CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In patients with low back pain, which prognostic factors predict disability using the Oswestry Disability Index?

AUTHOR

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CLINICAL SCENARIO

At my clinical rotation at the UNC Spine Center, I saw a wide variety of low back pain (LBP) patients, some of whom got better fast and others progressed very slowly. I began to wonder if there were any unifying elements to patients for either of these groups. Identifying prognostic factors could help LBP clinicians determine a plan of care for patients and possibly prioritize patient visits. In clinical practice, this translates to being able to schedule patients with poorer prognostic factors more frequently so they receive more focused care. Conversely, patients with more favourable prognostic factors may need less clinical attention, thus freeing up time and resources for patients who are at higher risk for poorer outcomes.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- Ten studies were identified that met the inclusion/exclusion criteria. Three higher quality studies that discussed slightly different aspects of prognostic factors for LBP were included for thoroughness.
- A variety of prognostic factors and outcome measures have been used in prognostic studies for LBP. Studies that used the Oswestry Disability Index (ODI) were the most prevalent, and thus were given preference for inclusion for review in this discussion.
- The prognostic factors mentioned often for predicting a positive outcome for LBP were younger age, lower initial disability score as measured by the ODI, lower severity of pain at baseline, presently employed, and eligibility for the clinical prediction rule for spinal manipulation (symptom duration < 16 days, fear-avoidance score < 19, lumbar hypomobility in at least one vertebral segment, at least one hip with internal rotation range of motion > 35º, and no symptoms distal to the knee)[1]
- Future research for prognostic studies of LBP should focus standardizing an acceptable absolute score on the ODI for the consideration of a successful treatment of LBP, considering the utilization of cost analysis in reference to certain prognostic factors, and specifying work demands when considering LBP disability in terms of employment status.

CLINICAL BOTTOM LINE

The most common factors that predict disability using the ODI are younger age, less disability and pain at baseline, and those who are eligible for the CPR for spinal manipulation. It may be assumed that these factors can guide clinical judgement when predicting how disabled a patient might become in regard to their LBP and creating a plan of care for that patient. In order to continue to refine and add to this list of prognostic factors, future research should include large sample sizes in a prospective design with standardized scores on the ODI to better reflect true disability in relation to predictive characteristics.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

The above information should fit onto the first page of your CAT

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Adult **Low back pain** **LBP** **Low-back pain** **Lumbago** Physical therapy Physiotherapy rehabilitation	Age Gender Sex Recurrence Initial pain score Initial ODI score Initial oswestry disability index Initial disability Acute Sub-acute Prognostic **Predict** **Predicts** **Predictor** **predictors**	[N/A]	**Oswestry disability index** **ODI** Disability

Final search strategy:

PubMed Search

1. "low back pain" OR LBP OR "low-back pain" OR lumbago
2. "Oswestry disability index" OR ODI
3. "predict" OR "predicts" OR "predictor" OR "predictors"
4. **#1 AND #2 AND #3**

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
PubMed	**74**	**Clinical trial, English Abstract, Meta-analysis, observational study, Reviews, Systematic Reviews. Revised number: N/A (74)**
CINAHL	**27**	**English language, Adults only (≥18 years old). Revised number: 18**
Cochrane	**8**	

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• English language • Meta-analysis, systematic review, observational studies, prognostic studies, controlled trials • Must have at least 2 prognostic factors studied

• Must have measured disability on ODI at discharge
Exclusion Criteria
• Under the age of 17 • Study protocols, abstracts, narrative reviews, dissertations • Less than 2 prognostic factors studied

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Each study was scored on a nine-point scale using Table 11-3, "Evidence About Prognostic (Risk) Factors: Quality Appraisal Checklist" from Evidence-Based Physical Therapist Practice, 2nd edition, by Dianne V. Jewell.[2]

Author (Year)	Study quality score	Level of Evidence	Study design
Eleswarapu et al (2016)[3]	**4/9**	**IV**	**A retrospective review (prognostic risk factors)**
Harris et al (2016)[4]	**6/9**	**IIa**	**Prospective observational (cross-sectional analysis of baseline employment status data)**
Koppenhaver et al (2015)[5]	**4/9**	**(Prognosis) Ib**	**Quasi-experimental, predictive single group pre-post design (dry needling for LBP)**
Brooks et al (2013)[6]	**6/9**	**II**	**Retrospective multicentre study, predictive single group pre-post design (BMI re: LBP)**
Cook et al (2012)[7]	**5/9**	**II**	**Predictive modelling using data from multicentre RCT (LBP manual therapy, thrust vs non-thrust)**
Hellum et al (2012)[8]	**5/9**	**II**	**Two-group prognostic multicentre prospective study (disc prosthesis vs rehabilitation)**
Park et al (2014)[9]	**4/9**	**IV**	**Single-group predictive prospective cohort study (discharge ODI value)**
Kerr et al (2015)[10]	**5/9**	**II**	**Two-group randomized and cohort multicentre prospective cohort study (surgical and non surgical)**
Van Hooff et al (2014)[11]	**5/9**	**II**	**Single-group Longitudinal prospective cohort (predictive LBP following rehab program)**
Pearson et al (2008)[12]	**5/9**	**III**	**Subgroup analyses of prognostic factors according to treatment received (listhesis vs disc height vs mobility)**

BEST EVIDENCE

The following 3 studies were identified as the 'best' evidence and selected for critical appraisal. Reasons for selecting these studies were:

