

# Contribution of Nonspinal Comorbidity to Low Back Pain Outcomes

Greg McIntosh, MSc,\* Hamilton Hall, MD, FRCSC,\*† and Christina Boyle, Reg PT\*

**Objective:** To determine the involvement of comorbidity to outcomes in a cohort of acute mechanical low back pain patients.

**Methods:** Incident low back pain cases ( $n = 7077$ ) in the acute or subacute phase assessed between January 1, 1999 and December 31, 2001 were included. Patients were categorized into 1 of 2 groups on the basis of their current medical history: (1) those with at least 1 of 7 medical histories considered (Comorbidity Group,  $n = 539$ ), or (2) those with only low back pain (Back Pain Group,  $n = 6538$ ). Main outcome measures were: change in perceived function and visual analog scale (VAS) pain rating from initial assessment to discharge, and total number of treatment days.

**Results:** There were no baseline statistically significant differences in VAS pain rating, questionnaire score, or symptom duration between groups. Odds ratios (ORs) were adjusted to reflect age and sex differences between groups. Logistic regression analysis revealed no statistically significant difference for change in functional score ( $OR = 1.002$ ) between groups; there were marginal differences in change in VAS pain rating ( $OR = 1.08$ ) and total number of treatment days ( $OR = 1.006$ ).  $\chi^2$  analysis revealed no statistically significant differences in medication use, global pain rating, or pain control ability posttreatment, between groups.

**Discussion:** Significant ORs were barely greater than 1.00 and were likely the result of the large sample size. The clinical course for comorbid patients, who may seem more complicated at the start of treatment, is just as favorable.

**Key Words:** comorbidity, back pain, outcomes, rehabilitation

(*Clin J Pain* 2006;22:765–769)

The role of comorbidities is poorly quantified in the back pain literature.<sup>1</sup> Only a few studies have addressed the affect of concomitant medical conditions on clinical course of low back pain.<sup>1–12</sup> Robinson et al<sup>2</sup> concluded that diabetes might lead to increased susceptibility to disc prolapse. There is conflicting evidence about the relationship between obesity and back pain.<sup>3–9</sup> Dickens et al<sup>10</sup> states that an association between depression and excessive back pain behavior is difficult to determine because depression ratings usually record symptoms attributable to physical disease. Thus, the literature is unclear whether these conditions result in or are the result of back pain.

Although chronic back pain and comorbidity has received limited attention, the literature contains even less about the role of comorbidity in acute patients. Coexisting conditions may have unforeseen yet clinically significant effects on patients' response to treatment and ultimate outcome.<sup>12</sup>

The objective of this study was to determine the relationship of comorbidity to outcomes in a cohort of acute low back pain patients. The research hypothesis was that those with comorbidity would have worse outcomes than those without comorbid condition. The research question: do nonspinal medical issues, associated with acute back pain, contribute to prolonged treatment periods and/or significantly worse outcomes?

## MATERIALS AND METHODS

This research project used a prospective inception cohort study design. The cohort was comprised of incident cases ( $n = 7077$ ) reporting for nonoperative treatment at 43 clinics across Canada.

All working and nonworking mechanical low back pain patients in the acute or subacute stage (less than 90 d postonset) who started a rehabilitation program between January 1, 1999 and December 31, 2001 were included. Minors, surgical candidates, those with previous back surgery, and chronic low back pain patients (greater than 90 d duration) were excluded.

Physiotherapy assessment and patient self-report were used to obtain baseline and outcome information. Registered physiotherapists with specialized low back pain training obtained a standardized history and performed standardized physical examination. The high intertester reliability of this assessment procedure has been documented previously.<sup>13</sup> Patients participated in a clinical interview, completed a baseline questionnaire on

Received for publication December 23, 2005; accepted June 1, 2006.

From the \*CBI Health (Canadian Back Institute) Research Department; and †Faculty of Medicine, Department of Surgery, University of Toronto, Toronto, Ontario, Canada.

Presented at the International Society for the Study of the Lumbar Spine, 31st Annual Meeting, May 31 to June 6, 2004, Porto, Portugal, and the Alberta International Low Back Pain Forum VII, October 9 to 11, 2004, Edmonton, Alberta.

Reprints: Greg McIntosh, MSc, CBI Health Research Department, Clarica Centre, West Tower 900-3300 Bloor St W, Toronto, Ontario, Canada M8X 2X2 (e-mail: gmcintosh@cbi.ca).

