Clinical course and prognostic factors in patients with low back pain and disability: a methodological and clinical study

Margreth Grotle, fysioterapeut og dr.philos.


Introduction
Limited knowledge of the causes of low back pain (LBP) (box 1) and how chronic LBP and disability develops has probably contributed to a negative trend of poor interventions, increasing disability and costs due to LBP. Waddell (1) and other back pain researchers (2) have claimed that the failure to distinguish between pain and disability might explain some of the poor effectiveness of most treatment interventions. Most clinicians have acted as if disability is caused by pain and ignored that pain and disability are both conceptually and clinically different. A pain experience is always subjective and involves several components such as localization, quality and intensity, but also affective and behavioural components (3) (box 2). For example, LBP is, for many patients, an intense and overwhelming experience that is closely associated with fear and anxiety responses, psychological distress and avoidance behaviour (4,5).

The relationship between pain, impairments, activity limitations and participation restrictions in the context of LBP is not straightforward. Neither pain nor different impairment factors can explain the magnitude of activity limitations or work restrictions (3). The report of LBP and the seeking of health care are influenced by a range of psychological variables such as cognitions (e.g., thoughts, beliefs, judgement, knowledge, attitudes and memory), affective factors (e.g., anxiety, depression, distress) and social factors such as social support and job satisfaction (6,7). In order to prevent the development of chronic LBP, early identification of patients at risk of becoming chronic is important. Development and use of screening procedures for early identification and early optimal interventions are great challenges in primary health care.

Box 1. Definition of LBP
LBP is defined as pain located between the lowest ribs and the inferior gluteal folds, with or without pain radiation to the lower limb(s). It should be distinguished between the following three spinal conditions (diagnostic triage):

1. Low back pain alone (non-specific): reflects the absence of objective findings e.g. lump, bago, dorsalgia etc.
2. Low back pain with nerve root affection: may be identified by a combination of neurological symptoms and signs such as:
   - radiating pain below knees with a pattern according to one or more dermatomes
   - reduced straight leg raising (reproduction of the pain)
   - numbness or paresthesia
   - motor, sensory and/or reflex changes according to one or more dermatomes
   - coughing/sneezing reproduce the pain
3. Possible serious spinal pathology
   (red flags)

Box 2. Definition of pain
The International Association for the Study of Pain (IASP) defines pain «as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage».

The definition is based on the gate control theory of pain by Melzack and Wall, in which the conceptualization of pain was expanded from a purely sensory phenomenon (nociceptive input) viewed in a simple disease model to a multidimensional biopsychosocial model that integrated motivational-affective and cognitive-evaluative components with sensory-physiological ones.

Early identification of potential future problems is dependent upon estimations of prognosis over time. A growing number of studies have attempted to identify the best prognostic factors for recovery from an episode of LBP. However, the estimations of clinical course and prognostic factors in the literature are hampered by conceptual and methodological difficulties, such as:
1. There is poor consensus on how to distinguish between pain and disability when it comes to assessment methods.
2. A number of assessment methods have been used, both as outcome and prognostic variables.
3. Wide selection criteria and heterogeneous study samples have made the estimations of prognosis across different subgroups of the back pain population difficult.

Sammendrag
Smerter i nedre del av ryggen (LBP) er den mest vanlige årsaken til medisinsk konsultasjon og den andre lederen til sykefravær. De fleste akutte episoder av LBP blir bedre i løpet av få uker, men mange oppnår ikke fullstendig bedring av smerter og funksjonsbegrensninger. For disse pasientene har smertene store konsekvenser for helse og livskvalitet. Økningen i langvarig sykefravær og uførepensjon viser hvilke konsekvenser LBP har i samfunnet. Denne artikkelen tar for seg bakgrunnen for et doktorarbeid med fokus på sentrale effektmål ved evaluering av smerte og funksjonsbegrensninger ved LBP og tidlig identifisering av prognostiske faktorer for å utvikle kronisk LBP. Nækelord: ryggsmerter (LBP), effektmål, prognostiske faktorer
4. There are few prognostic studies on patients at an early stage of LBP. This article provides a shortened overview of the background for the present thesis (8) which focused on two main topics: 1) outcome measures of pain and disability used for patients with LBP and 2) clinical course and prognostic factors for chronic LBP. In addition, a brief summary of the main findings is presented. Readers who are interested in the details regarding the methods, results and discussion of the findings are referred to the thesis or the published papers (8).