- **Cook CE, Learman KE, O'Halloran BJ, et al. Which prognostic factors for low back pain are generic predictors of outcome across a range of recovery domains? *Phys Ther*. 2013;93(1):32-40. doi:10.2522/ptj.20120216.**
- The Cook study also graded out well for a prognostic study. The intriguing aspect of this study that I believe deserves a more critical appraisal is that they used four outcome measures and adjusted prognostic factors based on the statistic modeling used for each measure. I believe this provides a valuable insight into how different statistical approaches affect the prognostic abilities of different factors.
- **Harris SA, Rampersaud YR. The importance of identifying and modifying unemployment predictor variables in the evolution of a novel model of care for low back pain in the general population. *Spine J*. 2016;16(1):16-22. doi:10.1016/j.spinee.2015.09.034.**
- The Harris study ranked as one of the highest quality studies out of the 10 articles I reviewed closely. The study included subgroups of employment status and conducted separate analyses and statistically adjusted for different prognostic factors. This study also provides a unique, quality insight into employment status in relationship to prognostic factors.
- **Van Hooff ML, Spruit M, O'Dowd JK, Van Lankveld W, Fairbank JCT, Van Limbeek J. Predictive factors for successful clinical outcome 1 year after an intensive combined physical and psychological programme for chronic low back pain. *Eur Spine J*. 2014;23(1):102-112. doi:10.1007/s00586-013-2844-z.**
- The Van Hoof study is elegant in that it examines easily identifiable prognostic factors that show promise for predicting success in a rehabilitation program or the need to switch to alternative treatments. A unique feature that I found nowhere else in the prognostic literature is that they used a random set of half of their data to determine a prediction model with multivariate logistic regression; they used the remaining cases to validate the model. This validation method is skillful in that it uses its own data to confirm their findings without needing to develop another study.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of "Which prognostic factors for low back pain are generic predictors of outcome across a range of recovery domains?" by Cook CE, Learman KE, O'Halloran BJ, et al., 2013.

Aim/Objective of the Study/Systematic Review:
The objective of this study was to identify prognostic factors for low back pain (LBP) and determine if any could be used to predict low back pain for 4 different outcome measures in various predictive models.
Study Design
This study was a secondary analysis of data from a multicentre randomized control trial (RCT) of 149 patients with low back pain. The RCT involved a comparison of manual therapy techniques, thrust manipulation versus non-thrust, for the treatment of LBP. **<u>Outcomes Used for Predictive Models</u>** The predictive models utilized 4 outcome measures that measured disability (Oswestry Disability Index (ODI)), pain (Numerical Pain Rating System (NPRS)), length of treatment (calculated using total visits), and the subjects' perception of how well they recovered (subjects asked how well they feel they have recovered based on a 0 to 100% scale, with 100% meaning they felt completely recovered). **<u>Statistical Methods for Predictive Models</u>** The predictive models were made after the above groups had been separated, using logistic regression modelling with backward stepwise deletion (0.05 enter and 0.10 exit). The prognostic models utilized a backward linear stepwise regression (0.05 enter and 0.10 exit) that identified the strongest significant model for change scores of the 4 major outcome measures mentioned above.
Setting
The original RCT whose data this study analysed took place in 16 outpatient physical therapy clinics across the United States. No specific clinics, cities, or states were mentioned in the study description.
Participants

There were 149 participants in the RCT this study used for prognostic data analysis. It appears that the study used a convenience sample, as no information was provided regarding recruitment strategies. The age of the subjects averaged at 48.2 (SD 14.9) years. There were 70 males and 79 females. The majority of the subjects were white (n=136), while black (n=3), Hispanic (n=3), Asian (n=2), and other/missing (n=4) rounded the rest of the races represented. The mean duration of symptoms was 33.9 weeks (SD 98.9).

At baseline, there was a fairly wide distribution of duration of symptoms. Half of the subjects were experiencing acute low back pain (n=75), 43 suffered from sub-acute low back pain, and 31 were experiencing chronic low back pain. After statistical analysis, there was approximately equal distribution of diagnosis between sprains/strains (n=70) and lumbago/degenerative/other (n=72) at baseline, with 7 diagnosis missing.

During the RCT, the sample was split into two groups of manual therapy based on their eligibility for spinal manipulation using a common clinical prediction rule: nonthrust manipulation (n=73) and thrust manipulation (n=76). The prognostic study used this group placement in its modelling to examine its overall effects on the outcomes. Additionally, 78 participants were categorized into the group that did not meet the clinical prediction rule (CPR) for spinal manipulation, and 71 participants did meet the CPR. There was no mention why there was a discrepancy between total number of CPR eligibility and manual technique.

There were no recorded dropouts and there was no mention of patients available for follow-up made by the authors of the study.

Intervention Investigated

There were 2 treatment groups in the RCT that was analysed secondarily for prognostic factors: comprehensive rehabilitation intervention that included thrust manipulation or non-thrust manipulation. Briefly, subjects received either thrust or non-thrust manipulation during their first two visits with a physical therapist experienced in orthopaedics and manual therapy; the following visits included care decided upon by physical therapists. The physical therapists were able to use whichever manual thrust or non-thrust technique they thought was best suited for the subject as long as they complied with the assigned thrust or non-thrust technique designated to the subjects.

The prognostic factors and outcome measures used in the prognostic studied are described elsewhere (Study Design and Outcome Measures sections).

Outcome Measures (Primary and Secondary)

The following 4 outcome measures were used in the predictive models in this secondary analysis. The outcomes were captured as part of the primary RCT. Details regarding administration of the measures (who, when) were not reported in this article.

