Physiotherapy Interventions for Low Back Pain - Subgrouping Patients with Improved Efficacy

Raymond Tsang
SPT, QMH
FHKCOP
24 April 2010

Background

• Low back pain (LBP) is a common condition encountered by orthopaedic surgeons, pain specialists, physiatrists and physiotherapists in acute orthopaedic wards and out-patient clinics
• LBP is the “most frequently reported acute condition second only to common cold/influenza-like illness” in Hong Kong (Population Health Survey 2003/04)
Table 1: People aged 15 and above reported that they had low back pain in one month before enumeration by sex, age group and occupation

<table>
<thead>
<tr>
<th>Sex</th>
<th>Number ('000)</th>
<th>Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>550.8</td>
<td>21.4</td>
</tr>
<tr>
<td>Female</td>
<td>998.9</td>
<td>32.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age group</th>
<th>Number ('000)</th>
<th>Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-24</td>
<td>137.5</td>
<td>15.3</td>
</tr>
<tr>
<td>25-34</td>
<td>242.5</td>
<td>26.3</td>
</tr>
<tr>
<td>35-44</td>
<td>353.9</td>
<td>27.2</td>
</tr>
<tr>
<td>45-54</td>
<td>393.0</td>
<td>34.5</td>
</tr>
<tr>
<td>55-64</td>
<td>177.4</td>
<td>37.9</td>
</tr>
<tr>
<td>65 and above</td>
<td>245.4</td>
<td>31.1</td>
</tr>
</tbody>
</table>

Occupation

<table>
<thead>
<tr>
<th>Category</th>
<th>Number ('000)</th>
<th>Rate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managers and administrators</td>
<td>70.0</td>
<td>29.9</td>
</tr>
<tr>
<td>Professionals/Associated professionals</td>
<td>115.3</td>
<td>27.2</td>
</tr>
<tr>
<td>Clerks</td>
<td>199.8</td>
<td>30.0</td>
</tr>
<tr>
<td>Service workers or shop sales workers</td>
<td>163.9</td>
<td>22.9</td>
</tr>
<tr>
<td>Craft and related workers</td>
<td>42.2</td>
<td>22.6</td>
</tr>
<tr>
<td>Plant and machine operators and assemblers</td>
<td>74.6</td>
<td>30.9</td>
</tr>
<tr>
<td>Non-skilled workers</td>
<td>130.2</td>
<td>30.4</td>
</tr>
<tr>
<td>Retirees</td>
<td>237.1</td>
<td>30.7</td>
</tr>
<tr>
<td>Unemployed</td>
<td>67.4</td>
<td>23.8</td>
</tr>
<tr>
<td>Full-time students</td>
<td>64.0</td>
<td>11.4</td>
</tr>
<tr>
<td>Home-makers</td>
<td>351.8</td>
<td>33.6</td>
</tr>
<tr>
<td>Unknown/missing</td>
<td>32.6</td>
<td>26.8</td>
</tr>
</tbody>
</table>

Notes: * Rate per 100 population in the respective sex / age group / occupation.

* Statistics for skilled agricultural and fishery workers were not released due to small sample size which is subject to large sampling errors.

Source: Population Health Survey 2003/04.

Classification

According to duration of onset of LBP

- Acute – < 6 weeks
- Subacute – 6 to <12 weeks
- Chronic - 12 weeks or more
Classification

According to identifiable causes
• Non-specific LBP (majority)
• Specific LBP
  – Fracture, infection, cauda equina syndrome, tumours (serious pathologies)
  – Spinal stenosis, spondylolisthesis, spondylolysis, disc prolapse, inflammatory disorders …

Impact

In developed countries, LBP as
• most frequent occupational problem with an estimated 2-5% of people having chronic LBP
• most frequent activity-limiting complaint in young & middle aged
• second leading cause of sick leave

(Hoy et al, 2010)
Prognosis

• Acute LBP has good prognosis
• Pooled mean reduction of 58% of initial scores in pain and disability within one month
  (Pengel et al, 2003)

Prognosis

• However, 1/4 to 1/3 people with acute LBP still have symptoms 6-12 months after a consultation (Hayden et al, 2010)
• Recurrence is common – approximately 60% people experience relapses of pain and 30% have repeated episodes of work absence (Hestbaek et al, 2003)
Interventions

