CLINICAL MANAGEMENT extra

Efficacy of Monitoring Devices in Support of Prevention of Pressure Injuries: Systematic Review and Meta-analysis

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GENERAL PURPOSE:

To present a systematic review of the literature assessing the efficacy of monitoring devices for reducing the risk of developing pressure injuries.

TARGET AUDIENCE:

This continuing education activity is intended for physicians, physician assistants, nurse practitioners, and nurses with an interest in skin and wound care.

LEARNING OBJECTIVES/OUTCOMES:

After participating in this educational activity, the participant should be better able to:

1. Explain the methodology of the literature review and its results.

2. Discuss the scope of the problem and the implications of the research.

ABSTRACT

OBJECTIVE: To assess the efficacy of monitoring devices for reducing the risk of developing pressure injuries (PIs).

DATA SOURCES: The authors systematically reviewed the literature by searching PubMed/MEDLINE and CINAHL databases through January 2016.

STUDY SELECTION: Articles included clinical trials and cohort studies that tested monitoring devices, evaluating PI risk factors on patients in acute and skilled nursing settings. The articles were scored using the Methodological Index for Non-randomized Studies.

DATA EXTRACTION: Using a standardized extraction form, the authors extracted patient inclusion/exclusion criteria, care setting, key baseline, description of monitoring device and methodology, number of patients included in each group, description of any standard of care, follow-up period, and outcomes.

DATA SYNTHESIS: Of the identified 1866 publications, 9 met the inclusion criteria. The high-quality studies averaged Methodological Index for Non-randomized Studies scores of 19.4 for clinical trials and 12.2 for observational studies. These studies evaluated monitoring devices that measured interface pressure, subdermal tissue stress, motion, and moisture. Most studies found a statistically significant decrease in PIs; 2 studies were eligible for meta-analysis, demonstrating that use of monitoring devices was associated with an 88% reduction in the risk of developing PIs (Mantel-Haenszel risk ratio, 0.12; 95% confidence interval, 0.04–0.41; $I^2 = 0\%$).

CONCLUSIONS: Pressure injury monitoring devices are associated with a strong reduction in the risk of developing PIs. These devices provide clinicians and patients with critical information to implement prevention guidelines. Randomized controlled trials would help assess which technologies are most effective at reducing the risk of developing PIs.

KEYWORDS: monitoring devices, pressure injuries, pressure ulcers, prevention, wound care

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INTRODUCTION

Pressure injuries (PIs) are localized damage to the skin and/or underlying soft tissue usually over a bony prominence. Pressure injury occurs as a result of intense and/or prolonged pressure or pressure in combination with friction and shear.[1]

Pressure injuries significantly contribute to the overall morbidity and mortality across multiple healthcare settings. Studies have shown that 3% to 14% of patients develop a PI during hospitalization, accounting for a large proportion of the estimated 2.5 million new cases each year in the United States.[2,3] Estimates of the incidence of PI range from 0.4% to 38% in acute care hospitals, 2% to 24% in skilled nursing care facilities, and 0% to 17% in the home care setting.[4] Not all PIs are preventable, according to the National Pressure Ulcer Advisory Panel (NPUAP).[5]

Pressure injury–related wounds increase hospital costs significantly. In the United States, PI care is estimated near $11 billion annually, with costs between $500 and $130,000 per patient.[3] An emphasis on PI prevention related to modifiable risk factors remains critical work. Innovative monitoring devices that alert healthcare providers to the presence of PI risk factors and facilitate timely interventions are a cornerstone in avoiding an actual PI.