Oswestry Disability Index (ODI)

- Measures disability related to low back pain
- 10 questions scored 0-5
- Max score – 50 points (higher score = greater disability)
- An improvement (reduction) of 50% on the ODI was considered the cutoff for positive result based of prior research.

Numerical Pain Rating Scale (NPRS)

- Used to assess patients pain intensity
- Ordinal scale from 0 (no pain) to 10 (worst pain)
- A positive improvement of ≥ 2.5 on the NPRS has been considered clinically meaningful in other studies, therefore the current authors used this score.

Duration of Treatment

- Number of total visits to physical therapy
- Authors independently decided an improvement of ≥ 75% would be considered a positive change, due to the lack of any standardized measurement in the literature.

Recovery Perception

- Self-reported
- Scale of 0 (not recovered at all) to 100% (completely recovered)
- The authors chose 6 total visits for their cut-off in this category because they felt that amount of visits were indicative of efficient and thorough care.

Main Findings

My main focus for this paper are the prognostic variables in relation to the ODI, since that is the subject of my PICO question. For the logistic regression modelling, there were 3 prognostic factors associated with a 50% reduction on the ODI:

- Eligible for CPR of spinal manipulation - ($p < .01$); Odds ratio = 2.9; 95% CI (1.4, 6.2)
- Younger Age – ($p < .01$); Odds ratio 1.04; 95% CI (1.01, 1.06)
- Strains and sprains diagnosis – ($p < .01$); Odds ratio 2.6; 95% CI (1.2, 5.5)

For the linear regression modelling, there were 5 prognostic factors associated with ODI change score:

- Initial ODI score – ($p < .01$); Unstandardized Coefficient ß Value: 0.48; 95% CI (0.38, 0.59)
- Met CPR – ($p < .02$); Unstandardized Coefficient ß Value: -4.2; 95% CI (-7.7, -0.69)
- Duration of symptoms - ($p < .01$); Unstandardized Coefficient ß Value: .35; 95% CI (-0.06, -0.01)
- Younger Age – ($p < .01$); Unstandardized Coefficient ß Value: -0.16; 95% CI (-0.27, -0.04)
- Strains and sprains - ($p < .04$); Unstandardized Coefficient ß Value: -3.39; 95% CI (-6.7, -0.08)

The actual pre- and post-scores of the variables or outcomes were not included in the study. Also, although "younger age" was specifically mentioned as a positive prognostic factor, a definitive number for what constituted "young" was not mentioned in this study.

Original Authors' Conclusions

For the ODI specifically, the authors concluded that 5 prognostic factors (age, sprain/strain diagnosis, eligible for CPR, duration of symptoms, and initial ODI score) could be used in determining a prognosis for a patient with low back pain. They found that eligibility for CPR was the only prognostic factor that was represented in each of their 4 predictive models, and the other prognostic factors were present depending on which outcome measures were being considered.

Critical Appraisal

Validity

(Jewell) Evidence About Prognostic (Risk) Factors: Quality Appraisal Checklist Score: 5/9

1. Was the sample defined? Yes.
2. Subjects representative of population from which they were drawn? No. The research question indicates low back pain, and this study excluded any cause of back pain that was not mechanical.
3. Did subjects enter study at the same stage of their condition? No. There were different stages of LBP chronicity included in the study.
4. Was the study time frame long enough to capture outcomes of interest? Yes.
5. Did the investigators collect outcome data from all subjects in the study? Yes.
6. Were outcome criteria operationally defined? Yes.
7. Was collection of outcome measures masked to the status of prognostic factors? No.
8. Does sample include subgroups for whom prognostic estimates will differ? If so, did investigators conduct separate subgroup analyses or statistically adjust for these different prognostic factors? Yes and yes.
9. Did investigators confirm their findings with a new set of subjects? No

There does not seem to be implicit bias in this study in that the authors used cut-off scores that were already established by the literature when possible. The fact that they used 4 different statistical models also bolsters the fact that they were truly looking at the variables from a variety of viewpoints and not with a biased lens. External bias is difficult for low back studies because of the heterogeneous samples that occur, making it hard to generalize results to a broader population of those who suffer with LBP. However, by running multiple models, the authors showed that a variety of prognostic factors remained constant, thus increasing confidence in the ability to generalize these prognostic factors.

A strength of this study is that the authors used multiple different outcome measures when assessing possible prognostic factors. This lessens the chance that prognostic factors were found from chance and also gave increased credence to a prognostic factor that was found to hold up across all four models (eligibility for CPR). When available, the authors used cut-off scores that were already supported by previous literature to dichotomize data.

That being said, a possible weakness is that rigid cut-off scores may not account for differing severity or duration of low back pain experienced by a patient. Including more information about the severity or nature of each patients' low back pain may help alleviate this weakness. Another weakness of the study is they used a randomized control trial for their data, rather than a cohort study which may be more appropriate for a

prognostic analysis. Although 149 is definitely not the smallest data set for a LBP study, a large sample size would improve the precision of the statistical analysis and perhaps made the results more generalizable.

Because "the assessment of the outcomes was not blinded to prognostic findings in the study," [p. 39] there is a chance for bias in that the authors could conveniently choose which factors or outcomes they thought may produce the most significant relationships.

Interpretation of Results

My interpretation of the results is that it is possible to determine prognostic factors for people suffering from LBP. Universally, only being eligible for the CPR for spinal manipulation served a prognostic factor that was revealed in each of the authors' four models. This would be a strong indication to me that these patients could be confident they have a better prognosis than if they did not meet the CPR eligibility criteria.