**Measurements of pain and disability in LBP**

There is a large amount of information that may be relevant in the process of examining a patient with LBP, to form basis for optimal treatment, setting relevant goals for the treatment and to evaluate the clinical progress and outcome during the treatment period. To guide this process and to make distinctions between related concepts regarding pain and disability, the multidimensional model and classification of WHO, the International Classification of Functioning, Disability and Health (ICF) (Figure 1) (9), may be helpful.

In this model, positive and negative aspects of human functioning can be described in three dimensions: impairments at the body level, activity limitations at the person level and participation restrictions at the level of society. Functioning and disability are conceived as a dynamic interaction between health conditions and contextual factors. Contextual factors include both personal and environmental factors. The definitions of the main concepts in the ICF are presented in Box 3.

The ICF may be used to provide an overview of domains frequently assessed in the clinic and research related to LBP (Table 1). The overview reminds researchers and clinicians that a diverse range of factors need to be considered when understanding the multifaceted nature of disability. It shows the wide range of measurements that may be applied, from laboratory tests, symptoms, joint mobility and muscle strength, to measures of daily life activities, employment status and costs related to health services. Selecting the relevant and optimal measurements is therefore a challenging task. In addition to considering the main purpose of the assessment, it is necessary to consider the appropriateness and practicality of the measure. The purpose of assessment may be to (10,11):

- Discriminate among individuals/groups of individuals.
- Predict prognosis.
- Evaluate change over time (outcome measurements).
- Measure the impact of the intervention.
- Predict prognosis.

During the past two decades, there has been considerable development of self-report questionnaires for evaluating disability related to LBP. Furthermore, there is a wide range of generic and utility measures which are frequently used as outcome measures in LBP (Box 4).

Several authors have suggested criteria to help in selection of outcome measures (12-14). These criteria mostly focus on the measurement properties of the outcome measures. There is, to date, no general agreement about how to define and operationalize functioning/disability (15-17). Some researchers have been using the ICF as a conceptual model when developing back-specific disability questionnaires (18-21).

However, for most questionnaires, e.g., the frequently used Roland Morris Disability Questionnaire (RMQ) (22) and the Oswestry Disability Index (ODI) (23), there is a lack of theoretical foundation. In these measures different domains of functioning are combined into a single disability score. There is also frequently a lack of distinction between capacity to perform an activity, perceived difficulty and actual performance of tasks. These shortcomings influence the content and construct validity of the measurements, making it difficult to know what is really measured by these instruments. Hence, there is a need for investigating the content and construct validity of frequently used outcome measures in LBP.

**Clinical course and prognosis**

Studies of clinical course assess how an...
episode of LBP develops subsequent to diagnosis and most often after initiation of treatment, whereas studies of the natural course of LBP assess the development and progress of LBP in the absence of clinical intervention. The clinical course of LBP has often been expressed as three phases – acute, subacute and chronic (Box 5) – as presented in Figure 2 (24). The curve shows that most patients return to work within six weeks. Workers absent from work after three months are very likely to still be absent at six months. After six months’ absence, the likelihood of returning to work is estimated to be 20%. These chronic patients have a poor prognosis for recovery. The important message is that the more time that passes, the less the likelihood of returning to work.

A recent systematic review (25) of prognosis in acute LBP confirms the widely held view that most people with acute LBP have rapid improvements in pain, activity limitations and work restrictions during the first month. Pooled estimates of reductions in pain and disability (mainly in terms of activity limitations) were reported to be 12-84% (mean 58%) and 33-83% (58%), respectively, of the initial levels during the first month. Of patients initially off work, 68-86% (pooled estimate 82%, 95% confidence interval [95% CI] 73% to 91%) returned to work. Further improvement occurred until about three months, whereas a constant level of pain, activity limitations and return to work was seen thereafter. At least one recurrence within 12 months occurred in 73% (59% to 88%) of patients.

