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ORIGINAL ARTICLE

Outcomes for those with or without physical comorbidity for a specific cohort of chronic low back pain patients in an active rehabilitation approach

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Abstract

The objective of the study was to determine the relationship between physical comorbidity and outcomes in a cohort of chronic low back pain (LBP) patients ($n = 2777$). Patients were treated at one of 48 physiotherapy clinics between January 1, 2005 and September 30, 2006. All patients were categorized into either: (i) physical Comorbidity Group ($n = 898$), or (ii) only Back Pain Group ($n = 1879$). There were no baseline statistical differences in symptom duration, visual analogue scale, function and medication use between groups. The Comorbidity Group was significantly older by 5 years and more females ($p < 0.0001$); odds ratios were adjusted for age and sex. Logistic regression analysis revealed no statistically significant differences for change in functional score (OR = 0.996), change in pain rating (OR = 1.013) and total treatment sessions (OR = 0.997), between groups. Those with LBP and a physical comorbidity (coronary artery disease, hypertension, rheumatoid arthritis, diabetes, non-spinal malignancy, chronic obstructive pulmonary disease, or any other non-spinal condition) had no statistically significant differences in outcomes compared with those with LBP only. The clinical approach to chronic low back patients with an associated physical comorbidity may initially seem more intimidating or complex, but the potential for recovery is just as favourable as that for patients with uncomplicated chronic LBP.

Key words: *Cohort, physical comorbidity, physiotherapy, treatment, recovery*

Introduction

Many possible comorbidities can exist for those with chronic low back pain (LBP). Associated comorbidity in addition to LBP has been shown to significantly contribute to increased costs (1,2) and negatively affect functional status (3,4) and generic quality of life scores (5). Unfortunately, results vary depending upon the population and other condition studied.

Specific comorbidity studies on diabetes (6), obesity (7,8), depression (9), anxiety and sleep disorders (10) present conflicting evidence about their role in the lack of recovery in patients with chronic LBP. Robinson et al. (6) concluded that diabetes might lead to increased susceptibility to disc prolapse, but Vaidya et al. (11) concluded that it is not known if the degree of obesity has an effect on clinical outcomes. Obesity is an independent disease and not simply a function of symptomatic spinal stenosis (12). Dickens et al. (9) states that an association between depression and excessive back pain behaviour is difficult to determine because depression ratings usually record symptoms attributable to physical disease. Glombiewski et al. (13) concluded that depression measured prior to treatment did not affect treatment outcomes.

The literature is unclear about whether some of these conditions result in or are a consequence of back pain. Coexisting conditions may have unforeseen yet clinically significant effects on patients' response to treatment and their ultimate outcomes (5). Unfortunately, the back pain literature poorly quantifies the role of comorbidities (3). Only Schneider et al. (14) investigated a comprehensive list of comorbidities in an effort to generate prevalence data and to identify the most common physical comorbidities in subjects with back pain. They concluded that the most common comorbidities associated with back pain are physical musculoskeletal disorders like rheumatoid arthritis, osteoarthritis and osteoporosis, followed by cardiovascular and cerebrovascular disease.

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The objective of this study was to further investigate a similar list of physical comorbidities – as previously published (14) – by assessing patient outcomes in a cohort of chronic low back pain patients. The research hypothesis was that those with comorbidities will have worse outcomes than those without a comorbid condition. The research question: do non-spinal medical issues contribute to prolonged treatment periods and/or significantly worse clinical outcomes in chronic low back pain?

Materials and methods

This was an observational cohort study that investigated consecutive mechanical low back pain patients who started a non-operative rehabilitation program between January 1, 2005 and September 30, 2006 (n = 2777). This study included only those in the chronic phase, defined as 90–365 days symptom duration (15). Mechanical LBP is not associated with identifiable red flags (tumours, infection, or fracture) and was defined as pain arising from physical structures within the spine that varies or fluctuates with movement and/or position (16). Mechanical LBP was established by the treating physiotherapist based on patients' history and physical examination. The cohort contained both those apart and those not involved in the workforce. Minors and surgical candidates were excluded. All patients provided a signed, written, informed consent for participation and release of information.

Comorbidity findings were determined a priori, during physiotherapy assessment. To eliminate treatment bias, the research team categorized patients into one of two groups – during the data analysis phase – based on the initial medical history data collected. Thus, patients and clinicians were not aware of any comorbidity categorization; treatment was similar regardless of any group assignment. The two groups were: (i) those with at least one of seven specific physical medical conditions identified on assessment (Comorbidity Group, n = 898), (ii) those with low back pain only (Back Pain Group, n = 1879).