Focusing on the ODI results, I was not surprised to see that younger age was associated with a more positive prognosis in regards to disability. This has been echoed in much of the other literature and I don't believe any of the weaknesses of the study would preclude me from thinking that age is still a significant prognostic factor. I was somewhat surprised to see that the diagnosis of sprain/strain showed up as a negative prognostic factor in both ODI statistical analyses.

Although irritability was accounted for, I would have liked to have seen the severity of symptoms in the descriptive statistics of the sample. I'm also curious as to why a cut-off for younger age was not explicitly defined in the study. Everyone in the RCT received manual treatment, either thrust or non-thrust manipulation. This is important to remember because the results of the prognostic study can only be generalized to patients who receive manual therapy. There was no control group or comparison group that received no or different treatment than manual therapy. I believe this is why a cohort study that involved multiple groups of LBP patients including those who opt not to have treatment would be more representative of a larger, more diverse population. This may also reduce the chance for measurement bias. If the cut-off scores are established at the beginning of a cohort study, there would be less chance for the implicit bias of choosing a number to make the statistics work more favorably.

(2) Description and appraisal of, "The importance of identifying and modifying unemployment predictor variables in the evolution of a novel model of care for low back pain in the general population." by Harris SA and Rampersaud YR (2016).

Aim/Objective of the Study/Systematic Review:

There are two major aims of this study involving a cohort of low back pain (LBP) sufferers. First, the authors wanted to determine modifiable risk factors in this cohort and how those factors negatively influenced the work status of subjects at the time of presentation to the clinic. Secondly, the authors examined longitudinal data to determine modifiable factors that could lead to a change in work status during a 6-month duration of treatment.

Study Design

- A prospective observational study
- Subjects appear to be the result of a convenience sample taken from December 2012 to August 2014
- Patients were examined by either physical therapists or chiropractors who had received specific training for LBP examinations and were split into 4 categories based on dominant pain patterns: P1 – back dominant pain brought on by flexion; P2 – back dominant pain brought on by extension; P3 – constant leg dominant pain; P4 – intermitten leg pain
- For the first objective (predictors of work status at initial presentation), cross-sectional analysis of baseline data from initial consultation (t_0) determined work status and was dichotomized into either an employed (E) or underemployed (UE) group
- Multvariate logistic regression modelling was used to determine independent predictors of UE status at t_0
- For the second objective (predictors for change in work status over 6 months), longitudinal analysis was completed on matched patient data at initial consultation (t_0) and 6-month follow-up (t_1)
- The cohort was then categorized into 4 groups of work status over the duration of a 6-month period: E/E – employed at t_0 and employed at t_1; E/UE – employed at t_0 and underemployed at t_1; UE/E – underemployed at t_0 and employed at t_1; and UE/UE – underemployed at both t_0 and t_1
- Outcome measures were measured at baseline (t_0) and at 6-month follow up (t_1), when subjects completed a comprehensive intake form including: pain and neurologic history, analgesia use, employment status, functional limitations, allied health utilization, investigations completed,

comorbidities, smoking history, Oswestry Disability Index (ODI), EuroQol-5D, Connor-Davidson Resilience Scale 2, self-efficacy of managing chronic disease questionnaire, and the STarT Back tool.
- There was no mention of randomizing subjects, blinding, or concealed allocation to groups.
- There was no mention of blinding when collecting or entering data for the outcome measures
- Patients with complete data sets were matched and baseline differences in modifiable factors between groups were identified using bivariate analysis.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

This study took place at the Inter-Professional Spine Assessment and Education Clinics (ISAEC) in Ontario, Canada. This clinic includes primary care physicians, physical therapists, and chiropractors.

Participants

Patients with unmanageable LBP of greater than 6 weeks are referred to ISAEC by primary care physicians. Although not specifically defined by the authors, it appears the subjects were recruited out of convenience when they were referred to ISAEC.

Inclusion Criteria

- Work-eligible, non-workers compensation patients with recurrent or persistent LBP ≥ 6 weeks and ≤ 12 months

Exclusion Criteria

- Red flag symptoms, established pain disorder, established narcotic dependency, pregnant, or postpartum < 1 year.

Participant data of the study were described in the following two categories, mentioned above in the Study Design section.

(1) Risk factors for underemployment at baseline ISAEC consultation

- Initial consultation data from 659 patients from December 2012 to August 2014
- Students (n=22), retirees (n=143), and other [not defined] (n=7) excluded due to focus on workforce
- There was n=462 subjects consecutively analysed (Employed at baseline n=344, underemployed at baseline n =118)
- The mean age of participants was 45 (SD 12.58) years.
- 52% of the participants were female, 48% were male.
- There was no statistical difference in subjects between employed and underemployed at baseline for age, gender, body mass index (BMI), pain pattern, LBP associated with injury, or duration of symptoms.

(2) Predictive factors for change in employment status over 6-month treatment program

- Data was taken from December 2012 to August 2014
- There was n=324 consecutive subjects who completed baseline and 6-month follow up
- There was n=168 work-eligible subjects with complete data sets
- No specific information regarding age, gender, or duration/severity of illness was provided for this data set.

There was no mention for either group objective of dropouts or subjects available for follow-up. The authors did not make it clear if all the subjects from (2) were inclusive of those subjects from (1), but this is assumed.