It is likely that due to the significant influence of a history of LBP on the report of LBP, patients with a first-time LBP should be distinguished from those with a recurrent episode of LBP. Furthermore, since time (duration of LBP) is a crucial factor in the clinical course of LBP, it is necessary to distinguish between patients with recent onset of an episode of LBP (acute) and those with pain for some weeks (sub-acute). The clinical course of LBP also depends on the outcome measure used, in particular whether pain, activity limitations or work restrictions are used as the outcome. When making these distinctions, the clinical course of LBP may be summarised as follows (1) (see page 15):

1. Clinical course in the short term (up to 3 months):
   - Patients with first-time onset of acute LBP, who seek help in primary care, will improve considerably over the first weeks; only 4-6% report pain after 4-7 weeks. In the few studies on first-time acute LBP, recovery rates for activity limitations and work restrictions in the short term were not reported.
   - Patients with recurrent episode of acute LBP who seek treatment in primary health care show large variations with regard to recovery/improvements during the first months. Of patients with short pain duration (< 3 weeks), 10-30% report pain and activity limitations and 6-38% report work restrictions. In mixed samples, 33-80% of patients report pain, 8-79% report activity limitations and 8-45% have work restrictions due to LBP.

2. Clinical course in the longer term (6 months – 1 year):
   - Patients with first-time onset of acute LBP, regardless of pain duration, have a good prognosis with regard to work restrictions: only 1-5% of these patients have not returned to work at 1 year. However, recurrences are common in this patient group; 30-84% report persistent or recurrent pain after 1 year’s follow-up. In the few studies of first-time onset, none report recovery rates for activity limitations.
   - Patients with recurrent episode of acute LBP also show high variations in recovery.
Table 1. Domains frequently assessed in low back pain categorised according to the ICF component.

<table>
<thead>
<tr>
<th>Body functions, physical</th>
<th>Body functions, mental</th>
<th>Activity/ participation domains</th>
<th>Environmental factors</th>
<th>Personal/ socio demographic factors</th>
<th>Other health-related aspects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (localisation, quality, intensity)</td>
<td>Depression</td>
<td>Leisure-time physical activity</td>
<td>Job demands</td>
<td>Age</td>
<td>Medical diagnosis¹</td>
</tr>
<tr>
<td>Neurological symptoms/signs</td>
<td>Anxiety</td>
<td>Interaction with family and friends</td>
<td>Job control</td>
<td>Gender</td>
<td>Comorbidity³</td>
</tr>
<tr>
<td>Joint mobility</td>
<td>Somatic perceptions</td>
<td>Work status</td>
<td>Job stress</td>
<td>Body height</td>
<td>Medication use</td>
</tr>
<tr>
<td>Muscles (strength, endurance, flexibility)</td>
<td>Distress</td>
<td>Type of work activities such as: Bending and twisting, Manual material handling (lifiting, carrying, pushing and pulling), Patient handling, Work load, Prolonged standing, walking and sitting</td>
<td>Social support</td>
<td>Body weight</td>
<td>Costs/utilization (number of visits/tests, charges, etc.)</td>
</tr>
<tr>
<td>Fitness/aerobic capacity</td>
<td>Cognitions (including fear-avoidance beliefs)</td>
<td>Coping strategies (including pain behaviours)</td>
<td>Compensation system</td>
<td>Smoking</td>
<td></td>
</tr>
<tr>
<td>Structural changes (leg length, structural changes identified on plain X-ray, MRI or CT)</td>
<td>Coping strategies (including pain behaviours)</td>
<td>Job satisfaction (37)</td>
<td>Relationship employer-worker</td>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Body posture</td>
<td>Job satisfaction (36-39;41)</td>
<td>Vibration on job (44)</td>
<td>Attitudes to sick leave/early retirement</td>
<td>Socioeconomic status</td>
<td></td>
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<tr>
<td></td>
<td>Job satisfaction (47;53;62)</td>
<td>Job satisfaction (37)</td>
<td>Unemployment</td>
<td>Job satisfaction</td>
<td></td>
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<tr>
<td></td>
<td>Job satisfaction (28;54;63;64)</td>
<td>Job satisfaction (37)</td>
<td>Unemployment</td>
<td>Job satisfaction</td>
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<tr>
<td></td>
<td>Job satisfaction (64)</td>
<td>Job satisfaction (37)</td>
<td>Botheredness</td>
<td>Botheredness</td>
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<tr>
<td></td>
<td></td>
<td>Job satisfaction (37)</td>
<td>Well-being</td>
<td>Well-being</td>
<td></td>
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</tbody>
</table>

