



Designing a Predictive Tool for Pressure Ulcer Occurrence in Bedridden Patients in Intensive Care Units: A Protocol for a Multi-Method Study

Iman Jafari-Iraqi ¹, Amir Vahedian-Azimi ², Salman Barasteh ², Masoud Sirati-Nir ^{3*}

¹ Student Research Committee, Baqiyatallah University of Medical Sciences, Tehran, Iran

² Nursing Care Research Center, Clinical Sciences institute, Nursing Faculty, Baqiyatallah University of Medical Sciences, Tehran, Iran

³ Behavioral Sciences research center, Nursing faculty, Baqiyatallah university of medical sciences, Tehran, Iran

***Corresponding Author:** Masoud Sirati-Nir, Behavioral Sciences research center, Nursing faculty, Baqiyatallah university of medical sciences, P.O. Box 19575-174, Sheykh Bahayi Street, Vanak Square, Tehran 1435 9153 71, Iran. ORCID ID: 0000-0001-8319-3220, Email: masoudsirati@gmail.com

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Abstract

Introduction: Early identification of pressure ulcers (PUs) is essential to provide timely therapeutic interventions and customized preventive measures for bedridden patients in the ICU. However, the current PU assessment tools lack transparency and objectivity, so developing a comprehensive and reliable tool suitable for ICU patients is necessary. The purpose of the protocol study is to demonstrate the design process of an assessment tool for predicting PUs in ICU bedridden patients using a multi-method approach.

Methods: This study will employ a sequential multi-method research design comprising three stages: a scoping review, Delphi methods, and a cross-sectional study. In the first stage, the scoping review examined ICU patients' risk factors for PUs. It will also identify potential predictors for PUs based on relevant published studies. Moving onto the second stage, a panel of experts in the field evaluated these predictors through three consecutive Delphi rounds. Their opinions will be considered, and any new factors suggested will be added to the list. The third Delphi round will aim to achieve over 75% agreement among the experts, resulting in the final version of the potential predictor list. Lastly, in the third stage, a cross-sectional study was conducted to assess the relative contribution of potential predictors to the development or worsening of PUs in ICU patients. The information and results from this study will be used to develop a pressure ulcer assessment tool for bedridden patients in ICUs.

Discussion: This study employs a multi-method approach that combines various assessment tools, including comprehensive reviews, expert opinions, and objective clinical measurements. The resulting assessment tool will enable clinicians to predict the occurrence of PUs accurately, implement personalized preventive strategies and optimize resource allocation. Enhancing early detection and prevention of PUs can significantly improve patient well-being, reduce healthcare burdens, and achieve better long-term outcomes.

Keywords: Pressure Ulcer, Pressure Injury, Bedridden Patients, Intensive Care Units.

Introduction

PUs, also known as pressure injuries (PIs), are a prevalent, painful and costly health issue in most healthcare centers, which pose significant challenges to healthcare professionals and often lead to detrimental consequences ^{1,2}. The cost of treating these ulcers is 2.5 times higher than preventing them ³. The existing literature indicates that the global prevalence of PUs ranges from 6% to 18.5% ⁴⁻⁶. A meta-

analysis conducted in Iran found the total prevalence of PUs in ICU patients to be 19.6% ⁷. PUs are localized skin and underlying tissue injuries caused by prolonged pressure or a combination of pressure and shearing on bony prominences such as the sacrum, heels, and elbows ⁸. Specific populations, such as those with spinal cord injuries, older adults, and ICU patients, are at a higher risk of developing PU ^{9,10}. The most common factors contributing to hospital PUs are immobility, poor

nutrition, sensory loss, impaired consciousness, and friction and shear^{11,12}. Patients in ICUs are particularly susceptible to PUs due to invasive procedures like central vascular lines and mechanical ventilation^{13,14}. If untreated, PUs can significantly harm patients' quality of life, leading to increased morbidity and mortality¹⁵. The effects of PUs go beyond physical pain, leading to psychological distress, extended hospital stays, and increased healthcare costs^{16,17}. This emphasizes the critical importance of implementing early intervention and prevention strategies.