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Patients who are referred to ISAEC receive consultation with physical therapists or chiropractors trained to treat LBP, as mentioned in the Study Design. Subjects received a "comprehensive assessment with multidimensional risk stratification" [p 17] as described in the Study Design section above. Patients at the ISAEC center received education, help with self-management of their LBP, and a multidisciplinary plan of care. Management plans were individualized by pain presentation patterns, and if the patients scored > 7 on the STarT Back tool, they were recommended for cognitive behavioural therapy as well. There was no mention of total hours or specific modes of treatment used by the providers at ISAEC.

Outcome Measures (Primary and Secondary)

Although additional outcome measures are mentioned when describing the intake data received from patients at baseline, the following are the only outcome measures mentioned again in the study.

Oswestry Disability Index (ODI)

- Administered at baseline and 6-month follow-up (no specific mention of who administered)
- Measures disability related to low back pain
- 10 questions scored 0-5
- Max score – 50 points (higher score = greater disability)

Numerical Pain Rating Scale (NPRS)

- Administered at baseline and 6-month follow-up (no specific mention of who administered)
- Used to assess patients pain intensity
- Ordinal scale from 0 (no pain) to 10 (worst pain)

STarT Back Screening Tool

- Administered at baseline and 6-month follow-up (no specific mention of who administered)
- Prognostic questionnaire to identify modifiable risk factors for back pain disability
- 9 questions scored as "agree" or "disagree," except a borthersomeness of back pain over previous 2 weeks item, which is scored on a Likert scale (0 for not at all, slightly, or moderately; 1 for very much or extremely
- Results in overall score (0-9, 9 being the highest risk) and a "distress" (psych) subscale (0-4, 4 being the most distressed)
- Patients stratified into low (≤3), medium (4-7), or high risk (≥7 including ≥4 on psych subscale)

Main Findings

(1) Bivariate analysis of risk factors for underemployment at baseline ISAEC consultation

- Statistically significant factors associated with unemployment at baseline (UEt_0) versus employment at baseline (Et_0) using bivariate analysis are listed below. Scores for pain use the Numerical Pain Rating Scale (NPRS).
- **Presence of a worker's compensation legal complaint or insurance claim** - Et_0 12/329 (3.65%); UEt_0 12/113 (10.60%); p=0.005
- **Higher LBP at rest** (NPRS) - Et_0 4.22 (SD 2.56); UEt_0 5.00 (SD 2.77); p = 0.007
- **Higher LBP with activity** (NPRS) – Et_0 6.62 (SD 2.62); UEt_0 7.38 (SD 2.33); p < 0.001
- **Higher leg pain at rest** (NPRS) - Et_0 3.50 (SD 2.87); UEt_0 4.33 (SD 3.10); p = 0.010
- **Higher leg pain with activity** (NPRS) - Et_0 5.32 (3.18); UEt_0 6.11 (SD 3.57); p = 0.030
- **Increased opioid use** – Et_0 71/344 (20.64%); UEt_0 38/118 (32.20%); p = 0.010
- **Less use of allied health providers** – Et_0 270/344 (78.48%); UEt_0 77/118 (65.25%); p = 0.006
- **Higher occurrence of self-reported depression history** - Et_0 50/328 (15.24%); UEt_0 35/109 (32.11%); p < 0.001
- **Higher rate of smoking** - Et_0 66/336 (19.64%); UEt_0 58/116 (50%); p < 0.001
- **Higher ODI** - Et_0 33.00 (SD 15); UEt_0 46.00 (SD 17); p < 0.001
- **Increased risk of higher chronicity (score of ≥ 7 on STaRT Back)** - Et_0 76/344 (22.10%); UEt_0 48/118 (40.67%); p < 0.001

(1b) Multivariate logistic regression analysis of independent risk factors associated with underemployment at baseline ISAEC consultation

- **Legal or insurance claim** (variable) versus no legal or insurance claim (reference variable); odds ratio = 2.77; 95% Confidence Interval (CI) 1.05 – 7.32; p = 0.040
- **Depression** (variable) versus no depression (reference variable); odds ratio = 2.28; 95% CI 1.15 – 4.54; p = 0.019
- Overall model of fit: chi-square=69.90; degrees of freedom=8; p < 0.001

(2) Predictive factors for change in employment status during 6-month treatment program

- The overall underemployed rate did not statistically change during the study period (UEt_0 = 25/5%, 6-month follow up (UEt_1) = 22.9%)
- 10.5% of those employed at baseline became unemployed at 6-month follow up
- Bivariate analysis demonstrated **baseline ODI** as the only significant factor to differentiate between E/E and E/UE, with a higher baseline ODI making a transition to UEt_1 more likely (p = 0.0101)
- To identify patients at risk of transitioning from Et_0 to UEt_1, a receiver operating characteristic (ROC) curve classified a cutoff score of greater than 37.8% of baseline ODI score.
- ISAEC improved employment status in 41% of UEt_0 to Et_1 (UE/E=16, UE/UE=23)

- For unemployed subjects at baseline, absence of depression was a significant contributor to improving to employment at 6-month follow up (0% at baseline, $p < 0.001$)

Original Authors' Conclusions

The authors conclude that treatment for LBP needs to be broader than their proposed model (patient education and cognitive behavioural therapy for high-chronicity risk patients) when considering overall employment rate. They believe an improved care model for LBP would address a multitude of factors, including smoking cessation and addressing depression. They also posit that identifying the predictive factors for underemployment early in a patient's plan of care might elicit a greater response in improving work status and disability in patients with LBP.