¹ Medical diagnoses and other potential co-morbidity diagnoses are not classified according to the ICF, but in the ICD-10 or other medical classifications. MRI=Magnetic Resonance Imaging. CT=Computer Tomography.

Table 2. Prognostic factors shown to be significantly associated with chronic LBP and/or disability based on prospective studies in acute and sub-acute LBP in a primary care setting.

| Prognostic factors significantly associated with chronic LBP/disability in acute LBP < 3 weeks |
|---|---|---|---|---|---|
| Prior sciatica (35;36) | Depression (42;43) | Daily activities (36;38;39;41;43) | Job satisfaction (37) | Vermont Disability Prediction Questionnaire* (31) Prognosis assessment by general practitioner (40) |
| Prior chronic LBP (36;37) | Fear-avoidance beliefs (45) | Work status (36;39;41) | Vibration on job (44) | |
| Previous LBP (38-40) | Self-rated health (41) | Sport activities (36) | |
| Prior back surgery (41) | | Lifting patients (38;39) | |
| Type of pain onset (37) (36) | | | |
| Pain intensity (40;42;43) | | | |
| Abnormal heel-walk and toe-walk (44) | | | |

| Prognostic factors significantly associated with chronic LBP/disability in acute/sub-acute LBP < 3 months |
|---|---|---|---|---|---|
| Prior LBP (46;47) | Distress (depression, anxiety) (51;53-56;60) | Daily activities (49;58;60;62) | Job satisfaction (47;53;62) | Education (46;47;52) | Acute Low Back Pain Screening Questionnaire* (28;32;33) Receiving physical therapy (48) |
| Prior back surgery (48) | Fear-avoidance beliefs (28;47;61) | Work status (27;28;47;51;52;61) | Work content (duration, tempo, quality) (28;54;63;64) | Smoking (53;54) | |
| Type of onset (49-51) | Coping (55) | Chronic Pain Grade (52) | Relationship with colleagues (64) | Age (27;55;60) | |
| Duration of LBP (48-53) | Personality (27) | Physical activity (51;53) | Satisfaction with retirement policies and benefits (47) | Race (27) | |
| Pain intensity (27) | Self-rated health (46;53) | | | Gender (women) (27;52;53) | |
| Pain localisation (49;51;53-56) | Neurological signs and symptoms (50;54;57;58) | | | | |
| Spinal mobility (53;59) | Back extensor endurance (59) | | | | |

Medical diagnoses and other co-morbidity diagnoses are not classified according to the ICF, but in the ICD-10 or other medical classifications. Factors are categorized as physical due to their close relationship with bodily factors. * Psychosocial screening questionnaires containing different types of questions, which may be classified in several of the components of the ICF in addition to items not classifiable.
The transition from acute to chronic LBP is influenced by many prognostic factors. A few systematic reviews on risk factors for chronic LBP based on prospective studies have been published (6,7,26). One of these systematic reviews (26) included only occupational studies with an inception cohort design, whereas the other two (6,7) reviewed only psychological risk factors. Table 2 provides an overview of prognostic factors shown to be significantly associated with development of chronic LBP/disability reported in prospective, clinical, cohort studies in patients with acute and sub acute LBP in primary health care.

