Unavoidable Pressure Ulcers

Development and Testing of the Indiana University Health Pressure Ulcer Prevention Inventory

Joyce Pittman ■ Terrie Beeson ■ Colin Terry ■ Jill Dillon ■ Charity Hampton ■ Denise Kerley ■ Judith Mosier ■ Ellen Gumiela ■ Jessica Tucker

ABSTRACT

PURPOSE: Despite prevention strategies, hospital-acquired pressure ulcers (HAPUs) continue to occur in the acute care setting. The purpose of this study was to develop an operational definition of and an instrument for identifying avoidable/unavoidable HAPUs in the acute care setting.

METHODS: The Indiana University Health Pressure Ulcer Prevention Inventory (PUPI) was developed and psychometric testing was performed. A retrospective pilot study of 31 adult hospitalized patients with an HAPU was conducted using the PUPI.

RESULTS: Overall content validity index of 0.99 and individual item content validity index scores (0.9-1.0) demonstrated excellent content validity. Acceptable PUPI criterion validity was demonstrated with no statistically significant differences between wound specialists’ and other panel experts’ scoring. Construct validity findings were acceptable with no statistically significant differences among avoidable or unavoidable HAPU patients and their Braden Scale total scores. Interrater reliability was acceptable with perfect agreement on the total PUPI score between raters (κ = 1.0; P = .025). Raters were in total agreement 93% (242/260) of the time on all 12 individual PUPI items. No risk factors were found to be significantly associated with unavoidable HAPUs.

CONCLUSION: An operational definition of and an instrument for identifying avoidable/unavoidable HAPUs in the acute care setting were developed and tested. The instrument provides an objective and structured method for identifying avoidable/unavoidable HAPUs. The PUPI provides an additional method that could be used in root-cause analyses and when reporting adverse pressure ulcer events.

KEY WORDS: Braden, Instrument, Pressure ulcers, Psychometric testing, Unavoidable pressure ulcers.

Introduction

Pressure ulcers (PUs) have been defined by the National Pressure Ulcer Advisory Panel (NPUAP) and European Pressure Ulcer Advisory Panel (EPUAP) as “is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear”. Nearly 2.5 million persons are treated for PUs annually and 60,000 acute care patients die from related complications. The reported incidence of PUs (number of new patients who develop a PU within a specified period) varies from 0.4% to 38% in acute care, from 0% to 17% in home care, and from 2.2% to 23% in long-term care.

Pressure ulcers cause pain, impair physical function, extend hospital stays, and increase costs. The cost of treating pressure injuries in the United States is approximately $11 billion a year. Since 1993, there has been a 78.9% increase in hospital stays related to PUs. Hospital stays with a secondary diagnosis of PUs increased by 86.4% during this same time period, while the total number of hospitalizations increased only by 15%. Mortality rates are reported to be higher for PU-related hospitalizations. In-hospital death occurred in almost 12% of stays; PUs were noted as a secondary diagnosis as compared with 4.2% of stays with PUs as a primary diagnosis and 2.6% for all other conditions.
Pressure ulcer development is considered a quality indicator across healthcare systems. Increased scrutiny and reduced payment or nonpayment for hospital-acquired pressure ulcers (HAPUs) by the Center for Medicare & Medicaid Services (CMS) has made the prevention and early detection of PUs a prominent quality improvement initiative of healthcare systems across the country. The goal for PU prevention is to achieve zero hospital-acquired pressure injuries. Prevention strategies are imperative to decreasing the number of HAPUs and have been implemented in most acute care settings. The 5 Million Lives Campaign by the Institute for Healthcare Improvement recommends “preventing pressure ulcers by reliably using science-based guidelines for their prevention.” The campaign promoted 2 steps in PU prevention: identifying patients at risk and reliably implementing prevention strategies for all patients deemed at risk. Key elements of a PU prevention program include (1) assessment on admission assessment for all patients, (2) daily risk assessments, (3) daily skin inspection, (4) moisture management, (5) optimizing nutrition and hydration, and (6) minimizing pressure. Considerable discussion among expert wound clinicians and providers has focused on whether all PUs are preventable. Pressure ulcer incidence rates have remained stable, indicating failure of known effective preventative treatment and safeguard strategies in some patients. This raises the question, are all PUs avoidable? Definitions for avoidable versus unavoidable PUs for the acute care setting have not yet been adopted officially by regulatory agencies. In contrast, the CMS has issued a statement that PUs should be prevented in residents of long-term care settings “unless the individuals’ clinical condition demonstrates that they were unavoidable.”