Timely diagnosis is crucial in managing PUs, as early identification allows for prompt therapeutic interventions to reduce their severity and prevent further development¹⁸. Given the multifactorial nature of pressure ulcer formation, identifying potential risk factors is essential. This process improves patient care practices and allows for tailored preventive measures^{19,20}. Risk factors may be associated with demographic elements such as age, sex, and body mass index, as well as clinical conditions, including anemia, hypoalbuminemia, diabetes, hypotension, and low physical activity. Additionally, the quality of care received—such as inadequate hospital and nursing care—can play a significant role. Medical devices, like mechanical ventilators or tracheostomy tubes, and the type of treatment administered, including vasoactive and sedative therapy, are also important factors to consider^{13,14,21,22}. Therefore, it is important to have a comprehensive understanding of all risk factors to adopt a proactive approach to managing PUs, predicting their occurrence, detecting them early, and reducing their incidence²³.

One preventive approach involves developing assessment tools to measure and predict the risk of developing PUs based on known risk factors. The three most widely used scales are the Braden, Norton, and Waterlow scales²⁴⁻²⁶. The Braden scale comprises six items: sensory perception, moisture, activity, mobility, nutrition, friction, and shearing^{24,27}. The Norton scale includes five items: physical condition, mental condition, activity, mobility, and incontinence²⁸. The Waterlow scale consists of nine items: build/weight for height, visual assessment of the skin in the at-risk area, sex and age, continence, mobility, malnutrition screening tool score, and unique risk factors such as tissue malnutrition, neurological deficit, and significant surgery or trauma^{25,29}. All three scales incorporate

several risk factors, but only a few are shared: activity, mobility, nutrition/malnutrition, incontinence, and cognition. Each scale assigns different weights to these factors, contributing to their variability. Although these scales are widely used in healthcare settings to assess the risk of developing PUs, they have limitations regarding transparency and objectivity^{28,30}. They primarily rely on clinical judgment and subjective assessments, leading to varying interpretations of subscales and inconsistencies in risk assessment for PUs and heterogeneity among assessors^{27,31,32}. These factors can also affect the accuracy and reliability of the predictions^{33,34}. Furthermore, these scales may not sufficiently consider individual variations and factors that increase the risk of PUs³⁵. For example, the assessment scales may not consider certain medical conditions or comorbidities that can increase the risk of developing PUs. As a result, despite the long-term use of these tools, they have limitations, including inadequate accuracy, limited transparency, and varying sensitivities and specificities among different assessors and patient populations^{30,36,37}. Healthcare professionals should be cautious and consider other factors when using these scales to ensure accurate risk assessments³⁸. There is an urgent need for more objective and comprehensive factors to predict the occurrence of PUs accurately. To improve the accuracy and reliability of pressure ulcer risk assessments, it is essential to develop and implement new or modified tools that effectively address the existing limitations. Designing a predictive tool for pressure ulcer occurrence in bedridden patients within intensive care units (ICUs) is essential to reduce the significant morbidity and mortality associated with these injuries. This study aims to develop a specialized tool specifically for bedridden ICU patients. Using this tool is expected to enhance clinical decision-making, encourage proactive interventions, and ultimately decrease the occurrence of PUs in this vulnerable population, thereby improving their overall care and well-being.

Methods

Protocol setting and ethical approval

This study will utilize a multimethod sequential research design³⁹ comprising three phases: a scoping review, Delphi methods, and a cross-sectional study. This comprehensive approach will combine three

research designs to achieve the study's objectives⁴⁰. The study protocol will be under review and was approved by the Ethics Committee of Baqiyatallah University of Medical Sciences based on the principles outlined in the Declaration of Helsinki by the World Medical Association⁴¹. Additionally, a segment of the initial phase of the study (scoping review) has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) under the registration code (CRD42023454892).