Copyright © 2006 by Lippincott Williams & Wilkins

how pain affected physical function, and provided socio-demographic information. The questionnaire contained 18 patient self-report items on the basis of a previously published instrument, the Low Back Outcome Score<sup>14</sup>; the higher the score, the greater the patient's perceived level of function.<sup>15</sup> At discharge, patients completed the same questionnaire to gauge changes and improvements.

All information from the 2 questionnaires and spinal assessment were entered into a computer program and then electronically transferred and stored in a central clinical database from which the clinical and outcome variable data for this study were accessed. The database was designed for research purposes and contains the clinical details necessary for epidemiologic research.<sup>16</sup>

The clinics are secondary care rehabilitation facilities that focus on pain control and recovery of movement in acute, subacute, and chronic ambulatory populations. The rare patients whose back pain results from malignancy, suspected systemic disease, cases sustaining trauma sufficient to produce severe bony injury or individuals with major neurologic sequelae are referred elsewhere. Treatment is active, exercise-based physiotherapy for mechanical spinal pain of musculoskeletal origin.<sup>17</sup> The number of treatment hours per day and the total treatment time were adapted to the needs of each patient.

Clinicians make discharge decisions in close consultation with patients and referral sources (physician and/or payor); discharge planning is usually a negotiation between the 3 parties involved. At assessment, the treating therapist and patient set mutually agreeable goals with respect to pain control, range of motion, and functional improvement. Discharge occurs when the parties conclude that all or most of the goals and objectives set out in the treatment plan have been fulfilled. If agreement is not reached, treatment continues unless a clinician believes that further improvement is not likely, and it is in a patient's best interest to discontinue treatment. In some cases, payors decide on maximum treatment length, only agreeing to pay for a certain number of treatments; when the maximum has been reached, patients must be discharged.

With the exception of an identification number, patient data were anonymized before analysis. No patient was contacted directly as part of this statistical review. The study design, approved by the Research Ethics Board of Sunnybrook and Women's College Health Sciences Center, ensured confidentiality of all participants.

Patients were categorized into 1 of 2 groups on the basis of the medical history provided at intake: (1) those with at least 1 of 7 medical conditions considered on assessment (Table 1) (Comorbidity Group,  $n = 539$ ), (2) those with low back pain only (Back Pain Group,  $n = 6538$ ).

Primary outcomes assessed were: (1) change in perceived function from initial assessment to discharge, on the basis of the change in questionnaire scores, (2) change in visual analog scale (VAS) pain rating from assessment to discharge, and (3) total number of treatment days. Secondary outcome measures were: (1)

**TABLE 1.** Comorbid Conditions Considered Among Acute Low Back Pain Patients Reporting for Conservative Treatment

Comorbidity	n
Coronary artery disease	22
Hypertension	118
Rheumatoid arthritis	18
Diabetes	21
Nonspinal malignancy	9
Chronic obstructive pulmonary disease	16
Any other comorbid condition	264
Multiple conditions	71
Total	539

change in medication usage from assessment to discharge, (2) subjective global pain rating at discharge (pain is: gone, decreased, same, increased), (3) perceived ability to control pain.

All analyses were conducted with SPSS for Windows release 11.0.1, November 15, 2001. Logistic regression analysis was used to model the relationship between the binary response variable (comorbidity present yes/no) and the outcome measures. Univariate logistic regression analysis was used to identify any significant associations between each independent variable and the dichotomous outcome. An  $\alpha$  level of 0.05 (2 sided) was used as the criterion for statistical significance.

## RESULTS

The mean age of the cohort was 39.2 years (SD = 10.3, range = 18 to 65) with 66% males. The mean symptom duration was 29.6 days (SD = 23.2, range = 0 to 89), with a median of 22.5 days. Constant pain was reported by 53% of the cohort; 49.8% reported at least occasional medication use for their back pain.

Table 2 reveals that there were no baseline statistically significant differences in VAS pain rating, questionnaire score, symptom duration, or percentage in constant pain between groups. The Comorbidity Group was significantly older by 4 years (43.1 vs. 38.9,  $P < 0.001$ ) and had significantly more females (44.9% vs. 33.4%,

**TABLE 2.** Baseline Differences Between Groups

	Comorbidity Group	Back Pain Group	SSD
Age—mean (SD)	43.1 (10.6)	38.9 (10.2)	*
VAS—mean (SD)	5.80 (2.2)	5.78 (2.1)	NS
Sex			
% female	44.9	33.4	*
Questionnaire Score—mean (SD)	37.1 (10.4)	37.2 (9.9)	NS
Symptom duration—mean (SD)	31.2 (23.2)	29.4 (23.2)	NS
Constancy			
% constant	53.4	52.5	NS

\* $P < 0.001$ .