Monitoring devices can assess PI risk factors (eg, pressure, friction/shear, mobility) in real time, providing the potential for prevention of PI development. With early intervention resulting from the use of PI-monitoring devices, the quality of care in healthcare settings could improve. Existing devices involve support surfaces or dressings designed to relieve pressure between the patient and the underlying surface to minimize the risk of inducing tissue ischemia. More recently, devices are now being used to monitor factors such as motion, heat, and pressure to change standard-of-care behavior and prevent the development of PIs. There is a range of devices and tools that can assist with the prevention and treatment of PIs; however, conclusive information for PI-monitoring devices that can lead to a change of behavior after assessing various risk factors is lacking. The objective of this study was to systematically review and meta-analyze whether PI-monitoring devices are effective in reducing the risk of developing PIs. The authors hypothesized that there have been recent innovations in the use of effective monitoring devices for PI prevention and wound care.

METHODS

Literature Search

A literature search was performed to identify studies involving clinical trials of monitoring devices and methods for PI prevention. The PubMed/MEDLINE and CINAHL databases were searched from January 2005 through January 2016 with the following keywords: monitor, prevention and control, pressure, shear forces, moisture, friction, risk assessment scale, and incontinence; these terms were cross-referenced with pressure injury, pressure sore, pressure ulcer, and bed sore. The MeSH (Medical Subject Headings) terms and entry terms related to the keywords were used in this comprehensive literature review. The language of publication was limited to English. This search was supplemented by a review of the reference list of potentially eligible studies.

Selection Criteria

Clinical trials and cohort studies of monitoring devices that evaluated PIs (ulcers) and risk factors (pressure, friction/shear forces, moisture/incontinence, mobility, nutrition) on people of any grade in any setting were included in this study. The authors' exclusion criteria included case reports; conference abstracts; cross-sectional studies; ecological studies; the following intervention groups: monitoring of variables other than PI risk factors, pressure-relieving support surfaces without risk factor monitoring, risk assessment scales without risk factor monitoring, and any other management/treatment group without risk factor monitoring; and publications written in a language other than English.

Three reviewers independently screened titles, and 2 reviewers independently screened abstracts and full texts for selection. Full articles were retrieved and examined when the abstracts did not provide enough information for a definite decision. When the 2 reviewers were not in agreement, a third investigator was included, and consensus was reached after discussion.

Primary Predictor Variable and Outcome

The primary predictor variable was the use of monitoring devices for patients who were at risk of developing PIs. The primary outcome measure was the incidence of PIs. The secondary outcome was the cumulative overall incidence of PIs, stage of PIs, risk factors leading to the development of PIs, and related complications.

Data Extraction

A standardized data extraction form was used to record the following information regarding each included study: patient inclusion/exclusion criteria, care setting, key baseline variables (age, sex, baseline risk, baseline area of existing injuries), description of monitoring device and methodology, number of patients included in each group, description of any standard of care, follow-up period, outcomes (development of PIs, stage of PIs, risk factor levels, related complications), monitoring device adverse effects, and acceptability/reliability of equipment, if reported.

Risk of Bias in Individual Studies

The methodological and reporting quality of each study was appraised by a single reviewer and checked by a second reviewer using the Methodological Index for Non-randomized Studies (MINORS) instrument. For noncomparative studies, the MINORS score ranges from 1 to 16, and an article with a score of greater than 12 is considered high quality. For comparative studies, the MINORS score ranges from 1 to 24, and an article with a score of greater than 18 is considered high quality.

Statistical Analysis

Data from studies that reported on PI incidence as an outcome were included for meta-analysis to obtain a pooled estimate of the association between the use of monitoring devices and the risk of developing PIs. Stata v13.1 (StataCorp LP, College Station, Texas) was used. Results were assessed using Mantel-Haenszel risk ratios with 95% confidence intervals. The authors used random-effects or fixed-effects models as appropriate according to the heterogeneity of study settings, outcomes, patients, and interventions. The authors calculated statistical heterogeneity using inconsistency statistics (I^2); an I^2 value of 50% or more represented substantial heterogeneity. They calculated the ''number needed to treat'' for a better understanding

of treatment value to both the clinical and quality-of-life outcomes at a population level.