Scoping review (Phase 1)

To conduct the scoping review, we will follow the methods proposed by Arksey and O'Malley⁴² and Levac et al.⁴³, which consist of five stages: defining research questions, identifying relevant studies, selecting eligible studies, extracting data, and summarizing and reporting results. The data extraction process will adhere to the Joanna Briggs Institute (JBI) methodology⁴⁴. This review will investigate the risk factors for PUs in bedridden patients within the ICU, adhering to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement⁴⁵.

Research questions

The primary research question of this scoping review is "What are the risk factors for pressure ulcer development or exacerbation in bedridden patients in the ICU?" This question served as a guide for the review and will be supplemented by additional specific questions such as:

1. Which demographic and clinical characteristics of ICU patients play a role in developing or exacerbating PUs?
2. Which care behaviors of the ICU medical and nursing staff play a role in developing or exacerbating PUs?
3. Which risk factors related to medical equipment and devices play a role in developing or exacerbating PUs in ICU patients?
4. Which risk factors related to treatment play a role in developing or exacerbating PUs in ICU patients?

Identifying relevant studies

To identify all relevant studies regarding the risk factors for pressure ulcer development or exacerbation in bedridden patients, we will conduct a comprehensive search in the following databases from their inception until November 1, 2023: MEDLINE/PubMed, Scopus,

Web of Science, Embase, Cochrane Library, MagIran, Iran Medex, and State Inpatient Databases (SID). The search strategy will use a combination of keywords and Medical Subject Headings (MeSH) terms related to the research question. These terms include "Pressure sor*," "Pressure Ulce*," "Pressure injur*," "Bed sor*," "Decubit* ulce*," "Decubit* sor*," "Decubit* injur*," "Skin sor*," "Skin Ulce*," "Skin injur*," "Skin defect," "Bed injur*," "Bed ulce*," "decubit* wound*," and "decubit* damage*." Additionally, we will use Boolean operators to combine these terms with keywords such as Predic*, "at risk," early, and risk.

Two researchers will independently perform all the search steps. To ensure the rigor and comprehensiveness of the search strategy, an expert informationist will conduct a peer review of electronic search strategies (PRESS). We will also search grey literature databases such as EThoS and OpenGrey to minimize publication bias and include relevant studies. Furthermore, we will manually search the reference lists of potentially eligible papers.

Eligibility criteria for relevant studies

We will apply the PICO framework to establish our inclusion and exclusion criteria, ensuring we consider all relevant studies on the risk factors for PUs in bedridden ICU patients. We will include all available full-text studies with various designs, encompassing randomized controlled trials (RCTs), case-control studies, cross-sectional studies, prospective or retrospective cohort studies, quasi-experimental studies, and systematic reviews, with or without meta-analysis. We will establish the following inclusion criteria for our scoping review: Population - bedridden ICU patients who are 18 years or older and have been in the ICU for more than 24 hours; Intervention/exposure - no specific intervention/exposure; Comparison - no specific comparison; Outcome - studies that investigate the risk factors for pressure ulcer development or exacerbation. We will only include studies conducted in English or Persian and have full text available without any restrictions on the year of study, publication, outcomes, or instruments used. Duplicate studies, not original research (such as commentaries, editorials, and letters), and those lacking sufficient data to address the research question will be excluded.

Study selection

To manage the search results, we will export them to EndNote software (version: 20.2.1) for data management, including removal of duplicates and referencing. Two pairs of independent reviewers will conduct title and abstract screening to select studies relevant to the research questions. In the second stage, the same pairs of reviewers will perform full-text screening to identify studies that meet the inclusion criteria. We will retrieve full-text articles that meet the criteria, while those that do not meet the requirements will be excluded. The reasons for exclusion were provided in the final report. To ensure reliability, we will assess inter-rater reliability between the two reviewers, and any disagreements will be resolved through discussion or with a third reviewer. To ensure quality, we will employ a blind method that conceals the names of journals and authors. Finally, we will present the final search results in a flow diagram following the PRISMA 2020 statement (Figure 1).