NS indicates not significant; SD, standard deviation; SSD, statistically significant difference.

**TABLE 3.** Outcomes by Group From Logistic Regression

Primary Outcomes		Comorbidity Group	Back Pain Group	OR*	95% CI	P
Function (QS)	Mean (SD)	16.8 (11.7)	16.2 (12.6)	1.002	0.99-1.01	0.752
VAS	Mean (SD)	-2.00 (2.94)	-2.40 (2.48)	1.079	1.013-1.149	0.018
Treatment days	Mean (SD)	20.1 (19.2)	18.2 (16.4)	1.006	1.001-1.011	0.013

\*Adjusted for age and sex.

CI indicates confidence interval; QS, questionnaire score; SD, standard deviation; VAS, Visual Analogue Scale; OR, Odds Ratio.

$P < 0.001$ ). Even though these demographic variables showed statistically significant differences between groups, they were not deemed clinically significant; however, odds ratios (ORs) were adjusted for age and sex.

Table 3 displays that logistic regression analysis revealed no statistically significant difference for change in functional score (OR = 1.002) between groups; there were marginal statistically significant differences in change in VAS pain rating (OR = 1.08) and total number of treatment days (OR = 1.006).  $\chi^2$  analysis revealed that there were no statistically significant differences in change in medication use, global pain rating, or pain control ability posttreatment, between groups (Table 4).

Of the 539 patients with comorbid conditions, Hypertension (n = 118) and Other (n = 264) were the most frequent conditions. These were the only 2 subgroups large enough to perform separate comparisons with the Back Pain Group.

For Other versus Back Pain, there were no statistically significant differences between groups for VAS pain rating and function score. There was a small statistically significant difference for treatment days.

For Hypertension versus Back Pain, there were no statistically significant differences between groups for treatment days and function score. There was a small statistically significant difference for change in VAS pain rating (“Hypertension” Comorbidity Group = -1.7 vs. Back Pain Group = -2.4, OR = 1.2,  $P = 0.02$ , 95% confidence intervals 1.04-1.48).

**TABLE 4.** Outcomes by Group From  $\chi^2$  Analysis

Secondary Outcomes	Comorbidity Group	Back Pain Group	$\chi^2$	SSD
Medication use (%)			4.64	NS
Never	41.1	47.5		
Occasional	37.3	42.5		
1-2/d	11.0	12.3		
Several	4.3	4.2		
Subjective symptom rating			2.45	NS
Gone	37.0	36.0		
Decreased	54.3	53.2		
Same	7.0	9.3		
Increased	1.7	1.5		
Pain control			1.02	NS
No control	9.1	9.9		
Can abolish	22.8	19.8		
Can reduce	68.1	70.3		

NS indicates not significant; SSD, statistically significant difference.

$\chi^2$  analysis revealed that there were no statistically significant differences in change in medication use, global pain rating, or pain control ability posttreatment, between Other and Back Pain and Hypertension and Back Pain Groups. The sample sizes of the remaining subgroups were not large enough for further individual comorbidity subgroup comparison to the Back Pain Group.

The mean number of treatment days for the cohort was 18.3 (SD = 16.7, range = 3 to 143), with a median of 13.5 days; 90% of the cohort had less than 39 days in treatment. The remaining 10% were not different in terms of within and between group baseline characteristics or outcomes pertaining to pain and function.

## DISCUSSION

In this study of acute patients with mechanical low back pain, associated comorbidity did not contribute to reduced function, more medication usage, worse global pain rating, or less pain control. The Comorbidity Group had significantly less pain reduction as measured on VAS and significantly more treatment days. But the ORs were barely greater than 1.00; the statistical significance of these ORs was likely the result of the large sample size. Large sample sizes have more likelihood of detecting even small statistical differences<sup>18</sup>; marginal differences are similar to a subtle but definite abnormality on a diagnostic test; the importance is a matter of judgement.<sup>19</sup> Between groups, a half point change in VAS rating (2.00 vs. 2.4) and a 2 day difference in treatment days (20.1 vs. 18.2) were not deemed clinically significant. Thus, the differences in outcomes between groups were not large enough to accept the research hypothesis.

These findings are in contrast to previous literature. Nordin et al<sup>11</sup> discovered that those with comorbidity were 1.31 times more likely to remain work disabled than those with uncomplicated back pain. The authors concluded that comorbidities should be routinely evaluated to better manage back pain disability. Xuan et al<sup>12</sup> suggest that comorbid conditions significantly affect patients’ scores on generic quality of life measures and estimation of treatment effect, whereas their influence on disease-specific quality of life scores and estimation of treatment effect is considerably smaller. In a predominantly chronic sample, Fanuele et al<sup>1</sup> stated that the prevalence of nonspinal medical pathologies contributes to decreased functional status. This previous literature used predominantly chronic patients. The current study

examined an acute sample, which may account for the contrasting results.