RESULTS

A total of 1866 publications were initially identified in the literature search, with an additional 19 identified through references of key articles. After removal of duplicate articles (342), exclusion of irrelevant titles or abstracts (1487), and reading the full texts of the remaining 56 retrieved articles, 9 articles with a total of 1270 patients met inclusion criteria (Figure 1).

Four of the studies were prospective controlled trials, 1 study was a retrospective controlled trial, and the remaining 4 studies were prospective observational studies (Table 1).[6–14] All of the studies demonstrated high methodological quality, with an average MINORS score of 19.4 for clinical trials and 12.2 for observational studies.

The primary outcomes varied among the 9 articles, including the number of new PIs developed and the amount of various measurements, such as peak interface pressures, deep muscle stresses, and motion to several biophysical measures, such as epidermal hydration, erythema (superficial reddening of the skin), melanin, and lipids.

Some instruments determine when risk factors have exceeded certain thresholds and subsequently notify either the patient or healthcare professional.[8] Other devices simply provide a visual tool, such as a pressure map, for the healthcare professional to utilize when repositioning each patient.[6,9–14] A few other included studies did not share the device measurements with patients or healthcare professionals. There seemed to be a clear emphasis on devices that are placed on, or embedded within, beds or wheelchairs.[6,8–13] Other included devices were external sensors that could be placed onto the patient's body and evaluate various risk factors, including moisture/incontinence and motion.[7]

Most studies found a strong decrease in PI incidence or peak pressure, or an increase in the particular study's favored outcomes (such as the rate of patient turns or amount of pressure reduction). Borzdynski et al[7] found significant positive correlations between visual inspection (using the Norton Risk Assessment Scale) and objective inspection (using a skin monitoring device) for epidermal hydration and erythema, which are both PI risk factors. Chenu et al[8] found a strong association between the use of a pressure-sensing mat placed on a wheelchair along with a tactical relaying unit and large reductions of pressure volume. They found that higher initial pressure volumes resulted in a greater decrease in pressure following use of the device.[8] In a prospective clinical study, Zimlichman et al[13] determined that motion level scores from a piezoelectric sensor placed under the bed have high positive correlations with several different components of the Norton Scale: physical condition, activity level, level of mobility, and incontinence. In another prospective clinical study, Sakai et al[10] found, using an interface pressure sensor built into a mattress, that patients who developed PIs were subject to high interface pressures (>100 mm Hg) for a mean of 8 hours, whereas patients subjected to only 4.5 hours did not develop PIs. Finally, Linder-Ganz et al[14] found that mean peak subdermal tissue stresses were estimated to be 3 to 5 times greater in subjects with spinal cord injury than without. This prospective clinical study showed that estimations via the Finite Element Analyses method can help change posture behavior to reduce the risk of developing PIs.[14] Behrendt et al[6] found that there was a significant reduction of 81.25% in the development of new and low-staged PIs when using a pressure-monitoring device placed on top of a bed. Siddiqui et al[12] also observed a significant reduction of 94% in the development of new and low-staged PIs with the use of a pressure-monitoring device placed on top of a bed. In a prospective clinical trial, Scott and Thurman[11] discovered that the use of a pressure-sensing mat on the bed along with a visible pressure map led to a mean peak

Figure 1.
PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES (PRISMA) STATEMENT OF SEARCH RESULTS

