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Non-invasive technologies for early diagnosis of pressure ulcers: a systematic review protocol

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ADMINISTRATIVE INFORMATION

Support - This review is conducted without external financial support..

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 January 2026 and was last updated on 31 January 2026.

INTRODUCTION

Review question / Objective Review question: To what extent do non-invasive instrumental diagnostic and monitoring methods (e.g. bioimpedance or thermography) enable earlier and more accurate detection of pressure ulcers and monitoring of their progression compared with standard visual clinical assessment?
Population: Adult patients at risk of developing pressure ulcers or with established pressure ulcers.
Intervention: Non-invasive instrumental diagnostic and monitoring methods for pressure ulcers.
Control: Standard clinical and visual skin assessment and risk assessment scales (e.g. Braden, Norton).
Outcomes: diagnostic accuracy of non-invasive methods (sensitivity, specificity, AUC); ability to detect tissue changes prior to clinical signs of stage I–II pressure ulcers; association between diagnostic parameters and subsequent clinical course (healing or progression), reflecting prognostic potential.
Study designs: randomized controlled trials, cohort studies, case–control studies, and prospective or retrospective clinical observational studies.

Rationale Pressure ulcers remain a serious clinical problem in intensive care, rehabilitation, and long-term hospital treatment. Traditional diagnostic approaches are mainly based on visual examination and clinical assessment, which often reveal tissue damage at a relatively late stage. In recent years, a number of non-invasive instrumental technologies have been proposed to detect early ischemic and structural tissue changes before obvious skin damage occurs. However, data on their diagnostic accuracy, clinical usefulness, and prognostic value are scattered and heterogeneous. A systematic review of current data is needed to assess the effectiveness, advantages, and limitations of these technologies compared to traditional approaches.

Condition being studied Pressure ulcers are localized injuries to the skin and/or underlying tissue, usually over a bony prominence, resulting from sustained pressure, shear and ischemia. Early tissue damage may occur before visible skin breakdown, making timely diagnosis challenging. This review focuses on early-stage pressure ulcers and pre-ulcer ischemic tissue changes.

METHODS

Search strategy

Electronic searches will be conducted in PubMed/MEDLINE, Cochrane Library, eLIBRARY.
Search terms will include combinations of:
"pressure ulcer", "pressure injury", "decubitus ulcer",
"early diagnosis", "non-invasive", "bioimpedance", "electromagnetic", "thermography", "infrared", "ultrasound", "optical spectroscopy", "tissue ischemia".
No date restrictions will be applied initially.

Participant or population Adult patients (≥18 years) with existing pressure ulcers or at increased risk of pressure ulcer development in clinical settings.

Intervention Non-invasive instrumental diagnostic and monitoring methods used to assess tissue condition in pressure ulcers, including but not limited to bioimpedance analysis, infrared thermography, ultrasound imaging, optical spectroscopy, and subepidermal moisture measurement.

Comparator Standard clinical and visual assessment of the skin and soft tissues, including commonly used pressure ulcer risk assessment scales (e.g. Braden, Norton).

Study designs to be included Randomized controlled trials, cohort studies, case–control studies, and prospective or retrospective clinical observational studies.

Eligibility criteria Inclusion criteria:
Randomized controlled trials, cohort studies, case–control studies, and clinical observational studies;
Studies evaluating non-invasive instrumental diagnostic or monitoring methods for pressure ulcers;
Adult patients with pressure ulcers or at risk of their development;
Use of a non-invasive diagnostic technology (e.g. bioimpedance, thermography, ultrasound, optical spectroscopy, subepidermal moisture);
Publications in English or Russian from 2015 onwards;
Full-text availability
Exclusion criteria:
Reviews, meta-analyses, expert opinions, and editorials;
Studies with insufficient statistical data or very small sample size (<10 patients);
Animal studies, in vitro studies, mannequin or tissue model studies;
Studies focused exclusively on prevention or device development without evaluation of diagnostic accuracy or tissue monitoring;
Studies on other chronic wounds (e.g. diabetic or venous ulcers) where pressure ulcer data are not reported separately.

Information sources Electronic databases including PubMed/MEDLINE, Cochrane Library, and eLIBRARY (for Russian-language publications).

Main outcome(s) Primary outcomes include diagnostic accuracy measures (sensitivity, specificity, AUC), ability to detect tissue changes before clinical manifestation of stage I–II pressure ulcers, and associations between diagnostic parameters and subsequent clinical outcomes.

Additional outcome(s) Secondary outcomes include feasibility, reproducibility, and potential prognostic value of non-invasive diagnostic technologies.

Data management Search results will be imported into reference management software. Duplicates will be removed. Data extraction will be performed using standardized extraction forms by at least one reviewer.

Quality assessment / Risk of bias analysis Methodological quality and risk of bias will be assessed using QUADAS-2 for diagnostic accuracy studies. The systematic review will be conducted and reported in accordance with PRISMA guidelines.

Strategy of data synthesis Extracted data on sample size, patient characteristics, diagnostic methods, and outcomes will be summarized in structured tables. A qualitative synthesis will be performed. If sufficient homogeneity is identified, quantitative synthesis may be considered.

Subgroup analysis Subgroup analyses may be conducted according to diagnostic modality, clinical setting, and patient risk profile, where data permit.

Sensitivity analysis Sensitivity analyses will be performed by excluding studies with high risk of bias or limited methodological quality to assess the robustness of the findings.

Language restriction English and Russian.

Country(ies) involved Russia.

Other relevant information This protocol follows PRISMA recommendations and is intended to support transparent and reproducible systematic review methodology.

Keywords pressure ulcers; non-invasive diagnosis;; early detection.

Dissemination plans Results will be submitted for publication in a peer-reviewed international journal and presented at relevant scientific conferences.

Contributions of each author

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