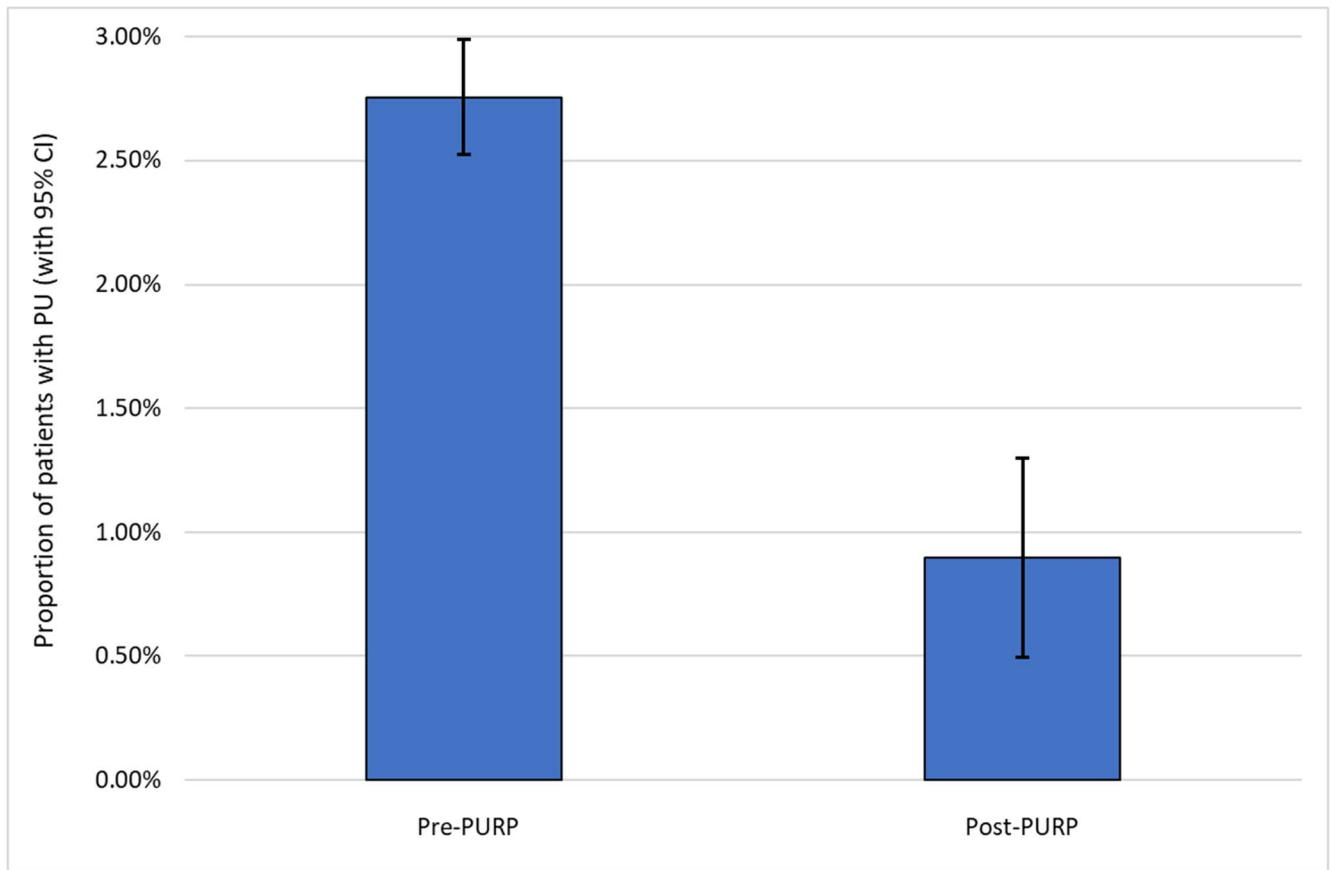
Site 27	34	377	9.02%	7	146	4.79%	1.612	0.107
Site 28	37	230	16.09%	2	17	11.76%	0.472	0.637

*Statistically significant at the 5% significance level

Pre-PURP implementation, the proportion of patients who were observed to have one or more PUs of Category 2 or above ranged from 35.1% to 0.12%. Post-PURP implementation, the proportion of patients scanned who were observed to have a PU of Category 2 or above ranged from 11.8% to 0.00% (several institutions). All 28 institutions observed a reduction in proportion of observed PUs between the two implementation periods, with statistically significant reductions (at the 5% significance level) in 6 institutions according to the Z-test. Institution category was not significantly associated with PU incidence, post-PURP implementation ($F_{1,25}=0.571$; $p=0.457$) and had an effect of low magnitude (partial- $\eta^2=0.022$) according to the ANCOVA procedure. The parameter estimate for institution category of 0.007 (95% confidence interval -0.012 to 0.026) indicated that at best estimate, PU incidence, post-PURP implementation was 0.7% higher in Category A institutions than in Category B institutions. However, this is a non-significant effect.