Critical Appraisal

Validity

(Jewell) Evidence About Prognostic (Risk) Factors: Quality Appraisal Checklist Score: 6/9

1. Was the sample defined? Yes
2. Subjects representative of population from which they were drawn? Yes. A major focus of this study the effect of LBP on employment status, and the study only included those who were eligible for the workforce.
3. Did subjects enter study at the same stage of their condition? No. There were different stages of LBP chronicity included in the study.
4. Was the study time frame long enough to capture outcomes of interest? Yes.
5. Did the investigators collect outcome data from all subjects in the study? Yes.
6. Were outcome criteria operationally defined? Yes.
7. Was collection of outcome measures masked to the status of prognostic factors? No.
8. Does sample include subgroups for whom prognostic estimates will differ? If so, did investigators conduct separate subgroup analyses or statistically adjust for these different prognostic factors? Yes and yes.
9. Did investigators confirm their findings with a new set of subjects? No

This study scored the best of the 10 reviewed studies on the above checklist. The study benefited from clearly defining that they were interested on predictive factors and LBP care within the scope of how they affect employment. Thus, they were able to accurately present a sample that is representative of their primary goal, something that is difficult in more generalized LBP literature. The chance for implicit bias is low because a wide variety of questions were asked at patient intake, demonstrating the authors were not simply looking for factors to validate a preconceived notion of what they thought they might find. The prospective design of the study also bolsters the case for minimizing implicit bias - the authors reported on what they found over a period of time rather than picking and choosing factors out of previously completed data sets. The strongest data comes from the bivariate analysis of factors affecting work status at baseline, where significance was reached on a large number of factors.

LBP studies in general suffer from a lack generalizability due to different stages of chronicity, multiple aetiologies, and heterogeneous samples. Furthermore, this study may be cautiously generalized to predictive factors and work status due to controlling for age of worker eligibility and specific tracking of employed versus underemployed. However, the study does suffer from not recording the type of work each individual was involved in. For example, heavy labour and a desk job would require different levels of physical exertion and LBP may negatively affect one's ability to more laborious jobs versus less laborious jobs. Many other LBP studies do not track employment status and a lack of standardization for outcome measures regarding employment related to back pain make the results of this study hard to compare to others in terms of employment status and predictive LBP factors.

There was no mention of blinding or concealed allocation, which potentially weakens the study. Since it was not mentioned, it must be assumed that those who measured data and performed treatment were not blind to employment status, which hurts the overall validity of the study.

Interpretation of Results

I think the importance of this study is the identification of baseline predictors in patients with LBP who are employed versus unemployed. The statistical difference between the two groups demonstrates that taking these factors into account when treating patients with LBP can be used to better establish an effective prognosis for patients. Since employment status is a major contributor to a patient's quality of life, identifying and treating specific factors such as smoking and depression could be especially important additional considerations when treating LBP.

Additionally, this study lends credence to the importance of using the ODI as not only an outcome measure for disability, but an important prognostic indicator at baseline testing. Subjects who were employed at baseline and scored greater than 37.8% on the ODI had a 77% chance of becoming unemployed at 6 months. This introduces an important prognostic number into the literature and suggests that patients who score higher than 37.8% may need more intensive care and attention to prevent them from becoming unemployed due to their LBP.

(3) Description and appraisal of "Predictive factors for successful clinical outcome 1 year after an intensive combined physical and psychological programme for chronic low back pain." by Van Hooff ML, Spruit M, O'Dowd JK, Van Lankveld W, Fairbank JCT, Van Limbeek J., 2014.

Aim/Objective of the Study/Systematic Review:

The objective of this study was to identify baseline factors in patients with chronic low back pain (CLBP) that would predict a positive outcome in terms of disability as measured by the Oswestry Disability Index (ODI). A positive outcome was defined as improved disability scores that matched healthy subjects' scores on the ODI after a one year follow-up.

Study Design

- This study used a prospective single group cohort design that measured potential predictive factors at baseline
- The prognostic factors of pain, disability, work status, and psychosocial issues were analysed prospectively.
- After the subjects completed a 2-week residential program for LBP, the prognostic factors were related to disability as measured by the ODI at 12 months' follow-up
- Outcome measures were measured by self-reported questionnaires and were collected at baseline, after the 2-week intervention, and at one-year follow up.
- There was no mention of blinding in regards to collecting outcome measures
- For data analysis, the cohort was randomly separated into two equal samples. The first sample was used to develop the prediction model; the second group was used to validate the prediction model.
- At baseline, categorical data was counted and described in percentages; continuous variables were reported with means and standard deviations.
- Differences between both groups used Chi square tests for categorical variables and independent Student's *t* tests for continuous variables

Setting

The study took place in a "hotel facility" [p 108] somewhere in the Netherlands. No further information was provided regarding location or setting.

Participants

- Between October 2006 and January 2011, n=524 patients participated in the study
- Patients were recruited from a group of CLBP patients who were referred to an outside orthopaedic hospital that specialized in spine care. Those who did not respond to conservative primary care treatment and were not eligible for spinal surgery were referred to the program for this study.
- Of this sample, 67 patients (12.8%) had missing data from at least one assessment after baseline
- Data for 25 patients (4.7%) was missing at the post-treatment assessment
- 15 patients (2.8%) left during the 2-week intervention
- The 67 total patients with missing data were not significantly different than those with complete data sets in regards to pre-treatment characteristics or pre-treatment outcome measures
- Inclusion criteria for patients: LBP ≥ 6 months, 18-65 years old, willingness to change behaviour, consent to follow a 2-week program in a hotel facility, and able to read and speak Dutch.
- Exclusion criteria for patients: involvement in litigation or compensation claims, or psychiatric disorders that have been clinically diagnosed by a psychiatrist
- Gender: 303 female, 221 male
- Age: 45.4 (SD ± 9.6) years
- Duration of LBP: 12.5 (SD ± 10.8) years
- Disability as measured by ODI (out of 100): 41.4 (SD ± 14.1)

Intervention Investigated

Briefly, the intervention used for CLBP patients in this study consisted of a 2-week multidisciplinary treatment involving cognitive behavioural training, physical activity, and patient education. Total contact time

with patients was 100 hours. Outcome measures and specific prognostic factors studied are included below in the Outcome Measures section.

