Prognostic Prediction Models for Patients with Low Back Pain: Systematic Review Protocol

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Protocol

Keywords: systematic review, low back pain, clinical prediction model, prognosis

Posted Date: October 12th, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-88541/v1>

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Abstract

Background: The prognosis of acute low back pain is generally favourable in terms of pain and disability; however, outcomes vary substantially between individual patients. Clinical prediction models help in estimating the likelihood of an outcome at a certain time point. There are existing clinical prediction models focused on prognosis for patients with low back pain. To date, there is only one previous systematic review summarising the discrimination of validated clinical prediction models to identify the prognosis in patients with low back pain of less than 3 months duration. The aim of this systematic review is to identify existing developed and/or validated clinical prediction models on prognosis of patients with low back pain of less than 3 months duration, and to summarise their performance in terms of discrimination and calibration.

Methods: MEDLINE, Embase and CINAHL databases will be searched, from the inception of these databases until January 2020. Eligibility criteria will be: (1) prognostic model development studies with or without external validation, or prognostic external validation studies with or without model updating; (2) with adults aged 18 or over, with 'recent onset' low back pain (i.e. less than 3 months duration), with or without leg pain; (3) outcomes of pain, disability, sick leave or days absent from work or return to work status, and self-reported recovery; and (4) study with a follow-up of at least 12 weeks duration. The risk of bias of the included studies will be assessed by the Prediction model Risk Of Bias ASsessment Tool, and the overall quality of evidence will be rated using the Hierarchy of Evidence for Clinical Prediction Rules.

Discussion: This systematic review will identify, appraise, and summarize evidence on the performance of existing prediction models for prognosis of low back pain, and may help clinicians to choose the best option of prediction model to better inform patients about their likely prognosis.

Systematic review registration: PROSPERO reference number CRD42020160988

Background

The prognosis of acute low back pain (LBP) is generally favourable in terms of pain and disability;^{1,2} however, outcomes vary substantially between individual patients. A systematic review³ investigating the course of LBP reported that mean pain and disability scores were greatly reduced by 12 months, and the majority of the patients recovered by 12 weeks.¹ The ability to identify individual patients likely to recover at different speeds would be helpful to clinicians and patients by providing a more accurate prognosis and help to inform decisions about the type and amount of care. International LBP guidelines recommend minimal care and no imaging for most patients presenting with acute LBP;^{4,5} however, these guidelines are commonly not followed.⁶ The ability to identify patients who are likely to recover rapidly can be used to reassure these patients and enhance implementation of current guidelines.

Clinical prediction models help in estimating the likelihood of an outcome at a certain time point.⁷ To be useful for clinicians, a prediction model needs to be easy to use, discriminate between patients with

different levels of risk and provide accurate predictions of outcomes. It is important that clinical prediction models are tested for external validity before being recommended for clinical practice, as many prediction models do not generalise well when tested in new populations.⁸ Model validation studies evaluate the performance of the original model using data from a different sample of patients to ensure that similar results are replicated in a different sample or a different health care setting.⁹ The final step of testing a clinical prediction model is an impact study, to identify if the prediction model produces a change in clinicians' behaviour or an improvement in patients' outcomes.¹⁰

There are existing clinical prediction models for patients with LBP.^{11–15} A systematic review¹⁶ of studies published prior to 2016 summarised the discrimination of clinical prediction models to identify the prognosis in patients with LBP of less than 3 months duration. New clinical prediction models for the prognosis of LBP have been developed since 2016.^{15,17–19} In addition, this review included only studies which have been tested for external validity. Although studies about the development of clinical prediction models cannot be considered sufficiently validated for clinical application, it is important to know all the clinical prediction models that exist, despite the stage of testing because some at the early stages of development may be currently undergoing testing for external validity, and others may present promising results that can be tested for its external validity in the future. Also, the previous review only described the performance of the prediction models in terms of discrimination. Although discrimination provides important information about how well the model differentiates between those who recover and those who do not, calibration is also important to inform about the accuracy of the predictions. Therefore, the aim of this systematic review is to identify existing model development and external validation studies focused on prognosis of patients with LBP of less than 3 months duration, and to summarise the performance (in terms of discrimination and calibration) of the clinical prediction models.