Data extraction

To extract data from the selected papers, two independent researchers will use the Joanna Briggs Institute's (JBI) template to examine the full text (Supplementary file, Table S1)⁴⁶. This template contains essential information such as the author's first name, publication year, country, study type, research methodology, sample size, interventions, objectives, and study findings. We will use a pilot test and validate the template against a subset of studies to ensure the reliability and validity of the process. In case of any discrepancies or disagreements, the researchers will discuss them with other co-authors to reach a consensus. A third researcher will be involved if they cannot resolve conflicts through discussion.

Quality assessment

Quality appraisals will be performed for each included study using an appropriate quality assessment tool based on the type of study. Observational cohort and cross-sectional studies will be evaluated using the National Institutes of Health (NIH) quality assessment tool (Supplementary file, Table S2)⁴⁷. Clinical trial and quasi-experimental studies will be evaluated using the Joanna Briggs Institute (JBI) critical appraisal tool (Supplementary file, Table S3 and S4)⁴⁸. In addition, the quality of systematic and meta-analysis studies will be assessed using the Assessment of Multiple Systematic Reviews (AMSTAR-2) measurement tools (Supplementary file, Table S5)⁴⁹.

Summarizing and Reporting Findings

We will summarize, review, and systematically report the extracted data. Firstly, we will analyze the data to identify all relevant risk factors as potential predictors for pressure ulcer development or exacerbation in bedridden ICU patients. Secondly, we will categorize the findings based on the demographic and clinical characteristics of the ICU patients, the care behavior of ICU medical and nursing staff, ICU medical devices and equipment, and the type of treatment. We will create tables or charts to visually represent the review's key findings. Finally, we will report the outcomes for each item in a formal report after consulting with stakeholders.

Delphi process (Phase 2)

Setting

The Delphi method will be selected for its capacity to refine ideas and perspectives from a large group of experts. It will aim to reach a consensus of at least 75% agreement on a set of core attributes⁵⁰. In three consecutive rounds, we will use the standard Delphi method to design the pressure ulcer occurrence predicting tool for bedridden patients in the ICU⁵¹. The agreement among panelists will be estimated in each session using Kendall's coefficient of concordance. The Delphi process can be conducted online or face-to-face based on the experts' preferences.

Panelist recruitment

We will recruit panelists who are specialists in the field of special care, including experts, university faculty members, wound care nursing specialists, ICU physicians, anesthesiologists, general surgeons, nursing service managers, supervisors, and experienced nurses with a strong theoretical knowledge of PUs. The panelists will be carefully selected based on specific inclusion criteria, and we will send them invitations before the start of the study. The inclusion criteria for specialists are as follows: (a) a professional experience of more than five years in the field of intensive care, (b) the ability to provide comprehensive opinions and suggestions, and (c) a high level of motivation and willingness to participate in this study.