The method of classifying comorbidity, in this study, is open to criticism from 2 perspectives. It could be argued that because most previous comorbidity research has focused on symptoms and health complaints, a similar subjective approach is warranted. At the other extreme, analysis by individual comorbidity may prove beneficial, because combining different health conditions into 1 category for analysis might mask any potential associations for some conditions and not others.

Determining comorbidity status involved a combination of both subjective and objective classification. Subjectively, the inclusion of the Other subgroup allowed for the capture of all possible health complaints not included in the specific significant medical history query. The Other subgroup was large enough to allow for comparison to the Back Pain Group, but failed to show statistically significant differences in outcomes. Objectively, different types of comorbid conditions interact with pain in different ways; this is particularly relevant with high blood pressure and pain.<sup>20,21</sup> The Hypertension subgroup was large enough to allow for comparison to the Back Pain Group, but failed to show statistically significant differences in outcomes. The sample sizes of the remaining subgroups were not large enough for further comparison to the Back Pain Group. However, the lack of significant findings in these subgroup analyses suggests that, in part, neither subjective nor objective classification seemed to influence results.

Other limitations of this study include the potential for several biases.<sup>22</sup> Because clinical caseloads, in these locations, were dependent on physician referral, there may be centripetal bias; physicians do not refer all of their back pain patients to this clinic system, so only specific mechanical pain patients may gravitate toward this type of treatment.

Similarly, because the treatment protocol was active, exercise-based rehabilitation, physicians may decide that for profoundly disabled or minimally restricted patients, this form of management is not appropriate, thereby creating a referral filter bias. However, recent evidence from a pilot project involving rehabilitation providers<sup>23</sup> suggests that patient pain severity and functional status measures for this clinic system are similar to 6 other nonrelated physiotherapy facilities in Ontario. There seems to be little, if any, selection bias in the cases used for this analysis.

All parties involved in the rehabilitation process have the potential to influence the outcome measure Days in Treatment. Patient, referral source or clinician, in either isolation or combination, all have a voice in how long treatment lasts. Treatment does not usually continue when: (1) patients announce that they feel ready to return to activities of daily living, (2) patients reach the set number of treatments as dictated by payors, and (3) a clinician believes that further improvement is not likely, and it is in a patient's best interest to discontinue treatment.

The wide range of treatment days shows that no one criterion is dominating the discharge process and yet the short mean and median reveal the emphasis not to make these people into long-term patients. Because the 2 groups showed similar frequency distributions and no baseline statistical differences for this measure, the decision process for discharge planning was similar for both groups.

Study strengths are the standardization of treatment and data collection. Because of the extensive steps taken to ensure a standardized protocol for all patients, there was little variation in actual treatment, thereby reducing the possibility of confounding by treatment regimen. Although there was variation in treatment length, the mean and median were less than 20 days and only 10% remained in treatment for more than 40 days. The frequency distribution and analysis of these few patients suggests that they were not true outliers in a statistical sense, they were influential observations; thus, they were not omitted from the study and did not bias results.

Using clinics that are fully integrated, with the same centrally coordinated data collection tools and philosophy of treatment, reduces the potential for unexpected treatment aberrations and inadequate data accumulation. An inception cohort was used to help eliminate any confounding factors that are often present in chronic pain populations.

In conclusion, those with a comorbid condition in addition to back pain (coronary artery disease, hypertension, rheumatoid arthritis, diabetes, nonspinal malignancy, chronic obstructive pulmonary disease, or any other comorbid condition) had no statistically significant differences in pain control, medication usage, or functional outcomes compared with a group with back pain alone. Thus, patients with comorbidities will likely improve at the same rate as regular back pain patients. The clinical course for comorbid patients, who may seem more complicated at the start of treatment, is just as favorable.

