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Systematic Review of the Risk Prediction Model for Radiation-induced Oral Mucositis

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ADMINISTRATIVE INFORMATION

Support - Zibo Central Hospital.

Review Stage at time of this submission - Data extraction.

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 20 February 2025 and was last updated on 20 February 2025.

INTRODUCTION

Review question / Objective Construct an evidence-based question based on the PICOTS model recommended by the Cochrane Methodology Group. The target population (population, P) is patients who have been diagnosed with malignant tumors and are undergoing radiotherapy. The index prediction model (index prediction model, I) is all the prognostic models that have been developed and can be used to predict the occurrence of Radiation-induced Oral Mucositis (RIOM). Comparison (comparator, C): Not applicable. Outcome indicator (outcome, O) is RIOM. The timing of model use (timing, T) is from the start of the patient's radiotherapy until the diagnosis of RIOM. The setting of model use (setting, S) is any environment.

Condition being studied Radiation therapy (referred to as radiotherapy) is a major treatment method for patients with malignant tumors. While

radiation destroys DNA and kills tumor cells, it can also cause damage to patients. Among them, radiotherapy-induced oral mucositis (RIOM) is the most common adverse reaction, manifested as redness, swelling and ulcers of the oral mucosa. For patients receiving conventional-dose radiotherapy, the incidence of RIOM is 20% to 40%, and 20% to 50% of these patients may progress to severe RIOM. This not only restricts the patient's diet and rest, but also causes discomfort symptoms such as oral pain, dry mouth, and difficulty swallowing. In severe cases, it can even lead to systemic infections and affect the prognosis of the disease. Early identification and effective prevention are the keys to improving the prognosis of patients, and the RIOM prediction model can help identify high-risk patients at an early stage.

METHODS

Participant or population Patients with malignant tumors who are undergoing radiotherapy.

Intervention Exposed group: Patients with malignant tumors receiving radiotherapy.

Comparator Control group: Blank group.

Study designs to be included RCT.

Eligibility criteria Inclusion criteria:

- ① The research subjects are patients with malignant tumors who are 18 years old or above and receiving radiotherapy.
- ② The research content focuses on the construction and validation of the risk prediction model for RIOM.
- ③ The research types include cohort studies, case-control studies, cross-sectional studies, or randomized controlled trials.
- ④ The literature can be in both Chinese and English.

Exclusion criteria:

- ① The method of model construction is not described.
- ② Conference abstracts, duplicate publications, and those for which the full text cannot be obtained.
- ③ The research only obtained the predictive factors without further constructing a model.

Information sources CNKI, VIP, Wanfang Database, China Biomedical Literature Database, CINAHL, PubMed, Cochrane Library, Embase.

Main outcome(s) RIOM.

Quality assessment / Risk of bias analysis In this study, two researchers independently evaluated the quality of the included literature using the Prediction Model Risk of Bias Assessment Tool (PROBAST), which was developed by Wolff et al. in the Netherlands in 2019 to evaluate the risk of bias and applicability of prediction model studies. The tool included 4 domains of study subjects, predictors, outcomes and analysis for the assessment of bias, with a total of 20 signal questions. The answers to each signal question are Yes/Pro, No/Yes, and No Information; Responses to risk of bias for each domain and overall study risk of bias were high, low, or unclear. The reviewers first answered the signal questions for each domain, and then used a "one-vote no" method to judge the overall risk of bias for each domain and the overall risk of bias, that is, the overall risk of bias of the study was judged to be low if the risk of bias was low for each item and domain, and as long as one item

was assessed as high risk of bias, the domain in which the item was lower.

Strategy of data synthesis The basic characteristics, model establishment and model performance of the included research were summarized. According to the standard error of the area under the curve and the 95% confidence interval of the prediction model in the included literature, MedCalc22.016 software was used to meta-analyze the AUC of the prediction model, the I² statistic was used to evaluate the heterogeneity of different models, and the random-effects model was used for pooled analysis. RevMan 5.4 software was used to meta-analyze the predictive value of the common predictors in the model, and the I² and Q tests were used to judge whether there was heterogeneity in the model, if the I² 0.1, it proved that the model heterogeneity was small, and the fixed-effect model was used for analysis. If I² ≥ 50% and P ≤ 0.1, it indicates that there is heterogeneity in the model, and a random-effects model was used for analysis.

Subgroup analysis None.

Sensitivity analysis None.

Country(ies) involved China.

Keywords Radiotherapy; oral mucositis; Forecast; systematic reviews; Evidence-Based Nursing.

Contributions of each author

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