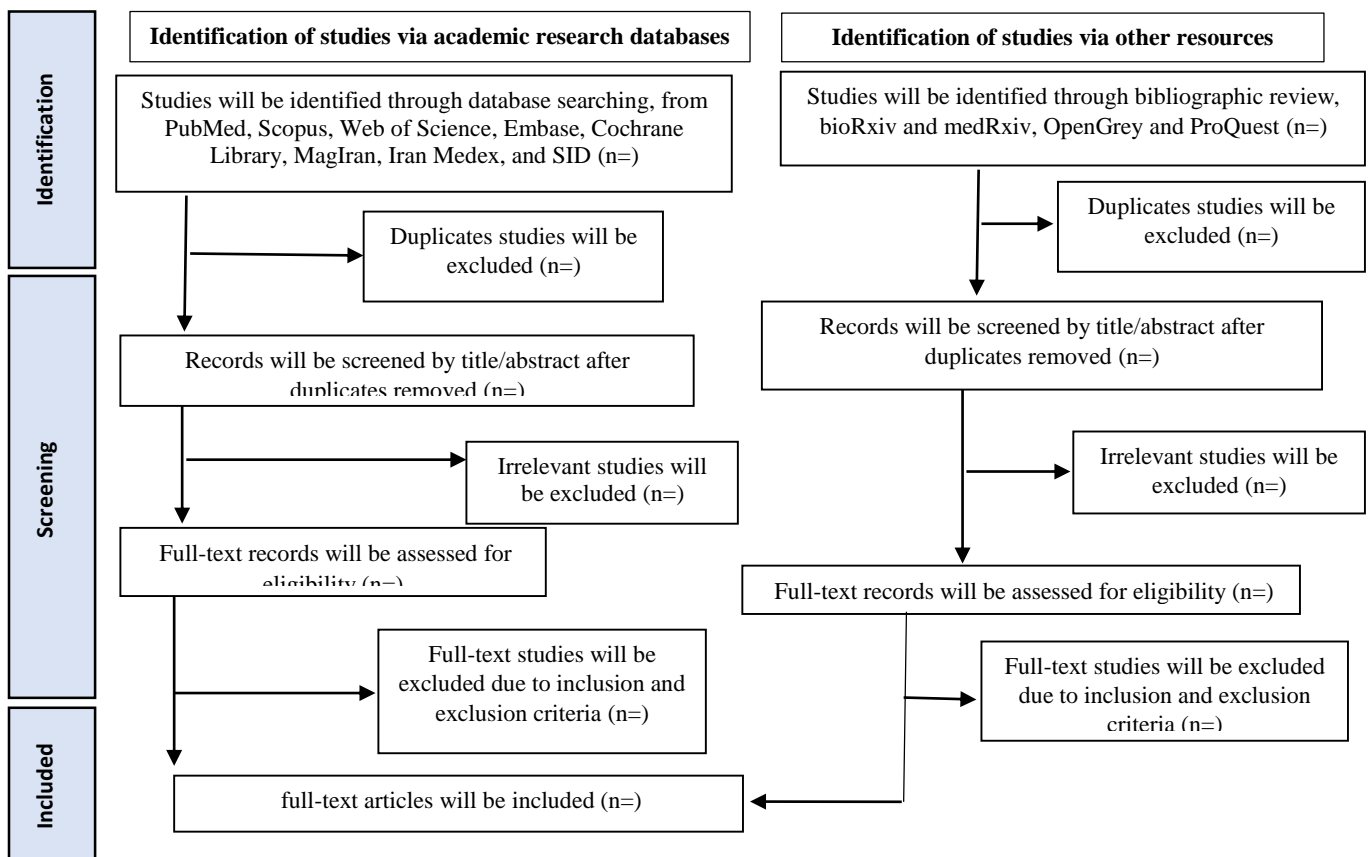


Figure 1: Flowchart of scoping review process which include searches of academic research databases and other resources according to PRISMA 2020

First round of Delphi:

The first round of the Delphi process will be conducted so that the identified risk factors for pressure ulcer development resulting from the scoping review will be presented to the experts for prioritization, and they will be asked about their importance and necessity. Also, an open-ended question will be included at the end of the checklist, asking the experts about the factors that may contribute to the development or exacerbation of PUs but may not have been included in the checklist. After collecting the initial draft of the potential predictors in the first stage, the experts' responses in the research team will be reviewed, and the modified initial checklists of variables will be prepared for the second stage.

Each factor will be scored on "necessity" and "importance." A score of 1 indicates the lowest level,

and a 10 indicates the highest level. For example, the target indicator has very low necessity when score one is assigned to the "necessity" dimension. Therefore, items that score less than five will be removed. In cases where there is a discrepancy in item scores, the research team will continue to discuss and investigate until a consensus is reached, with a high agreement of 75%.

Second round of Delphi:

In the second round of the Delphi process, experts will be informed that the list of potential predictors has been modified based on the feedback from panelists to confirm the initial items. They will be asked to re-score each item on a scale from 1 to 10, indicating its importance and necessity. After completion of this stage, the research team will collect the scores and review the items' importance and necessity using the same method as in the first round. The second version

of the modified list and the factors will then be prepared.