The pooled overall proportions of patients with pressure ulceration pre- and post-PURP (with associated 95% confidence intervals) is summarised graphically in Figure 1; revealing no overlap between the two sets of confidence intervals. This is indicative of a significant difference in proportions pre- and post-PURP ($p<0.01$).

Figure 1: overall proportions of patients with pressure ulceration pre- and post-PURP (with associated 95% confidence intervals)

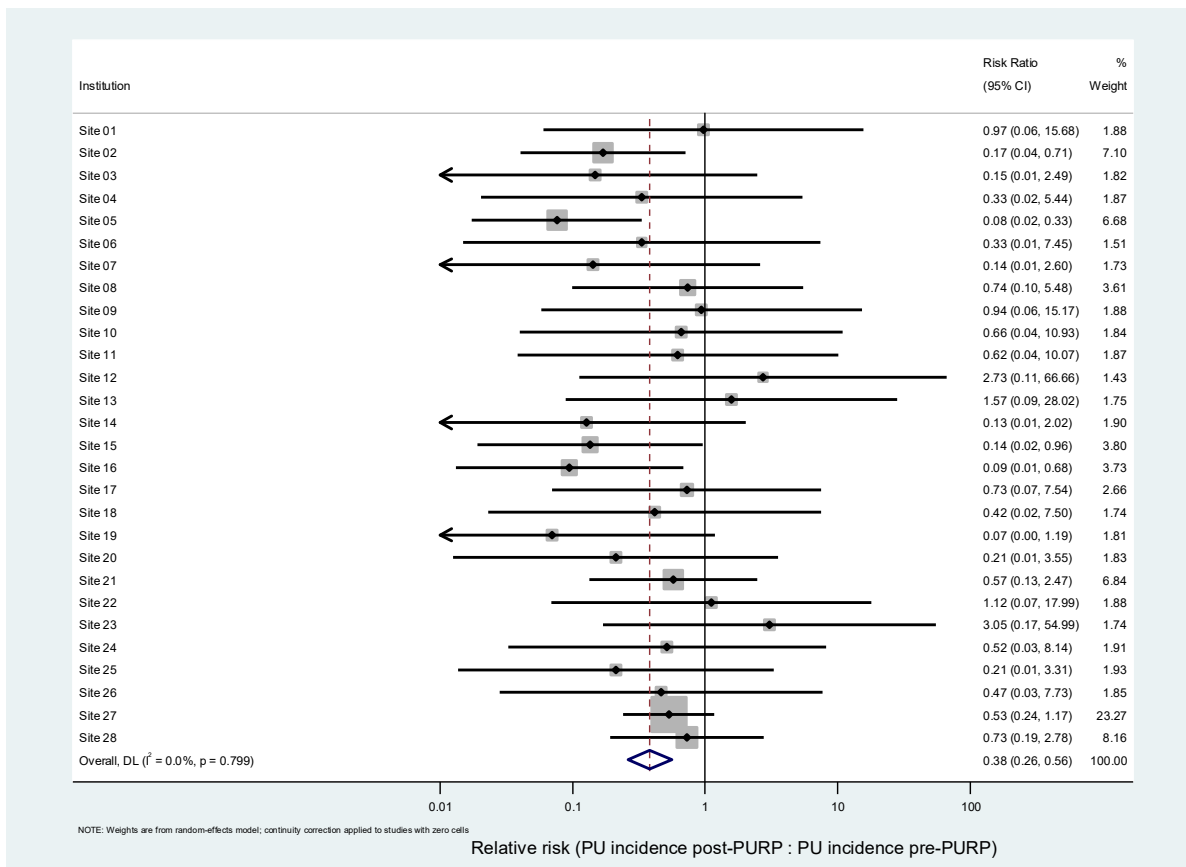


The meta-analysis revealed that a synthesised estimate of the overall RR was calculated to be 0.38 (95% confidence interval 0.26 to 0.56). Hence the risk of PU in the post-PURP cohort was about one third that of the corresponding risk in the pre-PURP cohort, notwithstanding the effects of the correction factor. A Z-test of the relative risk revealed strong evidence to reject the hypothesis of the risk of PU was equal in the two groups ($Z=6.33$; $p<0.001$).