• Non-operative interventions for non-specific LBP
  – Advice to stay active
  – Exercise therapy
  – Analgesia (paracetamol, NSAIDs, muscle relaxants)
  – Epidural steroids
  – Spinal manipulation
  – Back schools (van Tulder et al, 2006)

• Operative interventions for some specific LBP
  – Behavioural therapy
  – Traction
  – Massage therapy
  – TENS (van Tulder et al, 2006)
Evidence Review


- **Main Results:** Thirty-nine RCTs were identified. Meta-regression models were developed for acute or chronic pain and short-term and long-term pain and function. For patients with acute low-back pain, spinal manipulative therapy was superior only to sham therapy (10-mm difference [95% CI, 2 to 17 mm] on a 100-mm visual analogue scale) or therapies judged to be ineffective or even harmful.

Evidence Review

As...
Evidence Review


- **Main Results:** Sixty-one randomized controlled trials (6390 participants) met inclusion criteria: acute (11), subacute (6) and chronic (43) low-back pain (1 unclear). Evidence was found of effectiveness in chronic populations relative to comparisons at all follow-up periods; pooled mean improvement was 7.3 points (95% CI, 3.7 to 10.9) for pain (out of 100), 2.5 points (1.0 to 3.9) for function (out of 100) at earliest follow-up.

Evidence Review


- **Main Results:** In studies investigating patients (i.e. presenting to healthcare providers) mean improvement was 13.3 points (5.5 to 21.1) for pain, 6.9 (2.2 to 11.7) for function, representing significantly greater improvement over studies where participants included those recruited from a general population (e.g. with advertisements).
Evidence Review


• **Main Results**: There is some evidence of effectiveness of graded-activity exercise program in subacute low-back pain in occupational settings, though the evidence for other types of exercise therapy in other populations is inconsistent. There was evidence of equal effectiveness relative to comparisons in acute populations [pain: 0.03 points (95% CI, -1.3 to 1.4)].

Evidence Review


• **Authors’ Conclusion**: Exercise therapy appears to be slightly effective at decreasing pain and improving function in adults with chronic low-back pain, particularly in healthcare populations. In subacute low-back pain there is some evidence that a graded activity program improves absenteeism outcomes, though evidence for other types of exercise is unclear. In acute low-back pain, exercise therapy is as effective as either no treatment or other conservative treatments.
Lack of Evidence

• Lack of evidence of some common non-operative interventions (e.g. exercise therapy) can partly be explained by
  – Lack of high-quality RCTs (i.e. poor methodological quality of trials)
  – the “false assumption that sufferers of LBP are a homogeneous group” (Ford et al, 2007, p.33)

Recommendations

Improving Design, Conduct, and Reporting of Clinical Trials of Exercise Therapy for LBP (Helmhout et al, 2008)

• To specify a theoretical framework for exercise therapy for designing intervention and selecting appropriate treatment efficacy measures;
• To overcome blinding problems;
• To evaluate role of patient-provider interactions
Recommendations

Improving Design, Conduct, and Reporting of Clinical Trials of Exercise Therapy for LBP (Helmhout et al, 2008)

- To assure quality of treatment, and use of exercise interventions that reference existing exercise guidelines;
- To use subgroup analyses to identify subgroups of patients most likely to benefit;

Recommendations

Improving Design, Conduct, and Reporting of Clinical Trials of Exercise Therapy for LBP (Helmhout et al, 2008)

- To report detailed description of study population, exercise protocol, and measure of patient compliance;
- To further categorize exercise interventions in terms of concept, mode, intensity, duration, frequency, and length
Subgrouping

• “If patients could be subdivided into groups based on the nature of physical, psychological, and/or organizational barriers to recovery, matching them to appropriate interventions may improve outcomes and reduce overall costs.”
  (Helmhout et al, 2008)

• Identification of subgroups that are responders to specific treatment

Treatment Effect Modifiers

• “Characteristics that identify subgroups of patients who respond differently to a specific intervention”
  (Hancock et al, 2009)

• 3 stages of developing treatment-based subgroups (Kamper et al, 2010):
  – Hypothesis generation
  – Hypothesis testing
  – Replication and generalization
Hypothesis Generation