Third Round of Delphi:

The third phase of the Delphi study will be conducted in person, with virtual options available for participants who cannot attend in person. Participants received the third version of the list of factors and were asked to review and discuss the items based on their experiences and importance and necessity scores. The research team will continue to engage in discussions and reviews until a consensus of over 75% is achieved. Ultimately, this process will lead to the preparation of the final version of the potential predictors.

Reliability and validity

To evaluate the reliability of the assessment tool's items, we will employ the test-retest method and calculate the intra-class correlation coefficient (ICC) for quantitative variables and Cohen's Kappa coefficient for qualitative variables. An ICC or Kappa value greater than 0.6 is considered acceptable⁵².

Regarding content validity, we will request 10 experts to review and evaluate the items of the assessment tool based on four criteria: relevancy, clarity, simplicity, and necessity. The content validity ratio (CVR) will be calculated based on the responses to the necessity of questions (nE), using the formula $CVR = (nE - N/2) / (N/2)$ —Lawshe's table to determine what will be used as the cut-off point for CVR⁵³. According to Lawshe, each item must have a minimum CVR of 0.62 for 10 professionals. We will also use the Content Validity Index (CVI) based on the Waltz and Basel content validity index⁵⁴. The CVI for each item will be obtained by dividing the number of professionals who ranked the items as compatible or fully compatible for each criterion (relevancy, clarity, and simplicity) by the total number of professionals. The average value of the three criteria will be used as the total CVI for each item. Each item must have a minimum required amount of CVI of 0.79⁵⁵.

Cross-sectional study (Phase 3)

Study setting and ethical approval

A cross-sectional study will assess the relative contribution of potential predictors for pressure ulcer development or exacerbation in bedridden patients in the ICU. The patients will be recruited from medical or general ICUs at Baqiyatallah Hospital, University of Medical Sciences, Tehran, Iran, over 6 or 8 months. The

study has been approved by the Ethics Committee of Baqiyatallah University of Medical Sciences, following the principles outlined in the Declaration of Helsinki by the World Medical Association⁴¹. Written informed consent will be obtained from all participants or their legal guardians. The study results will be reported according to the Guidelines for Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)⁵⁶.

Participants

The study will consecutively enroll all patients who met the inclusion criteria upon admission to the ICU within six or eight months. Eligible patients will be adults aged 18 or above who are critically ill and had not been diagnosed with a pressure ulcer prior to their ICU admission. Patients with stage one PUs will be included, as defined by the National Pressure Ulcer Advisory Panel (NPUAP)⁵⁷. Stage one will be characterized by non-blanchable erythema (redness) of intact skin, which may appear lighter or darker than the surrounding skin and feel warmer or cooler. All eligible patients must provide consent to participate in the study. According to the NPUAP, patients will be excluded if they have pressure ulcer stages 2-4.

Data collection and measurement

An experienced researcher will collect potential predictors identified through scoping and reach a consensus among experts in three rounds of the Delphi process. These potential predictors will be registered for each patient upon admission to the ICU. Additional patient demographic and clinical characteristics, including age, gender, body mass index (BMI), severity of illness based on the Acute Physiology and Chronic Health Evaluation (APACHE) II, and pre-existing diseases, will be obtained from the patient's medical records and self-reporting⁵⁸. The Charlson Comorbidity Index (CCI) will be used to estimate the burden of pre-existing somatic disease⁵⁹. Two independent will-experience wound specialists simultaneously examined bedridden ICU patients to determine the presence or absence of PUs according to the NPUAP guideline⁵⁷. The occurrence of PUs, whether an ulcer occurs, does not occur, or progresses in the case of an existing stage 1 pressure ulcer, will be evaluated one day after admission. The inter-rater reliability between the assessors will be evaluated using the Kappa agreement test, with a Kappa value higher than 0.6 considered acceptable.