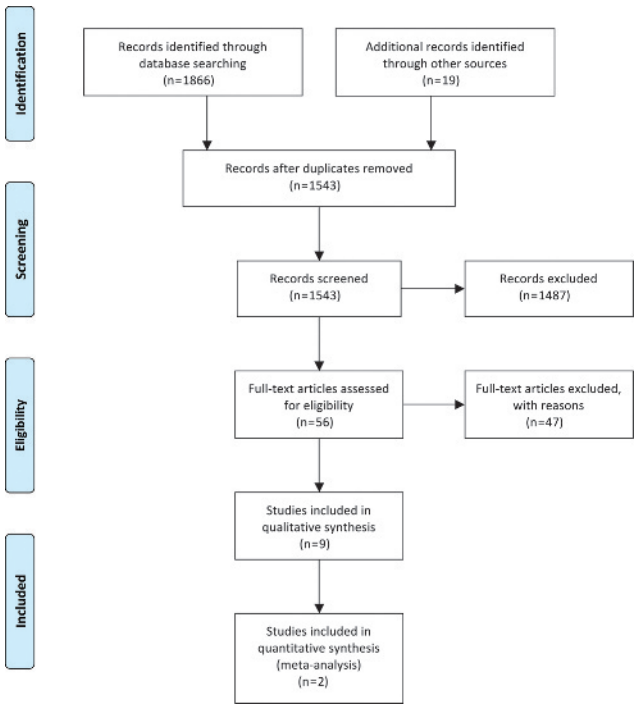


Table 1.
KEY CHARACTERISTICS OF INCLUDED ARTICLES

Article	Study Design	Monitoring Device	Measurement Feedback to:	n	Primary Outcome	MINORS Score
Behrendt et al[6]	Prospective controlled study	Pressure-sensing mat on bed	Healthcare provider	422	No. of new HAPUs developed	22/24
Borzdynski et al[7]	Prospective controlled study	Portable skin monitor	Data not shared	38	Measurements of epidermal hydration, melanin, erythema, and lipids	12/16
Chenu et al[8]	Prospective controlled study	Pressure-sensing mat on wheelchair	Patient	24	Amount of reduction in overpressure	19/24
Linder-Ganz et al[14]	Prospective controlled study	Personalized FE models	Data not shared	6	Interface pressure for FE analyses of deep muscle stresses	18/24
Motamedi et al[9]	Prospective clinical study	Pressure-sensing mat on bed	Healthcare provider	9	Rate of patient turns	19/24
Sakai et al[10]	Prospective clinical study	Pressure sensor built into mattress	Data not shared	30	No. of new HAPUs developed and interface pressure	13/16
Scott and Thurman[11]	Prospective clinical study	Pressure-sensing mat on bed	Healthcare provider	10	Peak interface pressures	13/16
Siddiqui et al[12]	Retrospective controlled study	Pressure-sensing mat on bed	Healthcare provider	627	No. of new HAPUs developed	19/24
Zimlichman et al[13]	Prospective clinical study	Piezoelectric sensor placed under bed	Data not shared	116	Motion data	12/16

Abbreviations: FE, finite element; HAPUs, hospital-acquired pressure ulcers; MINORS, Methodological Index for Non-randomized Studies.

pressure reduction of 31 mm Hg. In another prospective clinical trial, Motamedi et al[9] found an increase in the number of turns per hour after nurses observed the pressure map data from the sensors placed on top of the bed. The use of the pressure map in repositioning led to 0.491 (SD, 0.271) turns per hour, and the lack of pressure map data led to 0.327 (SD, 0.235) turns per hour.[9]

Of the 9 studies included in this review, only 2 cohort studies presented the same primary outcomes. Two studies were included in the meta-analysis of the primary outcome of incidence of PI, with 520 patients allocated to the PI-monitoring device group and 529 patients to the standard of care control group.[6,12] The groups' total sample size of 1049 patients was used to perform the meta-analysis. Both articles had homogenous patient groups and reported outcomes of the number of new PIs developed. Therefore, the authors used a fixed-effects model for the meta-analysis, which demonstrated that use of monitoring devices was associated with a statistically significant reduction of 88% in the risk of developing PIs (Mantel-Haenszel risk ratio, 0.12; 95% confidence interval, 0.04–0.41; $I^2 = 0\%$). The number needed to treat ranged from 21 to 26. The summary of the authors' meta-analysis data is shown in Table 2, with a corresponding forest plot in Figure 2.