The meta-analysis also determined that there was no evidence for heterogeneity between studies according to Cochran's test: $\chi^2_{(27)}=21.95$; $p=0.740$. The I^2 statistic (variation in RR attributable to heterogeneity) was approximately 0.0%; indicating negligible statistical heterogeneity.

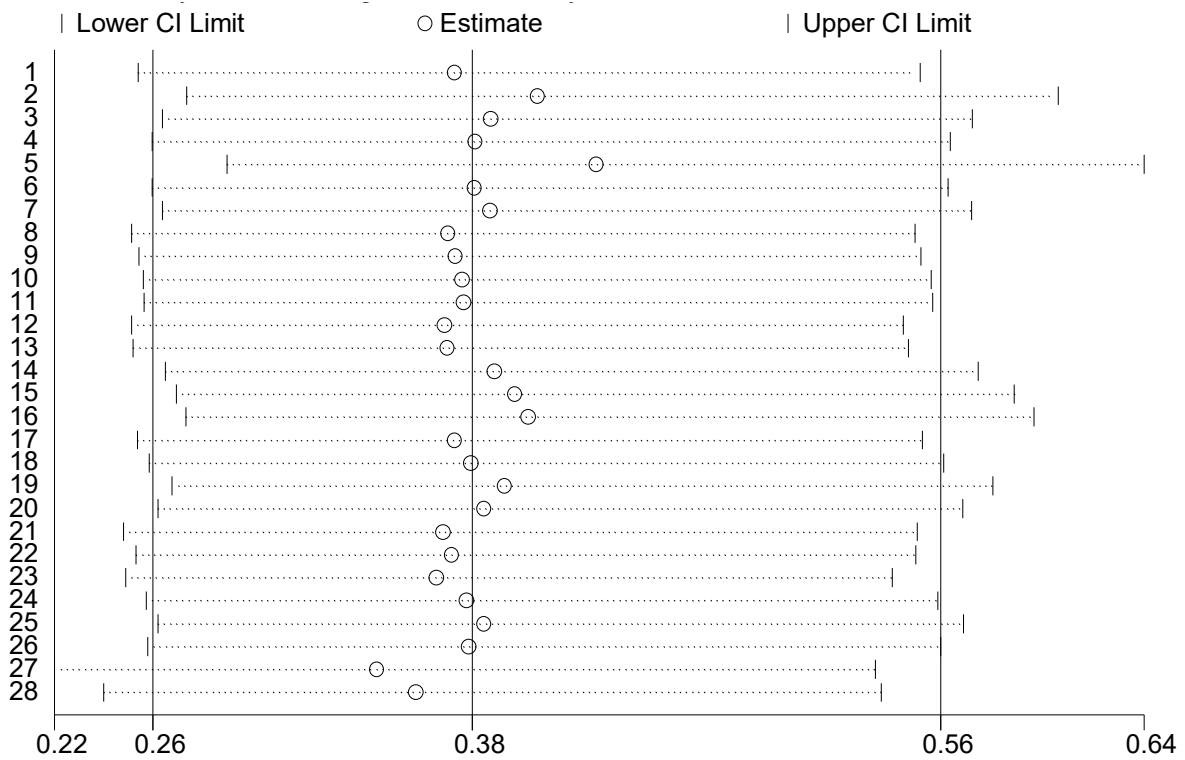
The data is summarised in a forest plot (Figure 2), in which the homogeneity of effects is apparent. All cases in which the relative risk appear to have increased post-PURP are artefacts, caused by the correction factor applied to the cases of zero post-PURP incidence.