Statistical analysis

The statistical analysis will involve several methods to analyze the data. Continuous variables were presented as either mean \pm standard deviation (SD) or median (inter-quartile range, IQR), while categorical variables will be presented as frequencies with percentages (%). A univariate binary logistic regression model will be used to predict the occurrence of PUs based on potential predictors. The results will be presented as odds ratios (OR) and 95% confidence intervals (95% CI). The multivariate binary logistic regression analysis included variables with a p-value less than 0.1. The receiver operating characteristic (ROC) analysis will be used to determine the model's predictive accuracy. Variables with a p-value greater than 0.05 were removed from the model one at a time as long as their removal did not significantly affect the ROC. The remaining variables will be then used to perform a new multivariate binary logistic regression model with ROC analysis. The significant variables' regression coefficients will be multiplied by a constant value to obtain integer scores for each variable. These scores will be considered the risk score for pressure ulcer occurrence. The total risk score will correspond to a 100% occurrence of PUs, and a percentage will be calculated based on the limited number of variables for each patient. The predictive model's performance will be evaluated using AUC, sensitivity, specificity, LR+, LR-, and Youden's index. Based on accepted criteria for AUC, values between 0.9-1.0, 0.8-0.9, 0.7-0.8, and 0.6-0.7 are considered excellent, good, fair, and poor, respectively, for the discriminative power of a test. The observed pressure ulcer risk will be compared to the predicted risk across different risk groups to assess and graphically display the model's calibration. Statistical analysis will be conducted using SPSS software (ver. 21), GraphPad Prism 9©, and MedCalc software. A p-value less than 0.05 will be considered significant in all analyses.

Discussion

The early assessment of the risk of PU occurrence in high-risk populations continues to necessitate further investigation. There remains considerable controversy regarding the evidence surrounding the association between potential predictors and the development or worsening of Pus⁶⁰. The quality and heterogeneity of studies highlight the requirement for future research

evidence regarding potential predictors for Pus^{28,61}. Many pressure ulcer risk assessment scales are available, but their effectiveness is still debated^{24-26,37,62,63}. These scales have limitations in assessing pressure ulcer risk. The validity of their scores is not sufficiently supported by empirical evidence, and they exhibit varying levels of measurement error. Moreover, pressure ulcer risk is closely associated with overall health status and illness severity. Currently, no evidence indicates that using these scales leads to a significant clinical impact³².

This protocol outlines designing a tool to predict PUs in bedridden ICU patients using a multi-method approach. The process will begin with identifying and preparing a checklist of risk factors for PUs in ICU patients through a comprehensive scoping review. Experts will evaluate and survey these factors in three consecutive Delphi rounds to create a thorough list of potential predictors, prioritizing them based on necessity and importance. In the final phase of the study, the relative contribution of each predictor to the occurrence of PUs in bedridden ICU patients will be assessed to establish a risk score in a cross-sectional study. Consequently, the final checklist is expected to include a minimum number of items (potential predictors) that are comprehensive and entirely objective, based on the risk score for determining the likelihood of occurrence or exacerbation of PUs in ICU patients. This information will be utilized to design a tool for early predicting PUs in bedridden patients in ICUs.

Risk assessment of pressure ulcer incidence is crucial in healthcare settings to identify at-risk individuals and implement preventive interventions^{25,64}. However, the current assessment tools for PUs often rely on subjective clinical judgment, which can lead to unreliable results⁶⁵. To enhance the objectivity and accuracy of the assessment, it is crucial to utilize factors that can be measured objectively or observed with minimal bias. Research indicates that movement monitoring devices can help predict PUs in at-risk adults by converting the subjective measurement of mobility into an objective one⁶⁶. This underscores the potential of technology to enhance the accuracy of pressure ulcer risk assessments. However, several technological challenges remain to be addressed in this field. In addition to mobility and activity, other critical parameters—such as the duration of pressure on specific body parts and the presence of moisture or perspiration—play significant roles in