- **Aim:** identify a small number of variables (treatment effect modifiers) to define a subgroup and a plausible reason as to why this subgroup would respond to a particular treatment
- **Methods:** variables may be identified via: previous research; biological rationale; clinical lore

Hypothesis Testing

- **Aim:** evaluate whether subgroups patients defined by the candidate variable respond differently to a particular treatment
- **Methods:** randomized controlled trial with attention to: pre-specified analyses; adequate power; limited number of comparisons; appropriate analysis (interaction tests)
Replication & Generalization

• Aim: Confirm the results found in the previous stage (replication) and test the extent to which they will hold outside the conditions of the original RCT (generalization)

• Methods: Repeat of RCT as above. Replication: similar – patients, setting, therapists, interventions. Generalization: slightly different – patients, setting, therapists, interventions.

An Example – Manipulative Therapy

Hypothesis Generation

A Clinical Prediction Rule for Classifying Patients with Low Back Pain Who Demonstrate Short-Term Improvement With Spinal Manipulation

Timothy Flynn, PT, PhD,*† Julie Fritz, PT, PhD,† Julie Whitman, PT, DSc,‡ Robert Wainer, PT, PhD,*† Jake Magel, PT, DSc,*‡ Daniel Rendeiro, PT, DSc,‡ Barbara Hufler, P1,*‡ Matthew Garber, P1, DSc,*‡ and Stephen Allison, P1, PhII* (Flynn et al, 2002)
An Example – Manipulative Therapy

Hypothesis Generation

• Study design – prospective cohort study of patients with nonradicular LBP
• Subjects – 71 subjects completing study, 41% were female; mean age=37.6 ± 10.6y; mean baseline ODI score=42.4 ± 11.7
• Assessment – history & physical examination (special tests for SIJ dysfunction), NPRS, pain diagram, Modified ODI, FABQ

(Flynn et al, 2002)

An Example – Manipulative Therapy

Hypothesis Generation

• Treatment – passive trunk rotation with posterior & inferior quick thrust through ASIS

Other Rx:

• Supine pelvic tilt exercises 10X; 3-4 sessions per day
• Maintain usual activity

(Flynn et al, 2002)
An Example – Manipulative Therapy

Hypothesis Generation

• Treatment – a maximum of 3 sessions within 2 weeks
• Treatment success - >50% reduction of baseline ODI score
• Treatment non-success - ≤50% reduction of baseline ODI score

(Flynn et al, 2002)

An Example – Manipulative Therapy

Hypothesis Generation

• Results

(Flynn et al, 2002)

Figure 2. Initial and final Oswestry scores for the success and nonsuccess groups. The mean percent change in the success group was 73.2 ± 15.8%. For the nonsuccess group, the mean percent change was 14.6 ± 18.2%.
An Example – Manipulative Therapy

Hypothesis Generation

• Results – 5 variables among 11 potential predictors able to predict treatment success in logistic regression:
  – Duration of symptoms <16 days
  – At least one hip with >35° internal rotation
  – Hypomobility with lumbar spring testing
  – FABQ work subscale score <19
  – No symptoms distal to knee (Flynn et al, 2002)

• Presence of ≥4 variables increased likelihood of success with manipulation from 45% to 95% (+ve LR=24.4, 95% CI 4.6 to 139.4)

Hypothesis Testing

A Clinical Prediction Rule To Identify Patients with Low Back Pain Most Likely To Benefit from Spinal Manipulation: A Validation Study

Maj John D. Childs, PhD, PT; Julie M. Fritz, PhD, PT; Timothy W. Flynn, PhD, PT; James J. Irrgang, PhD, PT; Maj Kevin K. Johnson, PT; Maj Guy R. Majkowski, PT; and Anthony Delitto, PhD, PT


(Childs et al, 2004)
An Example – Manipulative Therapy

Hypothesis Testing

- **Study design** – multicentre RCT of patients with nonradicular LBP with ITT analysis
- **Subjects** – 131 subjects completing study, 42% were female; mean age=33.9 ± 10.9y; mean baseline ODI score=41.2 ± 10.4
- **Randomization**
  - spinal manipulation + exercise (n=70)
  - exercise only (n=61)