The studies cited in Table 2 used different outcome measures for chronicity which makes a careful interpretation of the results necessary. The evidence for most prognostic factors in samples including only patients with acute LBP is limited. In the 12 identified prospective studies, only a few of the prognostic factors were significantly associated with chronic LBP in at least three of the studies: a history of LBP, baseline level of pain intensity, limitations in daily activities and work status. Most evidence for prognostic factors comes from studies on mixed samples of acute/sub acute LBP. In the 24 studies included in Table 2, a wide range of factors related to bodily functions of both physical and mental origin, different activities and social functions, the environment and socio-demographics were associated with chronic LBP. In at least three of the included studies, a significant association was found between chronic LBP and type of onset, duration of LBP, level of pain intensity, pain localization (radiating pain or not), neurological symptoms and signs, distress (depression/anxiety symptoms), fear-avoidance beliefs, level of limitations in daily activities, work status, job satisfaction, work content, education, age, and gender. Numerous other prognostic factors have been investigated for their potential impact on chronic LBP, of which some have appeared as significant factors in one or two of the studies included in Table 2.

Several researchers have attempted to explain why some patients develop chronic LBP and disability, and provide models to help clinicians understand and improve management to prevent chronic development (5,27-29). Common to these models is a biopsychosocial understanding of LBP which integrates the interaction of physical/biological, psychological (both cognitive and affective) and social factors on LBP experiences. In some models, cognitions, such as fear-avoidance beliefs and catastrophising ideas about back pain and its consequences, are the central mechanism through which pain may be maintained over time (29,30). Numerous studies in Table 2 support the association between fear-avoidance beliefs and chronic LBP. There was a wide variation in how the construct of fear-avoidance beliefs was measured across the studies cited in Table 2, however, so the results should be carefully interpreted. The importance of psychological distress on the development of chronic LBP is supported in numerous studies, whereas only a few studies provide evidence for different coping strategies and for personality factors. The findings reflected in Table 2 are consistent with two systematic reviews on psychological risk factors (6,7).

The influence of the social and cultural systems in which people live has been studied in recent years, in particular, the interaction between an individual with LBP, the treatment provider, the compensation and health care system, and the workplace. Several studies cited in Table 2 provide evidence for the role of work-related environmental factors and personal factors in the development of chronic LBP. Two screening measurements of psychosocial factors, which contain questions about pain, activity limitations and psychological and work-related factors, have shown promising results in discriminating between patients developing chronic LBP (28,31-34) and those who recover after an acute episode of LBP. However, more studies on the predictive abilities of these questionnaires are obviously needed.

Clinical and research implications

A biopsychosocial understanding of developing chronic LBP has gained high acceptance among back researchers and clinicians and is reflected in numerous international recommendations (task forces) and clinical guidelines published during the 1990s. Guidelines for acute LBP emphasise screening for patients with possible serious spinal pathology (red flags), provide reassurance and advice by reducing/removing fears and emotional responses connected to an episode of acute LBP, and reinforce early return to normal activity in cases of so-called «non-specific» (without identifiable cause) LBP. In those who have not recovered from an acute episode of LBP within the first six to eight weeks, an assessment of psychosocial factors (yellow flags) should be performed. However, from a preventive perspective, it may be important to identify patients at high risk at an earlier stage than after six to eight weeks. More research on prognostic factors is needed to improve understanding of the process of developing chronic LBP, to define risk groups based on early prognosis, to predict outcome more accurately and to guide clinical decision making.

The overall aims of this thesis were two-fold: Firstly, to investigate outcomes used to describe and evaluate pain and disability in LBP within the reference frame of the ICF. Secondly, to evaluate clinical course and prognostic factors in patients seeking help due to acute LBP of less than 3 weeks’ duration. The more specific objectives were:

− To investigate how patients with LBP and their physiotherapists describe main problem(s), clinical findings and treatment goals and to investigate the suitability of the ICF (ICIDH) to classify this information.
− To investigate the main concept, content and measurement properties of back-specific outcome questionnaires for the evaluation of functional status.
− To estimate the reliability, construct validity and responsiveness in commonly used outcome measurements.
− To evaluate the influence of fear-avoidance beliefs and distress on disability in patients with acute and chronic LBP.
− To examine the clinical course and prognostic factors at an early stage of acute LBP.