Outcome Measures (Primary and Secondary)

Oswestry Disability Index (ODI)

- Measures disability related to low back pain
- Primary outcome measure in this study to measure functional status
- 10 questions scored 0-5
- Max score – 50 points (higher score = greater disability)

Numeric Rating Scale

- Measures severity of pain
- Ordinal scale of 0-100
- Higher scores indicate greater pain intensity

Modified Zung Self-Rating Depression Scale (ZSDS)

- Measures depression and psychological distress
- 23 items, scored on a 4-point ordinal scale
- Scores range from 0-69
- Higher levels indicate depressed mood
- For CLBP, classifications of normal (<17), at risk (17-33), and depressed mood (>33)

Pain Self-Efficacy Questionnaire (PSEQ) (Dutch translation)

- Measures patient's belief in ability to accomplish activity regardless of pain
- 10 items, scored on a 7-point ordinal scale
- Scores range from 0-60, with higher scores indicating greater self-efficacy beliefs

Pain Catastrophizing Scale (PCS)

- Measures pain catastrophizing
- Items based on 5-point ordinal scale
- Scores range from 0-52, with higher scores indicating greater pain catastrophizing

Tampa Scale for Kinesiophobia (TSK)

- Measures fear of movement or (re)injury
- Unweighted sum scores range between 17 and 68
- Higher scores indicate greater fear of movement

In addition to the above outcome measures, the following potential prognostic factors measured at baseline included gender, employment status (dichotomized into employed=1, unemployed=0), taking pain medication (dichotomized into yes=1, no=0), history of surgery, age (categorized in tertiles – years; age ≤42, 43-50, >50), and duration of CLBP (in years).

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable]

- A univariate logistic regression model indicated that age categories, previous surgery, being employed, pre-treatment pain self-efficacy, and pre-treatment disability presented as possible predictors for a success (ODI score of <22 at 1 year follow-up)
- Using a forward selection model in one block, the above variables were analysed in the model.
- The final prediction model identified **employment** (odds ratio (OR) 3.61 [95% CI 1.80-7.26]) and **pre-treatment disability as measured by the ODI** (OR 0.94 [95% CI 0.92-0.97]) as significant predictive factors for a better prognosis of becoming less disabled as measured by the ODI
- When unemployed, a patient has a "1.3-fold risk of failure" [p 107]
- The pre-treatment ODI score was seen as protective, meaning that each point closer to "normal" (10 SD 12) on the ODI a patient was at baseline, they had a 6% better chance of meeting the success criterion (≤22 on the ODI at 1-year follow up)
- Validity of the above model was checked using the remaining patient cases (n=262) and found similar results, albeit less precise due to broader 95% CI limits around the OR's.
- None of the models reflected psychological distress as being a contributor to failure (>22 score on ODI at 1-year follow up), therefore no separate analysis was performed on these factors.

Original Authors' Conclusions

The authors conclude that being employed and having lower disability scores on the ODI are predictive of higher function one year after receiving treatment for CLBP. They conclude that even highly psychologically

distressed patients can benefit from a model of care that includes physical activity, education, and cognitive behavioural training to decrease disability in CLBP patients, and these changes can be maintained for a reasonably long period (12 months). They posit that identifying patients who are employed and are moderately disabled at the time of treatment should be relatively easy and lead to a positive prognosis in terms of disability for these patients.

Critical Appraisal

Validity

(Jewell) Evidence About Prognostic (Risk) Factors: Quality Appraisal Checklist Score: 5/9

1. Was the sample defined? Yes
2. Subjects representative of population from which they were drawn? No. CLBP patients are notoriously heterogeneous, and nothing about this study design makes it easier to generalize to the broad CLBP population.
3. Did subjects enter study at the same stage of their condition? No. There were different stages of LBP chronicity included in the study.
4. Was the study time frame long enough to capture outcomes of interest? Yes.
5. Did the investigators collect outcome data from all subjects in the study? Yes.
6. Were outcome criteria operationally defined? Yes.
7. Was collection of outcome measures masked to the status of prognostic factors? No.
8. Does sample include subgroups for whom prognostic estimates will differ? If so, did investigators conduct separate subgroup analyses or statistically adjust for these different prognostic factors? Yes and yes.
9. Did investigators confirm their findings with a new set of subjects? No. This point could be argued since they randomized the original cohort to validate their predictive model. However, that doesn't guarantee a true "newness" of subjects, since subjects in the validation group received all the same interventions, perhaps from the same providers at the same time period and at the same setting, although none of this is made clear.

