Outcome Evaluation of Surgical and Nonsurgical Management of Lumbar Disc Protrusion Causing Radiculopathy

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Background

- lumbar disc protrusion causing radiculopathy (LDPR)
  - a prevalent disorder (lifetime incidence of 2%)
  - little progress has been made in defining the optimal treatment strategy.
  - outcome measures that compare surgical with nonsurgical care.
Methods
Materials and Methods

- **Study Design:**
  - Prospective cohort study.

- **P’t selection:**
  - in an acute disc clinic (ADC) at a single tertiary care hospital in Canada.
  - 8 surgeons and 3 back care physicians participated in patient recruitment and treatment.
Materials and Methods

Inclusion criteria:
- age 16 years or older.
- leg pain and/or weakness in a specific dermatomal/myotomal pattern.
- with congruent findings from a disc protrusion on CT or MRI.

Exclusion criteria
- severe medical comorbidity (e.g., recent MI).
- Pregnancy
- presence of spinal deformity.
- with significant motor deficit.
Materials and Methods

- Patients were assigned to the surgical or non-surgical group following:
  - One physician and one surgeon, each of whom recorded the:
    - clinical symptoms/signs
    - imaging results
    - treatment plan
  - on a standardized data collection sheet.
  - Discussion between the 2 specialists.
  - Then discuss with the patient.
The primary reason for non-enrollment: lack of interest in participation.
Materials and Methods

Within-study standardized treatment plan:

- Surgery of a lumbar microdiscectomy:
  (consisted:
    - prone positioning
    - hemilaminotomy where necessary
    - resection of ligamentum flavum,
    - identification and protection of the nerve root,
    - disc fragment excision……. etc.)

- Non-operative treatment:
  - according to the NASS's Phase III clinical guidelines for multidisciplinary spine care specialists on lumbar herniated discs.
Outcomes Assessment

- **Baseline measurement**
  - by the study coordinator at the time of initial consultation

- **Follow-up assessments**
  - completed using mailed surveys

- **Using the:**
  - 1) NASS neurogenic symptoms score (NSS)
  - 2) the NASS pain and disability score (PDS)
  - 3) the SF-36
Statistical Analysis

- All scores were converted from standardized scores (0–100 scale) to individual normalized scores
  - using published algorithms.
  - By definition, the population mean for normative data is $50 \pm 10$ (standard deviation).
Statistical Analysis

- All analyses were carried out using S-PLUS version 6.1 (2002 Insightful Corporation).
- We used linear regression to model the association between surgical or nonsurgical care group and average change in outcome score at 2 different endpoints.
  - Significance of the estimates was tested by individual t tests.
  - Analysis was performed on an intention-to-treat basis.
Results
**Table 2. Demographic Characteristics of Patients Eligible but Not Enrolled, Patients Lost to Follow-up, and Patients Analyzed**

<table>
<thead>
<tr>
<th></th>
<th>Patients Eligible but Not Enrolled</th>
<th>Patients Lost to Follow-up</th>
<th>Patients Included in Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Data for 74 of 265</td>
<td>126</td>
<td>497</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>44</td>
<td>41</td>
<td>43</td>
</tr>
<tr>
<td>Duration of symptoms (days)</td>
<td>90</td>
<td>154</td>
<td>188</td>
</tr>
<tr>
<td>BDI score</td>
<td>14.3</td>
<td>12.6</td>
<td>12.2</td>
</tr>
<tr>
<td>Receiving compensation</td>
<td>NA</td>
<td>6%</td>
<td>18%</td>
</tr>
<tr>
<td>Baseline NASS NSS</td>
<td>NA</td>
<td>25.8</td>
<td>27.1</td>
</tr>
</tbody>
</table>

BDI indicates Beck Depression Inventory; NA, not available; NASS, North American Spine Society; NSS, neurogenic symptoms score.
Baseline demographic and clinical characteristics

Table 1. Baseline Demographic and Clinical Characteristics of the Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Nonsurgical Treatment</th>
<th>Surgical Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>164</td>
<td>333</td>
</tr>
<tr>
<td>Age (yr) [mean (SD); median]</td>
<td>44.0 (11.7); 43.5</td>
<td>42.4 (12.5); 40.0</td>
</tr>
<tr>
<td>Beck Depression Inventory score [mean (SD); median]</td>
<td>10.6 (8.6); 9.0</td>
<td>13.1 (8.4); 12.0</td>
</tr>
<tr>
<td>Duration of symptoms prior to baseline (days) [mean (SD); median]</td>
<td>148 (174); 83</td>
<td>213 (210); 141</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>52%</td>
<td>62%</td>
</tr>
<tr>
<td>Prior same level surgery</td>
<td>1%</td>
<td>11%</td>
</tr>
<tr>
<td>Receiving compensation</td>
<td>12%</td>
<td>20%</td>
</tr>
<tr>
<td>Disc involved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L2–L3</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>L3–L4</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>L4–L5</td>
<td>40%</td>
<td>44%</td>
</tr>
<tr>
<td>L5–S1</td>
<td>53%</td>
<td>52%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Nonsurgical Treatment</th>
<th>Surgical Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some high school</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>High school completed</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>Some college</td>
<td>10</td>
<td>22</td>
</tr>
<tr>
<td>College graduate</td>
<td>17</td>
<td>24</td>
</tr>
<tr>
<td>University graduate</td>
<td>41</td>
<td>19</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>58%</td>
<td>56%</td>
</tr>
<tr>
<td>Living together</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>8%</td>
<td>13%</td>
</tr>
<tr>
<td>Widowed</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Single</td>
<td>24%</td>
<td>21%</td>
</tr>
<tr>
<td>Dominant problem</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg pain</td>
<td>83%</td>
<td>56%</td>
</tr>
<tr>
<td>Leg weakness (MRC &lt;5)</td>
<td>1%</td>
<td>4%</td>
</tr>
<tr>
<td>Leg pain and weakness (MRC &lt;5)</td>
<td>16%</td>
<td>40%</td>
</tr>
</tbody>
</table>
Normalized baseline and follow-up