DISCUSSION

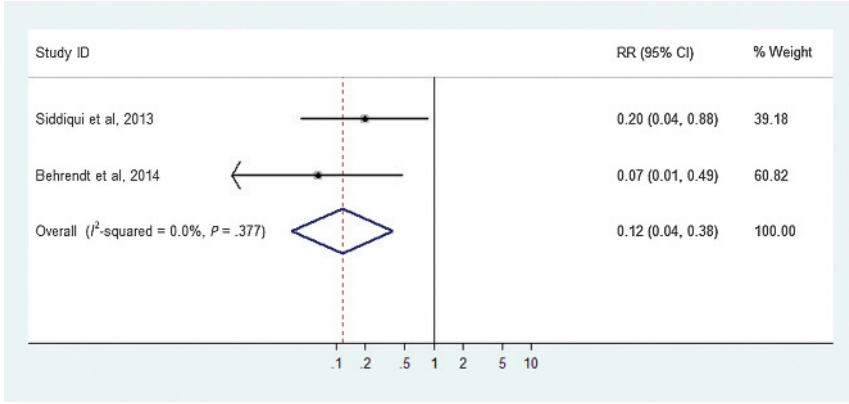
The purpose of this study was to determine whether pressure-monitoring devices decrease the risk of developing PIs in healthcare settings. The authors hypothesized that by providing clinicians and patients with critical early identification and evaluation of

Table 2.
META-ANALYSIS RESULTS

Study	Risk Ratio	95% Confidence Interval		% Weight
Siddiqui et al[12]	0.22	0.049–0.992		37.96
Behrendt et al[6]	0.066	0.009–0.495		62.04
Mantel-Haenszel pooled risk ratio	0.124	0.038	0.407	100

Heterogeneity $X^2_2 = 0.93$, $P = .335$.
I^2 (variation in risk ratio due to heterogeneity) = 0.0%.

Figure 2.
FOREST PLOT OF META-ANALYSIS DATA



the patient's real-time risk factors and encouraging the execution of PI prevention guidelines, PI-monitoring devices might decrease patients' risk of developing PIs. Through a scientific systematic review, all studies pertaining to the efficacy of monitoring devices in addressing and preventing PIs were identified and assigned a MINORS score. All studies included reported a significant reduction in the risk factors for and/or the incidence of PIs. The authors' meta-analysis showed that the risk of developing new PIs with the use of monitoring devices may be 88% lower than without the use of monitoring devices.

The types of monitoring devices used in the studies reviewed included pressure-sensing mats placed on beds or wheelchairs, and a skin care device with sensor technology.[6–8,11,12] Based on these results, pressure-monitoring devices may be an effective method of preventing PIs.

More literature has focused on PI prevention following the 2008 Centers for Medicare & Medicaid (CMS) nonpayment policies regarding hospital-acquired pressure ulcers (HAPUs [CMS terminology is HAPUs prior to NPUAP 2016 terminology changes]).[15] In response to the CMS economic policy incentives, more than 200 university hospitals have improved PI prevention efforts as shown by the significant decrease in HAPU incidence rates since the CMS nonpayment policy was implemented.[16] A previous cost-benefit analysis showed that preventive care of HAPUs not only decreased incidence and prevalence, but also led to lower expenditures and higher quality-adjusted life-years.[17]

Conventional PI prevention interventions aim to reduce either the magnitude or the duration of pressure. Support surfaces, positioning devices, and correct postures address the pressure magnitude, and repositioning, weight shifting, and active surfaces decrease duration of pressure.[18] Another common prevention technique includes frequent repositioning that involves lateral tilt and head elevation. However, Nanjo et al[19] suggested that these techniques may actually cause, instead of prevent, sacral skin ''leaf-type'' PIs in ICU patients.