The internal validity is strengthened in this study due to its prospective design. The large sample size also helps its validity. The investigators measured a large number of outcome measures and possible prognostic factors, thus lowering the chance they were trying to cherry pick factors they thought they might find. The fact that they defined a successful outcome as a patient reaching an ODI score (plus its standard deviation) reflective of the normal population (ODI= 10 SD 12) demonstrates a step further than only considering the MCID that is (somewhat arbitrarily) set at 10 points in the literature. This strengthens their outcomes in that true disability is tested at one year follow up, rather than an improvement on the ODI that may still result in disability. On the contrary, 60 of the 217 patients who reached a "normal" ODI score at one-year follow-up already had a score of < 22 when they began. Although a small percentage, it is not negligible and thus skews the internal validity of the success rate slightly.

Their predictive model is strengthened by the fact they used the remaining randomized data set to validate the model. This is a step further than many studies take when developing prognostic models, and this effort should be viewed as lessening the chance for internal bias. As far as generalizability, as mentioned above, it is hard to extrapolate these findings and say they are valid for the entire CLBP population. The intervention also contains a large aspect of cognitive behavioural training, which is not the case in much of the LBP literature, thus making it difficult to compare to existing literature or contemporary physical therapy practice.

Interpretation of Results

The strengths of the study discussed above, especially the secondary validation modelling, show that the prognostic factors of employment and initial ODI score should be considered as potential prognostic factors for patients with CLBP. The authors found no contribution of psychological distress to long term prognosis, which is the current overriding belief in the literature. However, I would be interested in them finding a way to measure "readiness to change," especially since it was part of their inclusion criteria. With CLBP and chronic pain in general, I think the psychosocial aspect cannot be underestimated. They may have purposefully avoided some of these patients by excluding those with a pre-existing psychological diagnosis in an effort to focus their study, but I believe this may have led a potential selection bias.

It might go without saying, but intuition would suggest that a patient who is still able to work and scores low on disability (per the ODI) will have a better prognosis. Perhaps what this study contributes is that identifying these patients might help over utilization of health care resources for patients who are highly likely to improve, and focus efforts and resources on patients who present as unemployed and more disabled. This study in no way offers a comprehensive, definitive look at prognostic factors for LBP sufferers, but it does add a well-designed study to support employment status and disability as part of the LBP prognostic puzzle.

EVIDENCE SYNTHESIS AND IMPLICATIONS

A difficult aspect of prognostic LBP research are the numerous methods and interventions used to treat LBP. The above 3 studies all used very different approaches to treating LBP, and much more variety can be found in the literature. This makes studying prognostic factors for LBP especially difficult when the inherent heterogeneity of LBP is taken into consideration. Care should be taken when considering how prognostic study results may transfer over into the clinical setting, particularly in regards to the types of treatment one is using. It may be worthwhile to attempt to find studies that use interventions similar to the intended clinical treatment when considering how applicable any prognostic factor may be. Additional thoughts on implications for clinical practice are below.

Implications for Clinical Practice

The result of this Critically Appraised Topic has provided some answers to the question of identifying prognostic factors for LBP patients in regards to disability as measured by the ODI. Identification of prognostic factors in this population is important for a multitude of reasons. First, LBP is extremely prevalent in our developed society. Causes of LBP are beyond the scope of this paper, but the sheer number of patients a physical therapist will see with LBP begs the inclusion of prognostic considerations when developing a plan of care. The examination of a patient is immediately followed by setting a prognosis that is reflected in the goals and planned interventions for that patient. Using evidence based prognostic factors to influence these decisions can affect multiple stakeholders in the health care system, from the patient to the therapist, the greater facility wherein they both first meet, and national and global health costs spent on treating LBP. Patients who present with positive prognostic factors may need less clinical resources devoted to help them improve. This frees up time, money, and other resources for those patients who have negative prognostic factors.

This paper demonstrates that a younger age, lower initial disability score on the ODI, being presently employed, eligibility for the clinical practice rule for spinal manipulation, and lower duration symptoms are all possible prognostic signs that a patient could be scheduled less often, referred to a specialist less often, and avoid prescription pain medication at the onset of care. These 3 factors alone would free up resources and lower the high burden of cost from LBP. Of course, a clinician must use their discretion at how many of these prognostic factors must be present and each patients' individual circumstances when determining these clinical considerations. However, multiple recent studies have suggested that the presentation of many of these factors show a positive chance of a patient becoming less disabled compared to those who do not present with these characteristics.

Future Research

A big consideration that must be made for future LBP research is to reach a more agreeable, standardized definition of the success of a treatment approach. Van Hoof et al[11] introduced an interesting concept in considering success of LBP treatment to be an ODI score that approaches that of the "normal" population (10, SD 12, or 22 points total). This could at least implement a standard of acceptable disability and more accurately reflect the success of a treatment, rather than improving the ODI score a "clinically relevant" amount that could still leave the patient highly disabled. This would also help frame prognostic studies in a more favourable light, making prognostic factors much more valuable if they can predict who will eventually approach a normal score on the ODI.

Another helpful consideration for future prognostic research should implement cost analysis. As mentioned in the clinical implications above, designing studies that tracked costs and identified prognostic variables would go even further to shed light on how certain predictive factors play into the cost of caring for LBP. In this vein, tracking patient's exposure to specialists, prescription of pain medication, and eventual surgeries could all be important variables related to cost.

Finally, prognostic considerations that measure disability are intricately tied into employment status. It is not enough to simply measure whether somebody is employed or not. The type of job and its demands would be valuable information to include in prognostic LBP studies that include employment as a factor of disability. This would provide a more accurate picture of how much disability actually predicts one's ability to work for different types of jobs. Identifying prognostic factors could be further stratified by their effect on return to work depending on employment demands.

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