Figure 2: forest plot for relative risk of PU incidence pre- and post-PURP implementation



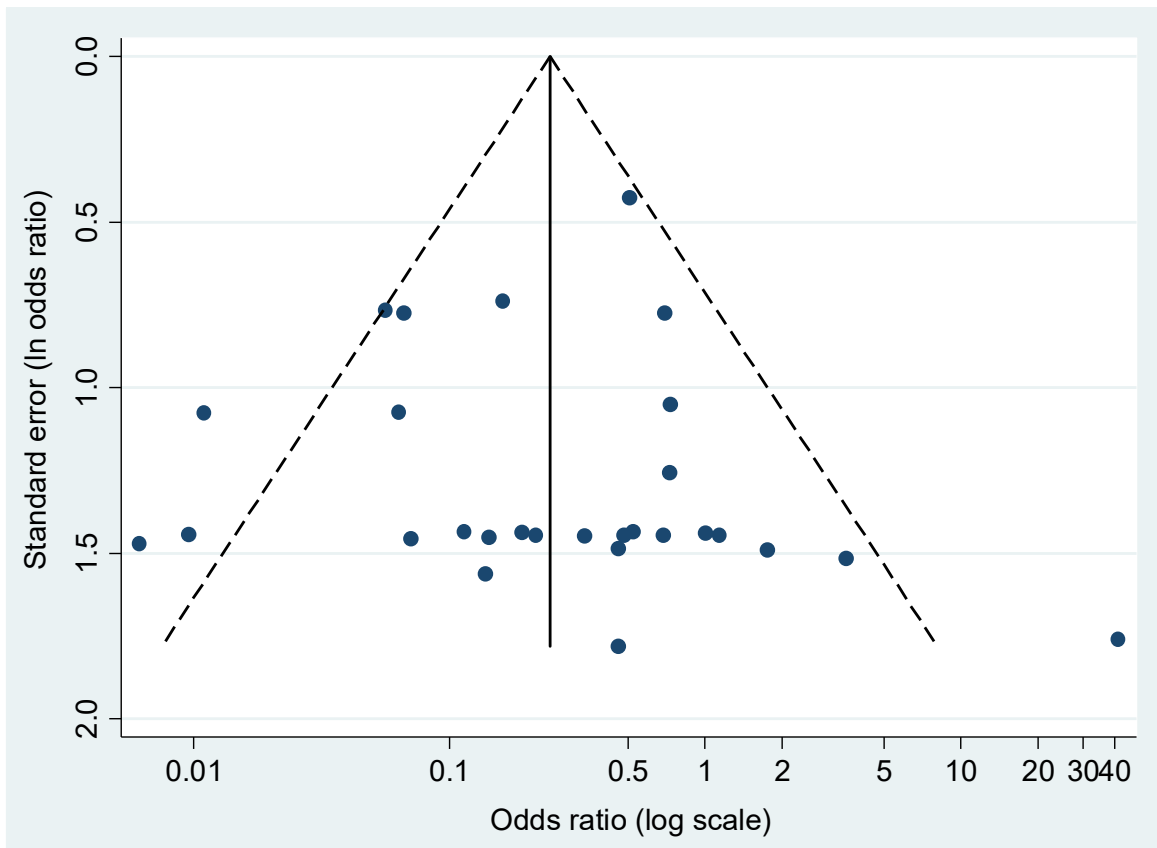
The sensitivity analysis revealed no evidence that any individual ward exerted excessively influence on the findings; with all point estimates of omitted analysis lying outside the confidence interval of the combined analysis; and no differences of significance between the estimates of the omitted analysis and combined analyses (Figure 3).

Figure 3: sensitivity analysis influence plot for PU incidence pre- and post-PURP implementation



