INPLASY PROTOCOL

To cite: Yang et al. Identification of risk factors of developing pressure injuries among immobile patient, and a risk prediction model establishment: Protocol for a systematic review. Inplasy protocol 2020100097. doi: 10.37766/inplasy2020.10.0097

Received: 25 October 2020

Published: 25 October 2020

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Support: **Gansu Province Project.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
The authors declare that they have no competing interests.

Identification of risk factors of developing pressure injuries among immobile patient, and a risk prediction model establishment: Protocol for a systematic review

Yang, KL[1]; Chen, L[2]; Kang, YY[3]; Xing, LN[4]; Li, HL[5]; Cheng, P[4]; Song, ZH[4].

Review question / Objective: **The aim of this study is to identify risk factors for the development of pressure injuries in immobile patients based on clinical practice guidelines, and establish a risk prediction model to predict the probability of occurrence of pressure injuries development for immobile patients on the risk factors we collected.**
Condition being studied: **Pressure injuries (PIs) is localized damage to the skin and underlying soft tissue usually over a bony prominence or related to the medical device, and it considerably threatens the health of humans due to high incidence rate and severe complications. Particularly, immobile patients seem to be at a higher risk of developing PIs. For these patients, risk assessment is a central component of clinical practice which helps to target appropriate interventions and prevent PIs development. However, agreement on the predictive risk factors is lacking has led to the propagation of different tools, such as Braden, Norton, and Waterlow scales, which have all shown low sensitivity and specificity in identifying at-risk patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 October 2020 and was last updated on 25 October 2020 (registration number INPLASY2020100097).

INTRODUCTION

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METHODS

Participant or population: Immobile adult patients or patients who are unable to reposition without assistance at least 24 hours.

Intervention: Any interventions related to prevent pressure injuries.

Comparator: Not applicable.

Study designs to be included: Clinical practice guidelines and systematic reviews.

Eligibility criteria: We will include the latest version of clinical practice guidelines and systematic reviews, which aim to identify the risk factors associated with pressure injuries development in immobile adult patients or patients who are unable to reposition without assistance at least 24 hours. Reasons for being immobile include: under sedation, disease-related immobility, and bed rest requirements for disease treatment. Any stage of pressure injuries and any setting will be covered without restriction. There is no time limitation, and language is restricted to English and Chinese. The summary of the CPGs; the translation of a CPG published in another language; consensus, evidence summary and protocols will be excluded. Duplicate publication of the patient dataset will be excluded.

Information sources: Search strategies will be performed in electronic databases and specific databases for clinical practice guidelines. The reference lists of eligible studies will be checked by reviewers in order to identify other possible guidelines. For guidelines published only in summary or where important information is missing, we will try to search for complete information by contacting the authors.

Main outcome(s): Different type of risk factors and odds ratio (OR) for all variables.

Quality assessment / Risk of bias analysis: Clinical practice guidelines will be assessed by using Appraisal of Guidelines for Research & Evaluation II (AGREE II). The methodological quality of each of the included systematic reviews will be assessed using A Measurement Tool to Assess Systematic Reviews 2 (AMSTAR 2).

Strategy of data synthesis: All the different data types will be converted to odds ratio (OR) and 95% confidence interval (95%CI). Then, the inverse variance method was used to combine the pooled odds ratio (ORP) by using RevMan 5.3, and the risk factors will be included if its ORP is greater than 1 and 95%CI does not include 1. We will measure statistical heterogeneity using the I2 measure. A fixed-effect model will be used if clinical heterogeneity was minimal and I2 was less than 50%; otherwise a random-effects model will be adopted due to I2≥75%. Logistic regression model refers to calculate the risk value of risk factors in order to evaluate the contribution of risk factors in the specific diseases and to predict the risk of developing diseases. The risk prediction model will be established based on the natural logarithm transformation value of the ORP.

Subgroup analysis: Not applicable.

Sensibility analysis: We will conduct a sensitivity analysis to identify and remove the literature of significant heterogeneity. We will also perform sensitivity for the included studies with "critically low" methodological quality one by one, and

exclude the studies which cause great change in overall effect size.

Country(ies) involved: China.

Keywords: Pressure injuries; Clinical practice guidelines; Systematic reviews; Risk prediction model.

Contributions of each author:

Author 1 - Kelu Yang - (1) conceived this study (2) designed the inclusion/exclusion criteria and the searching strategy (3) will search for the literature (4) will collect the data and make statistical analysis (5) drafted the protocol and revised the manuscript.

Author 2 - Lin Chen - (1) conceived this study (2) designed the inclusion/exclusion criteria and the searching strategy (3) will search for the literature (4) will collect the data and make statistical analysis (5) drafted the protocol and revised the manuscript.

Author 3 - Yingying Kang - will collect the data.

Author 4 - Lina Xing - will collect the data.

Author 5 - Hailing Li - will collect the data and make statistical analysis.

Author 6 - Peng Cheng - will collect the data and make statistical analysis.

Author 7 - Zonghui Song - (1) conceived this study (2) designed the inclusion/exclusion criteria and the searching strategy (3) drafted the protocol and revised the manuscript.