Methods

Protocol

This systematic review is reported in accordance with the statement for Preferred Reporting Items for Systematic Reviews and Meta-Analysis - Protocols (PRISMA-P),²⁰ and the CHecklist for critical Appraisal and data extraction for systematic Reviews of prediction Modelling Studies (CHARMS).²¹ The protocol of this systematic review was registered on the PROSPERO International prospective register of systematic reviews (CRD42020160988).

Eligibility criteria

We will include studies that meet all the following criteria:

- Study type: prognostic prediction model development and/or external validation study with or without model updating. Clinical prediction model was defined as the following criteria: (1) a self-

report questionnaire and (2) assesses multiple factors or constructs related to the probability of or risk for the future occurrence (prognosis) of a particular outcome.⁷

- Participants: (1) adults aged 18 or over; (2) with 'recent onset' LBP (i.e. less than 3 months duration); (3) with or without leg pain.
- Model predicts any of the following outcomes: pain; disability; sick leave or days absent from work or return to work status; and self-reported recovery.
- Time period of prediction: follow-up of at least 12 weeks duration.

Information sources

Systematic searches will be conducted of MEDLINE, Embase and CINAHL, from the inception of these databases until January 2020. Additional strategies to ensure all eligible studies are identified will include examination of reference lists from all included studies and citation tracking of included studies.

Search

The search strategy will include LBP terms suggested by the Cochrane Back and Neck Review Group²² and terms related to clinical prediction model studies as suggested by Ingui.^{23,24} The full search strategy is in **Additional file 1**. No search limits will be applied.

Study selection

Two reviewers (T.S. and F.S.) will independently screen all studies by title and abstract and exclude clearly irrelevant studies. For each potentially eligible study, two reviewers (T.S. and F.S.) will independently screen the full-text article and assess whether the study fulfilled the inclusion criteria. In cases of disagreement, a decision was made by consensus or by a third reviewer (L.P.C.) if needed.

Data extraction

The data will be extracted by two independent reviewers and in cases of disagreement consensus will be reached by discussion between the reviewers or by arbitration by a third reviewer. Authors will be contacted by email in order to obtain any additional information that might not be reported in the original articles.

Data items

Where available, the following summary data will be extracted from each study: type of study, source of data, participants, outcome predicted, candidate predictors, sample size, missing data, model development, model performance, model evaluation, results, authors interpretation and the information about a conclusion of the calibration graphs will be described. Where possible, measurements of discrimination will be extracted for the related outcomes: pain intensity as measured using a visual analogue scale, numeric rating scale (NRS), verbal rating scale or Likert scale; disability as measured by validated self-report questionnaires; sick leave or days absent from work or return to work status; self-reported recovery using a global perceived effect scale, a verbal rating scale, or a Likert (recovery) scale.

Risk of Bias of individual studies

The risk of bias of the included studies will be assessed by the PROBAST (Prediction model Risk Of Bias ASsessment Tool),^{25,26} recently developed through a consensus process involving a group of experts in the field. PROBAST includes 20 signalling questions across 4 domains: (1) participants, (2) predictors, (3) outcome, and (4) analysis. The questions are answered as yes (Y), probably yes (PY), no (N), probably no (PN), or no information (NI). The answers to these signalling questions assist reviewers in judging the overall risk of bias for each domain. A domain where all signalling questions are answered as Y or PY should be judged as “low risk of bias.” An answer of N or PN on 1 or more questions flags the potential for bias, whereas NI indicates insufficient information. Information and methodological comments that support the item assessment will be recorded. The studies will be rated as having low risk of bias, potential for bias, or insufficient information based on the 4 domains. Two independent reviewers will assess the risk of bias of the studies and discrepancies will be resolved by consensus, and if necessary, a third author will resolve any disagreement.

Overall quality of evidence

The overall quality of evidence will be rated using the Hierarchy of Evidence for Clinical Prediction Rules designed by Jull, DiCenso, and Guyatt.²⁷ The hierarchy of evidence can guide clinicians and researchers in assessing the full range of evidence supporting the use of a clinical prediction rule in their practice. The strength of recommendation is determined based upon the stage of the clinical prediction model regarding development, validation (and the quality of validation) and impact. Table 1 describes the Hierarchy of Evidence for Clinical Prediction Rules.