The NPUAP has agreed that not all PUs are preventable. A statement issued by the NPUAP in March 2010 stated that there are clinical situations in which the development of PUs can be unavoidable. In February 2014, the NPUAP held a consensus conference to explore this issue. Using an organ system framework, NPUAP experts explored the issue of avoidable/unavoidable PUs for the acute care setting have not yet been adopted officially by regulatory agencies. In contrast, the CMS has issued a statement that PUs should be prevented in residents of long-term care settings “unless the individuals’ clinical condition demonstrates that they were unavoidable.”

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Using the CMS’s definitions, the NPUAP defined unavoidable PUs as those PUs that develop even though the provider (1) evaluated the individual’s clinical condition and PU risk factors; (2) defined and implemented interventions consistent with individual needs, goals, and recognized standards of practice; (3) monitored and evaluated the impact of the interventions; and (4) revised the approaches as appropriate. This definition is helpful; however, it is conceptual rather than operational (ie, it does not provide practical application).

The NPUAP definition and the Braden conceptual model for PUs were used as an underlying framework to guide this study. The Braden conceptual model for the development of pressure ulcers is organized into 2 critical components: duration/intensity of pressure and tissue tolerance. Tissue tolerance is further classified into intrinsic and extrinsic factors that contribute to the development of PUs. In the Braden model, intrinsic factors are those that are inherent to the individual and contribute to the underlying structure and integrity of the supporting features of the skin and the vascular and lymphatic systems (nutrition, age, and arterial pressure). Extrinsic factors are those factors that influence tissue tolerance by affecting the skin surface (moisture, friction, and/or shear forces). Using both the NPUAP definition and the Braden concepts for intrinsic and extrinsic risk factors, we developed the operational definition and the instrument to identify avoidable/unavoidable HAPUs in the acute care setting.

Operational Definitions and Instrument Development

The NPUAP definitions for avoidable and unavoidable HAPUs were accepted for use in this study by the research team after a thorough review of the literature. The 4 concepts in the NPUAP’s definition include evaluating the clinical condition and risk of the individual, implementing appropriate interventions, monitoring and evaluating the effect of those interventions, and then revising the interventions if needed. However, the team recognized them as conceptual rather than operational definitions. Therefore, operational definitions were developed.

Evaluation of clinical condition was operationally defined as completion of (1) a history and physical assessment, (2) PU risk assessment upon admission and according to organizational policy using the Braden Scale for Pressure Risk, and (3) skin assessment upon admission. Determining and implementing interventions consistent with individual’s needs, goals, and recognized standards of practice were defined based on Braden subscale (sensory perception, moisture, activity, mobility, nutrition, and friction/shear) scores. The minimum number of appropriate interventions implemented was determined for each subscale score. Monitoring and evaluating the effects of the interventions were based on completion of a skin assessment every shift. Finally, revision of the interventions as appropriate was defined using Braden subscales and minimum number of appropriate interventions for each subscale score.

We then developed an instrument, the Indiana University Health Pressure Ulcer Prevention Inventory (PUPI), to measure the 4 components described earlier (Figure 1). The PUPI was used to review the medical record of patients who developed a stage II, III, IV, unstageable,
or suspected deep tissue injury during their hospital stay. Records were reviewed by trained research team members.

The PUI contains items requiring dichotomous responses (yes/no) for the patient’s history and physical examination, the Braden Scale for Pressure Ulcer Risk score according to policy, and skin assessment; all of these elements are completed upon admission. A dichotomous response (yes/no) was also used to determine the appropriateness of the interventions for each Braden sub-scale, skin assessment every shift, and revision of interventions as appropriate. If all items were answered as yes/appropriate, the HAPU was deemed unavoidable.

