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REVIEW ARTICLE

Validation and impact analysis of prognostic clinical prediction rules for low back pain is needed: a systematic review

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Abstract

Objectives: To identify prognostic forms of clinical prediction rules (CPRs) related to the nonsurgical management of adults with low back pain (LBP) and to evaluate their current stage of development.

Study Design and Setting: Systematic review using a sensitive search strategy across seven databases with hand searching and citation tracking.

Results: A total of 10,005 records were screened for eligibility with 35 studies included in the review. The included studies report on the development of 30 prognostic LBP CPRs. Most of the identified CPRs are in their initial phase of development. Three CPRs were found to have undergone validation—the Cassandra rule for predicting long-term significant functional limitations and the five-item and two-item Flynn manipulation CPRs for predicting a favorable functional prognosis in patients being treated with lumbopelvic manipulation. No studies were identified that investigated whether the implementation of a CPR resulted in beneficial patient outcomes or improved resource efficiencies.

Conclusion: Most of the identified prognostic CPRs for LBP are in the initial phase of development and are consequently not recommended for direct application in clinical practice at this time. The body of evidence provides emergent confidence in the limited predictive performance of the Cassandra rule and the five-item Flynn manipulation CPR in comparable clinical settings and patient populations.

Keywords: Clinical prediction rule; Low back pain; Prognosis; Decision support techniques; Systematic review; Derivation; Validation; Impact analysis

1. Introduction

The stratification of patients into meaningful subgroups is a priority area of low back pain (LBP) research [1]. Identifying patients with LBP with differing prognoses and targeting interventions based on the relative likelihood of treatment benefit provides individual and population-level benefits, including improved patient outcomes and efficiencies in resource consumption [2−6]. Clinical prediction rules (CPRs) are one of several overlapping methods proposed to facilitate such stratification [7].

CPRs are simple statistical prediction tools designed to be used with individual patients that comprise a small number of clinical variables that have been identified to be independently predictive of a given diagnosis, outcome, or treatment effect [8]. Prognostic forms of CPRs consist of nonspecific prognostic variables that inform predictions concerning future outcomes such as pain, disability, and return to work. Such tools are therefore well suited for screening and prioritizing patients for interventions and informing advice provided to patients and other parties regarding anticipated prognoses [7,9,10]. Prescriptive CPRs are a special type of prognostic CPR that inform predictions regarding the relative treatment effect a patient may experience from an intervention. The variables that comprise a prescriptive CPR are treatment effect modifiers, which are the baseline variables that differentiate patient subgroups who experience differing magnitudes of treatment effect [11−13]. Thus, prescriptive CPRs function to inform clinical decisions regarding treatment selection [9,14].

The development of a CPR broadly occurs across three main phases, whereby the tool is initially derived, then prospectively validated in new patient cohorts, and finally evaluated for its ability to positively impact clinical practice [15]. The validation of a CPR is important as predictor variables may simply reflect chance statistical associations or

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What is new?

Key findings

- Thirty prognostic clinical prediction rules relevant to the nonsurgical management of adults with low back pain have been derived. Three have also undergone validation, but none have undergone impact evaluation.

What this adds to what was known?

- Most clinical prediction rules for low back pain are in the initial phase of development and cannot be recommended for use in clinical practice at this time.

What is the implication and what should change now?

- The ''Cassandra rule'' is a clinical prediction rule that may be applied in comparable clinical settings and patient populations with some confidence in its modest prognostic accuracy in identifying patients with differing degrees of risk of developing a poor long-term functional outcome.
- The five-item Flynn manipulation clinical prediction rule may be applied in comparable clinical settings and patient populations to inform prognostic judgments about which patients receiving lumbopelvic manipulation are more likely to experience a favorable functional outcome.

the CPR may be specific to the study sample or setting in which it was derived [16]. CPRs that have been demonstrated to perform consistently across different patient groups and across broad clinical settings may be applied in practice with confidence in their accuracy [17]. Impact analysis is an important final step in the development of a CPR as it evaluates whether the implementation of a validated CPR is likely to have meaningful beneficial consequences [17,18]. Such benefits may include more accurate selection and prioritization of patients requiring intervention, improved patient outcomes, and reduced costs of care [7,9,19].

The limited data concerning the use of CPRs for LBP in clinical practice suggest that many clinicians have an awareness of such tools and consider their application in their clinical decision making [20–23]. Consequently, the identification of the range of existing prognostic CPRs for LBP, and an appraisal of their appropriateness to be applied in clinical practice at this time, is potentially of significant clinical benefit. Previous systematic reviews of CPRs relevant to the nonsurgical management of LBP have limited their scope to tools designed for specific interventions [12,24–27], a particular health profession [24,26–29], or to a particular stage of CPR development [24,26,27]. It is probable that many prognostic CPRs related to the nonsurgical management of LBP have not yet been identified in systematic reviews to date.

Therefore, the aim of this systematic review was to identify prognostic forms of CPRs related to the nonsurgical management of adults with LBP and to evaluate their current stage of development. It is anticipated that the evidence identified in this review will be informative to clinicians managing patients with LBP and to researchers involved in the development of LBP CPRs.

2. Methods

This systematic review sought to include studies reporting on the derivation, validation, or impact analysis of one or more prognostic or prescriptive CPRs related to the nonsurgical management of adults with LBP. A CPR was operationally defined as ''a clinical tool that quantifies the individual contributions that various components of the history, physical examination and basic laboratory results make toward the diagnosis, prognosis, or likely response to treatment in an individual patient''[16]. Eligibility criteria were developed by the research team to address the review's research question and are summarized in Table 1. No restrictions were placed on the year of study publication, stage of CPR development, types of predictor variables under consideration (e.g., physical tests, history items, psychosocial factors, and so forth), types of nonsurgical management interventions, or the professional disciplines involved in the development of a CPR. CPRs were included independent of whether they were developed specifically for patients receiving a particular nonsurgical intervention.

The database search strategy (Appendix A at www.jclinepi.com) incorporated search strings identified to have high sensitivity for prognostic prediction model studies [30–32] and disease-specific filters for back-related disorders [33]. Seven databases were searched from their inception to July 2013: MEDLINE (1946–), EMBASE (1947–), Cochrane Central Register of Controlled Trials (1898–), PsychINFO (1806–), CINAHL (1937–), AMED (1985–), and Index to Chiropractic Literature (1981–). Identified records were downloaded into EndNote (Thomson Reuters), and duplicates were removed. Citation tracking and hand searching were conducted as supplementary search strategies.

Two independent reviewers selected studies for inclusion using a two-step process [34,35]. First, the titles and abstracts of identified records were screened by both reviewers with studies deemed eligible by either reviewer progressing to the second stage of screening. In the second stage, the full text of studies were screened by both reviewers with concordance determining eligibility. Episodes