NASS Neurogenic Symptoms Scores

- 6 months post-baseline 44.6
- 6 months post-op 43.8
- age-matched normative 51.6

- 30.9 nonoperative
- 25.3 surgical
Normalized baseline and follow-up [2] NASS Pain and disability scores
Normalized baseline and follow-up 8 domains of the SF-36.
Normalized baseline and follow-up 8 domains of the SF-36.
Normalized baseline and follow-up

SF-36 Physical Component Score

- physical component score: a composite of the PF, RP, BP, and GH domains.
Normalized baseline and follow-up [5] SF-36 Mental Component Score

- Mental component score: a composite of the MH, RE, SF, and V domains
Crude and Adjusted Difference in Score Change from Baseline to Primary Endpoint Between the Two Groups

### Crude Results

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Difference in Score Change Between Treatment Groups (95% CI)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>North American spine society subscale scores</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Change NSS*</td>
<td>4.77 (2.08, 7.46)</td>
<td>0.001</td>
</tr>
<tr>
<td>2 Change PDS</td>
<td>6.99 (4.30, 9.67)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Short Form-36 component scores</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Change PCS</td>
<td>-1.14 (-3.99 to 1.71)</td>
<td>0.43</td>
</tr>
<tr>
<td>4 Change MCS</td>
<td>1.04 (-2.27 to 4.34)</td>
<td>0.54</td>
</tr>
</tbody>
</table>

### Adjusted Results

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Difference in Score Change Between Treatment Groups (95% CI)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>North American spine society subscale scores</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Change NSS*</td>
<td>0.95 (-2.36 to 4.26)</td>
<td>0.58</td>
</tr>
<tr>
<td>2 Change PDS</td>
<td>3.46 (0.17 to 6.75)</td>
<td>0.04</td>
</tr>
<tr>
<td>Short Form-36 component scores</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Change PCS</td>
<td>0.21 (-3.02 to 3.44)</td>
<td>0.90</td>
</tr>
<tr>
<td>4 Change MCS</td>
<td>3.52 (0.48 to 6.56)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

**Adjusted for:** age, gender, duration of symptoms, education, compensation status, prior same level surgery, clinical depression BDI score, and individual baseline NASS NSS.

- NSS, neurogenic symptoms score
- PDS, pain and disability score
- MH, mental health
- MCS, mental component score
Conclusions

- Patients of LDPR treated either surgically or nonsurgically showed *no* significant difference in change of NASS NSS scores at both endpoints of follow-up.
  - the improvement is not associated with the type of treatment.
Thank you for your attention
Discussion
Discussion

The last systematic review, the Maine Lumbar Spine Study (MLSS) by Atlas et al:


- 1-year results showed surgery was 4+ times in clinical improvement leg or back pain.
- At 10 years, the improvement in leg pain compared with baseline in surgical versus nonsurgical patients was no statistically significant (P = 0.56).

→ The relative advantage of surgery was greatest early after surgery and diminished over the 5-year interval.
Discussion

The only randomized control trial, by Weber's:

Weber H.
Lumbar disc herniation: a controlled, prospective study with ten years of observation.

- comparing surgical treatment to a nonsurgical control group
- better results in the surgical group at the 1 year follow-up
- by 4 and 10 years after surgery, however, this benefit was no longer observed.
Discussion

The results of this study do not agree with those of Atlas et al or Weber both of which documented an early (1 year) beneficial effect of those treated with lumbar discectomy.
Discussion

Possible reasons for this differences:

1. Our study sample obtained from a government insured healthcare system.
   - The wait times are often prolonged.
   - Some permanent adverse change occurred within the nerve root, thus minimizing the effect of the eventual surgery.
Discussion

Possible reasons for this differences:

2. A referral bias may exist:
   - MLSS was a community-based study.
   - Ours was conducted at a tertiary care center with referral required from a primary care physician.
Discussion

Possible reasons for this differences:

3. the primary outcome measure was different.
   - We chose a primary outcome that measured the severity of leg symptoms.
   - The MLSS assessed the predominant symptom, either back or leg pain.
Discussion

Possible reasons for this differences:

4. We served a more objective decision making process:
   - our patients were assessed by both surgeons and nonoperative back care specialists
   - the patients were familiarized with both treatment options before making a decision
Discussion

Possible reasons for this differences:

5. We attempted to standardize the procedure of treatment in study:
   - Even though lumbar discectomy is common, it is likely that each patient received slightly different surgery.
   - For the non-surgical group, current clinical practice guidelines afford practitioners a wide spectrum of care options.