The purpose of this study was to (1) develop an operational definition for hospital-acquired avoidable and

<table>
<thead>
<tr>
<th>HAPU Location:</th>
<th>Sacrum/Coccyx</th>
<th>Ischium</th>
<th>Hip</th>
<th>Heel</th>
<th>Occipital</th>
<th>Ear</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAPU Laterality:</td>
<td>1=Right</td>
<td>2=Left</td>
<td>3=Midline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HAPU Stage:</td>
<td>1=DTI</td>
<td>2=2</td>
<td>3=3</td>
<td>4=4</td>
<td>5=Unstageable</td>
<td></td>
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Review medical record 3 days prior to the documented development of the HAPU
Assign the appropriate score for each item:
1= NO, not appropriate 2= YES, appropriate

1. Clinical Condition Evaluation
   - History and Physical completed upon admission
   - Braden Pressure Ulcer Assessment upon admission
   - Braden Pressure Ulcer Assessment per policy (daily or every shift)
   - Skin assessment (Nursing) completed upon admission

2. Defined and Implemented Intervention(s) consistent with Patient’s Needs
   - 2.1 Sensory Perception Interventions
     - Date______ Appropriate?
   - 2.2 Moisture Interventions
     - Date______ Appropriate?
   - 2.3 Activity Interventions
     - Date______ Appropriate?
   - 2.4 Mobility Interventions
     - Date______ Appropriate?
   - 2.5 Nutritional Interventions
     - Date______ Appropriate?
   2.6 Friction & Shear Interventions
     - Date______ Appropriate?

3. Monitored/ Evaluated Impact of Interventions
   - Skin Assessment completed every shift

4. Revised Interventions as Appropriate

Summary/ Conclusion

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FIGURE 1. Indiana University Pressure Ulcer Prevention Inventory. HAPU hospital-acquired pressure ulcer; DTI, deep tissue injury.
unavoidable PUs, (2) develop an instrument to identify hospital-acquired avoidable and unavoidable PUs (PUPI), and (3) examine the validity and reliability of the newly developed instrument. Specific aims include evaluation of (1) content and criterion validity of the PUPI, (2) construct validity of the PUPI, and (3) interrater reliability of the PUPI.

Methods

A descriptive, retrospective, nonexperimental design was used to test the psychometric properties of the instrument we designed to identify avoidable/unavoidable HAPUs. During phase 1, we developed and tested an operational definition for avoidable/unavoidable HAPUs and the PUPI based on the NPUAP’s conceptual definition for avoidable/unavoidable PUs, the Braden conceptual model for PUs, and a thorough review of the literature. A multidisciplinary group of 10 healthcare experts from academic and specialty areas, including a nurse educator/researcher (PhD), nursing administrator (PhD), 2 direct care nurses (RN), physician (MD), and 5 wound specialists (4 certified WOC nurses and a clinical wound specialist [CNS]) was used to determine content and criterion validity.

During phase 2, pilot testing of the PUPI was performed, collecting data from the medical records of 31 adult hospitalized patients with an HAPU from 3 acute care settings within a large academic healthcare organization. One site was a 750-bed level I trauma hospital, the second was a 400-bed university academic teaching hospital, and the third was a 300-bed community hospital. Construct validity and interrater reliability of the newly developed PUPI were tested. Relationships among demographic, intrinsic, and extrinsic factors were also examined. Indiana University Health institutional review board approval was obtained prior to the onset of data collection.

Study Procedures

Guidelines for developing instruments, established by DeVellis,14 were followed for the development of the instrument to measure unavoidable PUs. These guidelines recommend a stepwise approach that begins with (1) clearly identifying the construct to be measured, (2) choosing items that reflect the instrument’s purpose, (3) determining the format for measurement, and (4) including expert review of the items.14 The panel of experts was asked to rate the content for relevance, clarity, comprehensiveness, and appropriateness using a content validity survey.

In order to determine reliability of the newly developed PUPI and to examine potential risk factors, a pilot study of adult patients who developed an HAPU (stage II, III, IV, unstageable, or deep tissue injury) during their hospital stay was conducted. Thirty-one patients were identified through International Classification of Diseases, Ninth Revision, coding procedures, monthly PU prevalence surveys, or incidence reporting process. Trained research team members collected data from the electronic medical record on these patients using the PUPI.