Summary of findings of the thesis

This thesis provides six papers (Box 6) with different designs, materials and methods. An exploratory field study on how patients with LBP and their physiotherapists defined the patient’s problems and goals (paper I) showed that:

− Patients with LBP and their physiotherapists mainly focused on pain and impairments related to muscles, joints and structures of the lower back, pelvis and hips.
− Treatment goals were typically vaguely described, but involved functioning in various «activities of daily living».
− The ICF was a useful tool to identify the information provided by patients and physiotherapists.

A systematic literature review of back-speci-
fic outcome questionnaires (Paper II) showed that:
- The ICF was a useful tool to explore the main concepts and four types of content in 36 back-specific outcome questionnaires.
- In the 36 back-specific outcome questionnaires, there was a great variation in the concepts used, the main construct assessed, the contents and measurement properties.
- Only a few of the questionnaires had been thoroughly examined with regard to measurement properties.

Commonly used outcome measures for pain and disability were tested among Norwegian patients with acute and chronic LBP in two methodological studies (Paper III and IV) showing that:
- The Norwegian versions of the RMQ and ODI had acceptable test-retest reliability and construct validity.
- The RMQ, ODI, Disability Rating Index (DRI) and Physical Function of the SF-36 (PFSF-36) had equally good responsiveness among patients with acute LBP, whereas among patients with chronic LBP the responsiveness was equally good for all the measures except for the PFSF-36.
- The responsiveness of the numerical pain ratings scale (NRS) was significantly higher than that of the visual analogue scale (VAS).

A cross-sectional study employing an acute (n=123) as well as chronic (n=233) group of patients (paper V) showed that:
- The levels of fear-avoidance beliefs and distress were significantly lower in patients with acute LBP compared to patients with chronic LBP.
- Fear-avoidance beliefs for physical activity and distress were significantly associated with activity limitations as measured by the ODI, whereas fear-avoidance beliefs for work and distress were significantly associated with work loss due to LBP. These associations remained equally strong in acute and chronic LBP.

A prospective cohort study on patients (n=123) seeking help for their first time due to acute LBP (paper VI) showed that:
- 76% of the patients had recovered at 4 weeks and 3 months follow-up.
- Sickness absence was low at 4 weeks and 3 months, at 8% and 6%, respectively.
- The most important prognostic factors for non-recovery at 3 months follow-up were age above 45 years, two or more neurological signs, a score of 90 or more on the psychosocial screening questionnaire and a high level of distress.
- A history of LBP, job satisfaction and fear-avoidance beliefs were not associated with non-recovery in the present material.

Final comments and future perspectives
Given the limitations in most outcome measures of pain and disability, a variety of research tasks remain to be carried out. The most important tasks seem to be:
- Further investigations of the constructs assessed in LBP. In particular, more research is needed when distinguishing between pain and disability and between the different components of disability when providing estimations of clinical course, effect of treatment interventions and prognostic factors.
- More knowledge of measurement error and measurement bias in commonly used measurements of pain and disability, as well as for variables used as prognostic factors.

The present results also suggest that there are numerous challenges connected to the diagnostic process, treatment decisions and information regarding prognosis due to LBP. The results suggest further research in the following areas:
- Prospective investigations of how fear-avoidance beliefs and distress, and other potential affective and cognitive factors, vary with pain and disability over time. A longer follow-up than 3 months is also necessary.
- Investigations on how to improve diagnostics and identification of subgroups with affective and cognitive disturbances associated with LBP.
- Development of treatment interventions for patients with increased psychological distress and psychosocial profile for chronic LBP.

The need for reproducible, reliable clinical measurement goes beyond the requirement for powerful diagnostic, prognostic and treatment data. It may also prevent misinterpretations by poorly collected or biased clinical observations in making incorrect diagnoses. The importance of considering how we define acceptable and achievable outcomes requires further research. Further investigations are necessary on how social and cultural systems in which people live influence persistence of LBP and activity limitations, as well as social measures of chronicity (work restrictions, sickness and disability compensations, health care use).

References