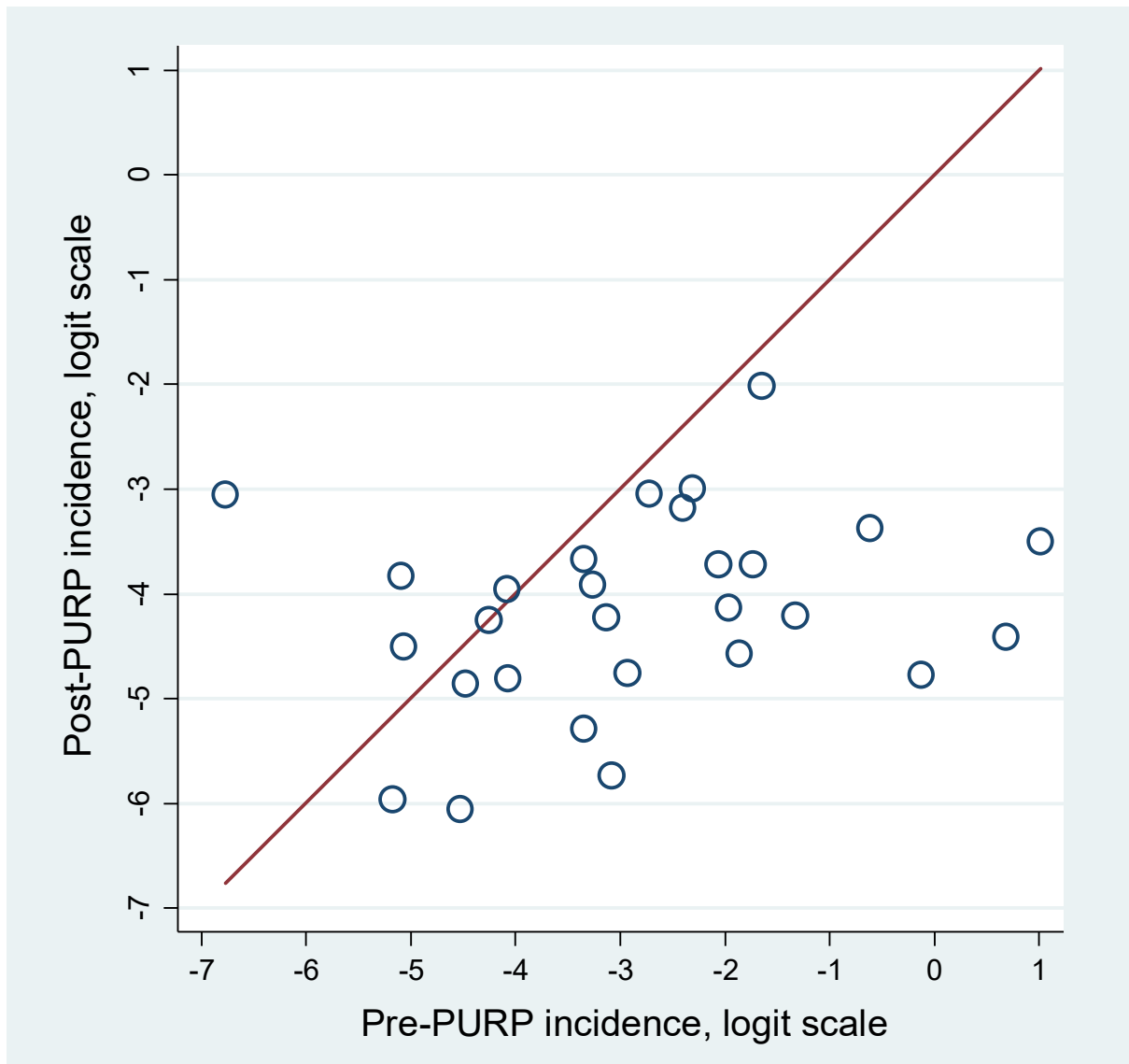
The funnel plot (Figure 4) revealed some limited evidence for small-study (i.e. ward) effects, with moderate departure from the symmetrical (inverted) funnel shape indicative of absence of effects.

Figure 4: funnel plot for PU incidence pre- and post-PURP implementation



The L'Abbé plot (Figure 5) illustrates the scale of the preponderance of studies with higher levels of PU incidence pre-PURP; and the relative heterogeneity of data, with most results clustered within narrow limits. Points falling below the line of equality indicate wards with higher levels of PU incidence pre-PURP. While points falling above the line of equality would normally indicate wards with higher levels of PU incidence post-PURP, all are in fact data artefacts arising from the necessity to apply a correction factor to zero-event cases.

Figure 5: L'Abbé plot for PU incidence pre- and post-PURP implementation



Discussion

There was universal reduction in PU incidence from the pre-PURP to post-PURP implementation periods across all departments and settings, with no evidence for a differential effect across different categories of settings. In many individual settings, post-PURP incidences drop to zero. This may have been a result of practitioners being increasingly aware of potential skin damage and implementing effective preventative strategies in a timely manner. However, Raizman et al.¹⁷ concluded that there was no evidence for the Hawthorne effect (a change in outcomes due to a change in behaviour of

participants as a result of observation of their involvement in a study) associated with usage of the SEM Scanner. Raizman et al. conducted a 2-phase study was conducted with patients provided with standard care for risk assessment and scanned in both phases, but scanner readings were used to determine interventions in the 2nd phase only; finding that PU incidence decreased only when the scanner was used to influence clinical interventions.