Recently, pressure-monitoring devices have been implemented in an attempt to objectively target and prevent PIs. Most of these devices incorporate pressure sensor mapping on patient beds and/or wheelchairs. This is a beneficial adjunct in PI prevention, especially for immobile and cognitively unaware patients. The care staff is alerted, and reminded, that timely pressure relief and redistribution are necessary. Therefore, these devices have the potential to reduce the incidence of PI development. One limitation is that current monitoring devices address pressure, which is only one of the numerous risks responsible for PI development. Device limitations are noted in the inability to address other modifiable risk factors, such as skin care, moisture level, microclimate, or nutrition. Other limitations involve the caregiver's response to the actual device alert, including available resources, protocols, staff experience, and overall quality of care execution. Although pressure recognition and management represent a single effort in PI reduction, an approach addressing the multiple causes of PI development could prove a more reliable and successful tool.

When implementing PI prevention protocols, it is important to incorporate evidence-based practice protocols. Five quality improvement (QI) interventions have been shown to be clinically effective in reducing Stages 3 and 4 HAPU incidence rates: leadership initiatives, visual tools, HAPU staging, skin care, and nutrition.[3] The last 3 QI interventions—HAPU staging, skin care, and nutrition—are considered part of the set of recommended evidence-based

practices by the NPUAP to prevent HAPUs and should be considered when developing new PI-monitoring devices.[20]

The authors' literature search focused on actual monitoring devices rather than preventive PI devices. Of the 9 studies that met the inclusion criterion, only 2 studies used the same primary outcomes and were cohort studies with large sample sizes (n > 100). Although this meta-analysis demonstrated a significant decrease in PI incidence, this estimate is based on 2 observational studies conducted in very similar sets of patients and identical settings, providers, and interventions. This field lacks high-quality studies to investigate whether this association is truly causal or if it may have resulted from bias or confounding. An expanded evidence base may also help recommend predictively valid risk factors.

Well-controlled, large, prospective cohort studies or randomized controlled trials are needed to evaluate the efficacy of PI-monitoring devices. Although not included in this study's inclusion criteria, a cost-benefit analysis of the pressure-monitoring devices should also be considered when evaluating its efficacy. None of the studies reviewed assessed the cost-benefit of the pressure-monitoring device; however, it is important to assess cost when implementing a device as part of a prevention protocol in clinical practice.

The future of PI prevention may lie in the integration of technology and preventive care. Although some medical centers are incorporating pressure-monitoring devices into their prevention protocols, most devices display only pressure areas and remind nurses to reposition the patient. A PI prevention device is needed to not only alert and monitor, but also to actively prevent the development of PIs by integrating a response to the identified risk factors. The authors suggest that a device that could address the 5 QI interventions and identify underlying causes would be more effective in decreasing PI incidence.

LIMITATIONS

As with all meta-analyses, the most significant limitation is the included studies. Although all were high quality as determined by the MINORS scoring system, they were all observational studies, with no randomized controlled trials available in the literature to review. Differences between patient populations and classification of PIs and related complications between publications further limit this review. Another limitation is that not all available monitoring devices are studied or discussed in publications. In addition, a few monitoring devices have formal evaluations for efficacy that are available in the literature. This systematic review also limited the inclusion criteria to study publications in only English.

CONCLUSIONS

Based on systematic review and meta-analysis, the current literature demonstrates that PI-monitoring devices are associated with a strong reduction in the risk of developing PIs. These devices provide clinicians and patients with critical information to implement prevention guidelines. Randomized controlled trials would help assess which technologies are most effective at reducing the risk of developing PIs.

PRACTICE PEARLS

- This study reports that the use of current monitoring devices is associated with an 88% reduction in the risk of developing PIs.
- These devices provide clinicians and patients with critical information to successfully implement prevention guidelines.
- Future monitoring devices should monitor risk factors, alert healthcare providers, and actively respond to identified risk factors.
- A cost-effectiveness analysis of monitoring devices must be taken into account to ensure the best possible integration of the technology into prevention protocols.

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