developing PUs. Currently, these parameters are assessed subjectively, which can introduce bias and compromise the accuracy of evaluations. Therefore, it is essential to measure these parameters objectively. For instance, if it is objectively determined that a patient has been immobile for an extended period and is malnourished, appropriate interventions—such as regular repositioning and nutritional improvement—can be implemented to prevent or mitigate the risk of PUs. Accuracy is also a crucial factor in determining the presence or absence of PUs⁶⁷. Accuracy refers to how well predictive factors identify whether individuals have or do not have PUs. High accuracy indicates that these factors are reliable and distinguish between those at risk of developing pressure damage and those without. Additionally, customizing the tool for different patient communities can enhance its effectiveness^{19,25,68}.

Developing a reliable and comprehensive tool for predicting PUs in bedridden ICU patients is paramount. This tool should incorporate objective and accurate predictive factors that can effectively assess the risk of PUs. By utilizing these factors, healthcare professionals can closely monitor and evaluate the likelihood of PUs, enabling them to proactively implement necessary measures to prevent or minimize the risk for their patients. This is particularly crucial in optimizing the care provided, creating appropriate prevention strategies, reducing healthcare costs, and ultimately improving the overall health of patients admitted to the ICU^{17,25,66}.

Strengths and limitations

The main strength of this study protocol is its use of a multi-method approach to design a tool for predicting PUs for ICU bedridden patients. By integrating quantitative and qualitative methods, the study can provide a more comprehensive and objective assessment of PUs in this population. The utilization of Delphi rounds involving expert's aids in ensuring the accuracy and validity of the checklist of potential predictors. Moreover, during the clinical phase of the cross-sectional study, using univariate and multivariable regressions will enable the determination of the relative contribution of each predictor and the establishment of a specific risk score. Developing a predicting tool for pressure ulcer occurrence in ICU patients through this study can have noteworthy implications for healthcare practice, policy, and patient care. This tool can allow healthcare providers to implement targeted

interventions and strategies that effectively reduce the incidence of PUs.

However, there are some limitations to consider in this study protocol. First, there is a potential for selection bias. The study focuses solely on bedridden patients in ICUs, which may not accurately represent the occurrence of PUs in different healthcare settings. Therefore, the findings may not apply to other populations or patient groups outside of the ICU, limiting the generalizability of the results. Second, the study protocol is limited to a cross-sectional design, which may not provide a comprehensive understanding of the long-term risk factors for PUs in ICU bedridden patients. A longitudinal study design would be more appropriate for capturing the temporal relationship between risk factors and the development of PUs over time. Despite these limitations, this study protocol offers a valuable framework for developing an assessment tool to predict PUs in ICU bedridden patients. Utilizing a multi-method approach enhances the comprehensiveness of the assessment tool, taking into account various risk factors and utilizing multiple data collection methods.

Conclusion

The ongoing debate about the effectiveness of pressure ulcer risk assessment scales emphasizes their shortcomings in accurately evaluating pressure ulcer risk. The validity of these scores is not well-supported by empirical evidence, and there are different levels of measurement error. To address this issue, a study protocol has been created to develop an assessment tool for predicting PUs in bedridden patients in the ICU. This multi-method approach involves creating a checklist of risk factors through a comprehensive scoping review, gathering expert input to assess these factors, and analyzing the relative contribution of each predictor in a cross-sectional study. The final checklist is designed to include only a few essential items and will be entirely objective, centered on the risk score. This will be a valuable tool for predicting PUs in ICU patients. This research aims to improve the accuracy and effectiveness of pressure ulcer risk assessments for high-risk, bedridden patients in ICUs.

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Conflict of Interest Disclosures

The authors do not express any conflict of interest in this Study

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Authors' Contributions

All authors contributed equally in this study

Ethical Statement

This study was approved by the Ethics Committee of Baqiyatallah University of Medical Sciences, Tehran, Iran (Ethical Code: IR.BMSU.REC.1402.059).

Declaration of Generative AI and AI-assisted technologies

None.

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