Table 1
Hierarchy of Evidence for Clinical Prediction Rules.

Level IV	Rules that need further evaluation before they can be applied clinically
	These rules have been derived but not validated or have been validated only in split samples, large retrospective databases, or by means of statistical techniques
Level III	Rules that clinicians may consider using with caution and only if patients in the study are similar to those in their clinical setting
	These rules have been validated in only one narrow prospective sample.
Level II	Rules that can be used in various settings with confidence in their accuracy
	At this level, rules must have demonstrated accuracy either by one large prospective study including a broad spectrum of patients and clinicians or by validation in several smaller settings that differ from one another.
Level I	Rules that can be used in a wide variety of settings with confidence that they can change clinician behaviour and improve patient outcomes
	At this level, rules must have at least one prospective validation in a different population plus one impact analysis, along with a demonstration of change in clinician behaviour with beneficial consequences.

Summary measures

Predictive validity is usually assessed by measures of discrimination and calibration. Discrimination indicates how well the model differentiates between those who recover and those who do not.⁷

Calibration refers to how closely the predicted risk agrees with the observed risk.⁷

Synthesis of results

Meta-analysis may be conducted if adequate on discrimination exists for a single clinical prediction model, specific outcome, and considering only the results of validation studies. For data pooling to be appropriate, we will also require that (1) the outcome measure is defined consistently, (2) the clinical settings are similar (e.g. all primary care), and (3) uniform statistical analyses have been applied. Calibration findings will be descriptively synthesised.

Discussion

This systematic review will identify, appraise, and summarize evidence on the performance of prediction models for the prognosis of LBP. Recommendations for the management of LBP in primary care frequently suggest using available screening instruments to obtain information about 'risk' of an outcome and target resources to those most likely to benefit.^{2,6} This systematic review will be useful for clinicians and future research, considering that systematic reviews of prediction models are relatively new and this is a rapidly evolving area.^{9,28,29}

To our knowledge, this is the first review summarising evidence on the performance of prediction models for LBP in terms of both discrimination and calibration. This study was prospectively registered, and the methods are in accordance with the CHecklist for critical Appraisal and data extraction for systematic Reviews of prediction Modelling Studies (CHARMS). Risk of bias will be assessed by the PROBAST (Prediction model Risk Of Bias ASsessment Tool),^{25,26} which was recently developed specifically to evaluate prediction model studies. The overall quality of evidence will be rated using the Hierarchy of Evidence for Clinical Prediction Rules. Our study also has one potential limitation. Analysing data from prediction models that were designed to predict different outcomes and using different measures can be challenging, and, may limit the strength of the conclusions that can be drawn from the study.

The findings of this study will have significant clinical and future research implications. Previous studies have shown that prediction models may enable a more cost-effective use of healthcare resources, a better classification of patients in risk groups than clinicians' judgement only, and minimize patient burden.³⁰⁻³² Considering that many prediction models for prognosis of LBP have been developed in the last 10 years, the review may help clinicians to choose the best available prediction model for their patients. However, this systematic review's results will not inform whether the implementation of the prognostic models in clinical practice improves outcomes for patients. Future impact studies are needed to evaluate if the prediction models are effective in producing changes in clinicians' behaviour and/or improving patient outcomes.

Abbreviations

LBP: low back pain; PROSPERO: Prospective Register of Systematic Reviews; PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analysis - Protocols; CHARMS: CHecklist for critical Appraisal and data extraction for systematic Reviews of prediction Modelling Studies; PROBAST: Prediction model Risk Of Bias ASsessment Tool.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

FGS PhD is funded by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES) - Brazil - Finance Code 001. TS receives a fellowship from FAPESP (São Paulo Research Foundation) with grant number: 2018/20035-7.

Authors' contributions

LPC, MJH and TS contributed to the conception and design of the review. FGS and TS drafted the protocol and derived the search strategy. LPC, MJH, GAP and LMC contributed to the review of the manuscript and approved the final version. All authors read and approved the final manuscript.

Acknowledgements

Not applicable.

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