(Childs et al, 2004)

An Example – Manipulative Therapy

Hypothesis Testing

- **Treatment** – patients in both groups attended physical therapy 2x in first week and then 1x per week for next 3 weeks, with a total of 5 sessions
  - Manipulation group – high-velocity thrust spinal manipulation (same technique used in Flynn et al’s study) & ROM exercise
  - Exercise group – low-stress aerobic and lumbar spine strengthening programme

(Childs et al, 2004)
An Example – Manipulative Therapy

Hypothesis Testing

• Results

“Interaction effect”

(Childs et al, 2004)

An Example – Manipulative Therapy

Hypothesis Testing

• Implication – patients were more likely to benefit from spinal manipulation if they met the clinical prediction rule

(Childs et al, 2004)

Replication & Generalization

• Studies pending

(Childs et al, 2004)
Evolution of Treatment-based Subgrouping

4 major subgroups (Hebert et al, 2008)

- Specific exercise
  - Extension
  - Flexion
- Stabilization
- Manipulation
- Traction

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Subgroup criteria</th>
<th>Treatment approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific exercise: extension</td>
<td>Symptoms distal to the buttock</td>
<td>End-range extension exercises</td>
</tr>
<tr>
<td>(Browder et al, 2007)</td>
<td>Symptoms centralize with lumbar extension</td>
<td>Mobilization to promote extension (PA)</td>
</tr>
<tr>
<td></td>
<td>Symptoms peripheralize with lumbar flexion</td>
<td>Avoidance of flexion activities</td>
</tr>
<tr>
<td></td>
<td>Directional preference for extension</td>
<td></td>
</tr>
<tr>
<td>Specific exercise: flexion</td>
<td>Older age (&gt;50 y)</td>
<td>End-range flexion exercises</td>
</tr>
<tr>
<td></td>
<td>Directional preference for flexion</td>
<td>Mobilization or manipulation of the spine and/or lower</td>
</tr>
<tr>
<td></td>
<td>Imaging evidence of lumbar spine stenosis</td>
<td>extremities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exercise to address impairments of strength or flexibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Body weight–supported ambulation</td>
</tr>
<tr>
<td>Table 1</td>
<td>Subgroups of patients with low back pain with subgroup criteria and treatment approaches</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Stabilization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Hick et al, 2005)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Younger age (&lt;40 y)</td>
<td>Exercises to strengthen large spinal muscles (erector spinae, oblique abdominals)</td>
<td></td>
</tr>
<tr>
<td>Average straight-leg raise (&gt;91°)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aberrant movement present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive prone-instability test</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Manipulation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Childs et al, 2004; Flynn et al, 2002)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No symptoms distal to knee</td>
<td>Manipulation techniques for the lumbo-pelvic region</td>
<td></td>
</tr>
<tr>
<td>Duration of symptoms &lt;16 d</td>
<td>Active lumbar range-of-motion exercises</td>
<td></td>
</tr>
<tr>
<td>Lumbar hypomobility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fear-Avoidance Beliefs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire for Work &lt;19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip internal rotation range of motion &gt;35°</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Traction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Fritz et al, 2007)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms extend distal to the buttock(s)</td>
<td>Prone mechanical traction</td>
<td></td>
</tr>
<tr>
<td>Signs of nerve root compression</td>
<td>Extension-specific exercises</td>
<td></td>
</tr>
<tr>
<td>Peripheralization with extension movement; or positive controlateral straight-leg raise test</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Evolution of Treatment-based Subgrouping

- Clinical prediction rules for “specific exercise”, “stabilization” and “traction” subgroups would require further hypothesis testing, replication and generalization.
- Clinical prediction rules for “manipulation” subgroup would require further replication and generalization.

\[\rightarrow\text{to establish sufficient certainty to recommend the incorporation of these prediction rules into clinical practice}\]

Take Home Messages

- Growing evidence exists to support the efficacy of subgrouping patients with non-specific LBP to match with appropriate treatment according to clinical prediction rules to achieve better clinical outcomes.
- Future studies should be emphasized to complete the 3 stages of developing treatment-based subgroups.
References


References


• Population Health Survey 2003/04. Department of Health and Department of Community Medicine, University of Hong Kong.