Two investigator-developed forms were used to collect (1) demographic and clinical information; and (2) Braden subscale and total scores, and (3) which pressure ulcer prevention interventions were implemented. The information collected on these forms was chosen based on the Braden conceptual framework of extrinsic and intrinsic factors. Extrinsic factors included length of stay, moisture status (incontinence), prolonged duration of pressure (emergency room time, procedure time, operating room time), level of care, prehospital location (home, nursing home, etc), and PU prevention interventions implemented. Intrinsic factors included age, gender, race, ethnicity, comorbidities, tissue perfusion (FiO2, hemoglobin, hematocrit, blood pressure, mechanical ventilation, chemically sedated, vasopressor use, etc), hypothermia (induced, permissive) measures, steroids, nutrition status, body temperature, dialysis, smoking status, and glucose. The clinical data for each subject were collected 7 days prior to development of a PU. Braden Scale scores (subscale and total) and interventions implemented were measured 3 days prior to development of a PU.

Data Analysis

Demographic measures were summarized using descriptive statistics. These data were summarized for all patients. We also summarized for 2 patient subsets, those with avoidable PU and those with unavoidable PU. Continuous variables were reported using mean (standard deviation) and were compared between patient subgroups using Student t tests. Categorical variables were reported as count (percent) and were compared between patient subgroups using the Fisher exact tests. Analyses were performed using SPSS Statistics (IBM Corp, Chicago, Illinois) and R (R Foundation for Statistical Computing). Specific analytic procedures used to address each study aim are described in detail later.

Results

The medical records of 31 hospitalized patients were examined. Patient characteristics are summarized in Table 1. Twelve (39%) of the 31 patients’ HAPUs were determined to be unavoidable. Clinical characteristics of those patients with an unavoidable HAPU are summarized in Table 2. None of the extrinsic or extrinsic characteristics were found to be significantly associated with unavoidable HAPU except Braden subscale mobility day 1.

Aim 1: Evaluate the Content and Criterion Validity of the PUPI

Content validity of the PUPI was examined using a 2-stage approach: (1) developmental stage in which a thorough literature review and generation of instrument items were
performed; and (2) judgment/quantification stage in which a select panel of content experts evaluated and rated the instrument item’s relevance to the domain of interest. Content validity indices (CVIs) were calculated to determine validity of the criteria for describing avoidable and unavoidable PUs. The CVI was computed for the proportion of experts who are in agreement on individual items and the overall scale. The overall total CVI of 0.99 and individual item CVI scores (0.9-1.0) demonstrated excellent content validity.

We also examined criterion validity. Criterion validity is concerned with measuring the instrument against a known or standard measure. We wanted to know if the content validity scoring differed between the wound experts (WOC nurses and clinical wound specialists) and the other experts (1 MD, 2 direct care nurses, 1 nurse researcher PhD, 1 nurse administrator PhD) on the panel. We found no statistically significant differences comparing the wound specialists’ and other experts’ scoring on all survey items, demonstrating acceptable PUPI criterion content validity.

**Aim 2: Evaluate the Construct Validity of the PUPI**

No statistically significant differences were found between avoidable and unavoidable patient groups or the Braden conceptual model concepts (sensory perception, activity, moisture, nutrition or friction/shear subscale scores, or total Braden Scale scores) except for one, mobility. There was a significant difference between the avoidable and unavoidable groups related to the Braden mobility subscale score ($P = .000$) only on day 1 (not day 2 or 3).

**Aim 3: Evaluate the Interrater Reliability of the PUPI**

We used the Cohen $\kappa$ to assess the interrater reliability of the PUPI. Five subjects were evaluated by 2 raters who were in perfect agreement on PU avoidability ($\kappa = 1.0; P = .025$). Since the number of patients evaluated by both raters was relatively small, each item of the PUPI was also assessed to check the percentage of agreement between raters. Of the 260 individual items, the raters agreed on 242 (93%) items.

In summary, the PUPI demonstrated acceptable psychometric properties. We also found no significant relationships among all but one of the risk factors and avoidable or unavoidable HAPUs.