## ACKNOWLEDGMENTS

*The authors thank the Canadian Back Institute clinics across the country for data collection: British Columbia (Burnaby, Coquitlam, Fraser Valley, Prince George, Richmond, Surrey, Vancouver, Victoria), Alberta (Calgary Downtown, Calgary South, Deer Valley, Edmonton, Lethbridge, Red Deer), Saskatchewan (Regina, Saskatoon), Ontario (Barrie, Brampton, Cambridge, Danforth, Eglington, Etobicoke, Hamilton, Kanata, Kitchener, Leamington, London Central, London East, London Westminster, Mississauga, Niagara Falls, Ottawa East, Ottawa West, Plaza Club, Sarnia, Scarborough, Sudbury, Thunder Bay, Windsor), and Quebec (Gatineau, Montreal, Pierrefonds, St Foy).*

## REFERENCES

1. Fanuele JC, Birkmeyer NJ, Abdu WA, et al. The impact of spinal problems on the health status of patients: have we underestimated the effect? *Spine*. 2000;25:1509-1514.

2. Robinson D, Mirovsky Y, Halperin N, et al. Changes in proteoglycans of intervertebral disc in diabetic patients. A possible cause of increased back pain. *Spine*. 1998;23:849–855.
3. Kaila-Kangas L, Leino-Arjas P, Riihimaki H, et al. Smoking and overweight as predictors of hospitalization for back disorders. *Spine*. 2003;28:1860–1868.
4. Webb R, Brammah T, Lunt M, et al. Prevalence and predictors of intense, chronic, and disabling neck and back pain in the UK general population. *Spine*. 2003;28:1195–1202.
5. Bener A, Alwash R, Gaber T, et al. Obesity and low back pain. *Collegium Antropol*. 2003;27:95–104.
6. Melissas J, Volakakis E, Hadjipavlou A. Low-back pain in morbidly obese patients and the effect of weight loss following surgery. *Obesity Surg*. 2003;13:389–393.
7. Yip YB, Ho SC, Chan SG. Tall stature, overweight and the prevalence of low back pain in Chinese middle-aged women. *Int J Obesity Related Metabol Disord*. 2001;25:887–892.
8. Mortimer M, Wiktorin C, Pernol G, et al. Sports activities, body weight and smoking in relation to low-back pain: a population-based case-referent study. *Scand J Med Sci Sport*. 2001;11:178–184.
9. Leboeuf-Yde C, Kyvik KO, Bruun NH. Low back pain and lifestyle. Part II—Obesity. Information from a population-based sample of 29,424 twin subjects. *Spine*. 1999;24:779–783.
10. Dickens C, Jayson M, Creed F. Psychological correlates of pain behavior in patients with chronic low back pain. *Psychosomatics*. 2002;43:42–48.
11. Nordin M, Hiebert R, Pietrek M, et al. Association of comorbidity and outcome in episodes of nonspecific low back pain in occupational populations. *J Occup Environ Med*. 2002;44:677–684.
12. Xuan J, Kirchdoerfer LJ, Boyer JG, et al. Effects of comorbidity on health-related quality-of-life scores: an analysis of clinical trial data. *Clin Therapeut*. 1999;21:383–403.
13. Wilson L, Hall H, McIntosh G, et al. Intertester reliability of a low back pain classification system. *Spine*. 1999;24:248–254.
14. Greenough CG, Fraser RD. Assessment of outcome in patients with low back pain. *Spine*. 1992;17:36–41.
15. McIntosh G, Frank JW, Hogg-Johnson S, et al. Prognostic factors for time receiving workers' compensation benefits in a cohort of patients with low back pain. *Spine*. 2000;25:147–157.
16. McIntosh G. *Back Pain Prognostic Factors: A Cohort Study of 1,752 Patients of a National Rehabilitation Clinic System*. Masters of Science Thesis in Epidemiology Toronto: University of Toronto Press; 1999.
17. Hall H, McIntosh G, Melles T. A different approach to back pain diagnosis: identifying a pattern of pain. *Can J CME*. 1994;6:31–42.
18. Hulley SB, Cummings SR, ed. *Designing Clinical Research. An Epidemiologic Approach*. Baltimore, MD: Williams & Wilkins; 1988.
19. Browner WS, Newman TB. Are all significant p values created equal? The analogy between diagnostic tests and clinical research. *JAMA*. 1987;257:2459–2463.
20. Campbell TS, Ditto B, Seguin JR, et al. A longitudinal study of pain sensitivity and blood pressure in adolescent boys: results from a 5-year follow-up. *Health Psychol*. 2002;21:594–600.
21. D'Antono B, Ditto B, Rios N, et al. Risk for hypertension and diminished pain sensitivity in women: autonomic and daily correlates. *Int J Psychophysiol*. 1999;31:175–187.
22. Sackett DL. Bias in analytical research. *J Chron Dis*. 1979;32:51–63.
23. Quality Management System for Soft Tissue Injuries (QMS-STI). A joint pilot project with rehabilitation providers in Ontario and the Institute for Work & Health, 1998.