Despite this, not all reductions are statistically significant at the 5% significance level as measured in individual settings. This is likely to be due to underlying low pre-PURP incidences, leaving limited scope for improvement in the post-PURP implementation phase); and small sample sizes in some institutions, particularly in the post-PURP implementation phase. Additionally, the pre-PURP implementation periods and post-PURP implementation time periods and the number of patients admitted, or scanned during these phases were not similar in multiple settings which may have attributed to the lack of statistical significance at the 5% level as measured in these settings.

There were a wide range of clinical areas used to collect the data. However, data were collected by a range of clinicians, and therefore it is difficult to ensure there was consistency across grading of ulcers. Future studies should ensure data collection is from a research team, ensuring inter-rater reliability. While the current analysis was conducted at the patient level, research by Jayabal et al.²⁶ has revealed differences in SEM values across different anatomical sites in a healthy cohort of participants. Hence consideration of both site specific and individual demographic factors may be required in the assessment of the utility of the SEM scanner as a predictive tool, which will be addressed in a future analysis.

The meta-analysis reveals the risk of PU incidence post-PURP implementation to be approximately one third the risk of PU incidence pre-PURP implementation; i.e. an approximately 3-fold decrease in PURP incidence. Because of the correction factor applied to a substantial fraction of the wards included in the analysis which had zero post-PURP incidences, this figure may be a considerable underestimate. No single ward or setting excessively influenced the findings of this analysis, with high levels

of homogeneity inferred from the forest plot and L'Abbé plot. In general, precision of estimated intervention effects increased with setting size, with effect estimates from small studies scattering more widely at the bottom of the funnel plot illustrated in Figure 3, albeit with some departure from expectations in terms of the shape of the data.

There has been discussion in the literature regarding effectiveness of pressure ulcer risk assessment tools and their effectiveness in prevention of skin damage^{27, 28, 29}; the authors concluding that there was no RCT evidence suggesting that conducting a structured risk assessment made any difference to pressure ulcer incidence. Hence options for limiting skin damage and PU incidence are limited, and in this context, the current analysis reveals the value of the PURP with the conclusion that there is strong evidence to suggest that incorporating the PURP into clinical practice for the early identification of Category 2 or above pressure ulcers has the potential to reduce the PU incidence. Budri et al.³⁰ draw attention to movement values for an older person, highlighting that the median number of movements per hour of the older person was almost half the median number of movements per hour performed by healthy adults. The authors suggest that in immobile patients, pressure-related forces over bony prominences may link to tissue damage by pressing tissue layers down and causing occlusion of lymphatic and blood vessels. However, they warn that attention must be paid to those who can move as they may not necessarily move into a good position. They concluded that PUs occurred both in low and high movers, and the addition of a more objective skin assessment enabled greater detection of impending tissue damage.

The programme has been shown to produce positive patient outcomes and associated cost benefits through limiting the number of patients who may potentially go on to develop severe and enduring chronic wounds. Incorporating such an approach for the strategic management of PU has the potential to enable clinicians to identify developing tissue damage before it is visible on the patient's skin and employ appropriate early interventions to limit the devastating effects that PU can cause to patients

in their care. Future research should focus on adopting the PURP into clinical practice for the treatment and management of PUs in different clinical settings.

Keywords

Pressure ulceration

Pressure ulcer reduction programme

Sub-epidermal moisture

SEM Scanner

Meta-analysis

Key points

Recent advancements in SEM (sub-epidermal moisture) assessment technology has been used to reduce pressure ulcer (PU) incidence alongside standard PU care pathways as an adjunct to visual assessment.

The Pressure Ulcer Reduction Programme (PURP) is a potential tool to reduce incidence of pressure ulceration in hospital patients by enabling clinicians to collect data on the inclusion of the SEM Scanner in clinical practice, for the early identification of PU and assess the impact on clinical practice, nurse decision making and financial impacts in healthcare service delivery.

Institution and patient-level data demonstrates that the PURP has the potential to prompt appropriate interventions with associated financial benefits.

There is universal reduction in PU incidence from the pre-PURP to post-PURP implementation periods across all wards and settings, with no observable differential effects across categories of wards: in many individual wards, post-PURP incidences drop to zero.

Reflective questions

Can implementation of a reduction programme reduce incidence of category 2 and above pressure ulcers?

Can a sub-epidermal moisture (SEMS) scanner be effectively used as an adjunct to visual assessment to reduce pressure ulcer (PU) incidence alongside standard PU care pathways?

Are there any differential effects across ward types in the effectiveness of the programme?

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