**Discussion**

This study provides important new knowledge regarding the identification of avoidable and unavoidable HAPUs in the acute care setting. Contributions of this study include an evidence-based operational definition for determining avoidable/unavoidable HAPUs in the acute care setting, important evidence of validity and reliability of an instrument to measure unavoidable HAPUs, and information regarding relationships among risk factors and the development of HAPUs. In order to complete the PUPI, trained research team investigators reviewed the medical record for documentation of appropriate and specific PU prevention interventions for each Braden subscale to determine if appropriate care was given to the patient in our setting. The Braden Scale scoring deemed necessary was a minimum of every 12 hours to assess patient acuity changes with appropriate measures implemented and documented. While the PUPI was designed with most healthcare settings in mind using general time frames, completion of the Braden Scale every 12 hours is the standard in our acute care setting and was used in this study. It was imperative that 100% of the interventions or supporting documentation be present consistently in order for the pressure ulcer to be considered unavoidable.

The demographic intake form consisted of demographic and potential risk factors identified on admission.
and 7 days prior to the development of HAPUs. Although no risk factors were found to be statistically associated with avoidable or unavoidable HAPUs, it has been recognized that extrinsic and intrinsic factors influence tissue tolerance. This study collected data retrospectively, and all patients had an HAPU. As a result, there was no control group (patients with no HAPU) to compare relationships among risk factors and subjects. Risk factors have been studied independently and in combination with other factors in multiple venues of acute care looking for predisposing indicators to PU development. Other researchers have identified sepsis, temperature, and mechanical ventilation as risk factors for PU development.

Our study results are consistent with these findings; half of the patients with unavoidable HAPUs in our study were mechanically ventilated in a critical care unit. In addition, we found that 58% of patients with an unavoidable HAPU had fecal incontinence. Fecal incontinence increases the patient’s vulnerability for skin and soft tissue infection, urinary tract infection, and nosocomial infection. It is a major cause of incontinence-associated dermatitis and is associated with PU development.

Aim 1 focused on establishing content and criterion validity of the PUPI. The PUPI demonstrated excellent content and criterion validity. We found no statistically significant differences comparing wound experts’ and other experts’ scoring on all survey items. Experts’ level of wound knowledge ranged from direct care nurses to certified wound specialists to physicians and doctorally prepared nurses. These findings demonstrate the ease of use of the PUPI in a clinical setting.

In order to address aim 2, we examined construct validity, which is concerned with the theoretical relationship of the underlying concepts the instrument is based on. We examined relationships within the PUPI items and the Braden conceptual model concepts (extrinsic and intrinsic variables). All patients in this study had an HAPU, and we did not expect to find any differences among these patients and the Braden Scale scores. As anticipated, we found no statistically significant differences among both patient groups (avoidable and unavoidable) and the Braden conceptual model concepts (sensory perception, activity, moisture, nutrition, or friction/shear subscale scores or total Braden Scale scores) except for one, mobility. However, the direction of the relationship between mobility on day 1 and avoidable/unavoidable HAPUs is unclear and warrants further study.

In aim 3, we examined interrater reliability in 5 patients; a larger sample is needed to confirm these findings. For this reason, the percentage of agreement between raters was also examined and confirmed the interrater reliability findings.

**Limitations**

Several limitations of this study are evident. The sample was small, which limits generalizability of our findings. Second, the study was conducted at a large healthcare system with high patient acuity and may not be generalized to other settings. Outcomes relied upon the accuracy of the documentation in the electronic medical record. In our medical record review, the complexity of the electronic medical record was evident. Finally, a larger sample with a control group is needed to explore relationships of extrinsic and intrinsic risk factors to unavoidable HAPUs.

This study had several strengths, one being the inclusion of direct care nurses on the research team. These nurses were crucial in the development of the PUPI, data collection forms, and the review of the medical record of the participants. They kept the research team grounded in real-life nursing practice and enabled the team to be clinically practical and focused. Another strength was the expertise and interdisciplinary composition of the expert panel. Finally, the study provides a clinically practical instrument for determining whether an HAPU is unavoidable and whether all appropriate care was provided according to the patient’s condition. The PUPI provides an additional technique for root-cause analyses and when reporting adverse PU events in a highly reliable organization.

**Conclusion**

The NPUAP has provided a conceptual definition for avoidable and unavoidable PUs. However, this definition is difficult to operationalize and put into practice. We operationalized these definitions and developed a valid and reliable instrument for identifying avoidable and unavoidable HAPUs.

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**References**