For this study, physical comorbidity was defined using the conditions listed in Table I; these are some of the conditions that result in a physical change to the body's normal function. There were 12 senior physiotherapist teachers/mentors within the rehabilitation system that determined this list of physical comorbidities to query. The list was based on their clinical experience of the most common medical conditions seen in their practices. Psychosocial-type comorbidities were not assessed because this would have involved including other clinicians to the multidisciplinary team, which would have increased treatment cost. Determining physical comorbidity status was largely subjective and determined via physiotherapist questioning of the patient. Verification with primary care physicians was not performed. This approach is similar to previous comorbidity research where the focus was on symptoms and health complaints (3,17). While a definitive or comprehensive list was not used, the inclusion of an 'Other' comorbidity category allowed for the capture of possible health complaints not included in the specific significant medical history query.

Table I. Physical comorbid conditions in a cohort of chronic low back pain patients reporting for non-operative treatment.

Comorbidity	n
Coronary artery disease	20
Hypertension	205
Rheumatoid arthritis	10
Diabetes	50
Non-spinal malignancy	24
Chronic obstructive pulmonary disease	27
Other comorbid conditions	406
	742*

*An additional 156 had multiple conditions (total 898).

The cohort was comprised of those who attended any one of 48 physiotherapy clinics across Canada. The clinics were part of one large rehabilitation system and were not linked to, but operated independently of patients' employers. Physiotherapy assessment was based on the recognition of four syndromes or patterns of pain with no direct reference to anatomic site or pathological process. In this system of sub-classifying LBP, the essential elements of the four Patterns of Pain are determined by the location of the dominant pain, whether that pain is constant or intermittent and the particular movements or postures that exacerbate or alleviate the symptoms. This method purposely avoids the label "non-specific". The system is intended to describe all possible presentations of mechanical LBP with and without associated direct nerve root involvement. Assessment was strongly linked to a subsequent management strategy. The high intertester reliability of this assessment method has been previously documented (18).

Treatment was active, exercise-based physiotherapy. Treatment started after clinical syndrome identification (16,19). The treatment was based on three sequential stages of recovery: (i) pain control, (ii) recovery of movement and (iii) physical conditioning. Each stage was individualized to the specific patient. In Stage 1, the goal was to decrease symptoms or abolish the pain if possible through exercise, manual therapy and education about basic anatomy and teaching proper posture. In Stage 2, the objective was to help patients recover or perform some of the movements they were not able to do while in pain, in order to regain as much range of motion as possible. Strength, endurance and aerobic training were also components of Stage 2.

Stage 3 involved physical conditioning based on the current level of fitness and job demands. Job simulation, work conditioning tasks and further increases in strength and endurance were essential components of this stage. Physiotherapists provided sole instruction and treatment in Stage 1. Physiotherapists supervised Stage 2 and 3; kinesiologists, exercise therapists and/or occupational therapists delivered the bulk of the instruction. The underlying philosophy of all three stages was to transfer responsibility to patients so they could help control their own pain and take a conscientious role in their own recovery. Within the clinic, the number of treatment hours per day and the total duration of treatment were adapted to the needs of each patient. The treatment time ranged from one to four hours per day. The effectiveness of this treatment approach was addressed in a study that compared two cohorts; one cohort received assessment and treatment based on syndrome identification; the other cohort had a generic-type treatment, whereby modalities and general exercises were utilized. The cohort who received classification-based treatment had significantly less pain and medication use, higher functional improvement and achieved those outcomes in significantly less time than the generic treatment group (19).

Physiotherapy assessment and patient self-report were used to obtain baseline and outcome information. Patients participated in a clinical interview, completed a baseline questionnaire on how pain affected physical function, and provided socio-demographic information. The questionnaire contained 18 patient self-report items based on a previously published instrument, the Low Back Outcome Score (20). The higher the score, the greater the patient's perceived level of function (15); the score range was 3–70. At discharge, patients completed the same questionnaire to gauge changes and improvements.

All clinical and socio-demographic information devoid of individual patient identifiers was assigned an identification number, entered into a computer program, electronically transferred and stored in a central clinical database. The database was designed for research purposes and contains all the clinical details necessary for epidemiological research (21). The study design was approved by the Research Ethics Board of Sunnybrook Health Sciences Centre, and ensured confidentiality of all participants.

Primary outcomes assessed were: (i) change in perceived function from initial assessment to discharge, based on changes in questionnaire scores, (ii) change in visual analogue scale (VAS) pain rating from assessment to discharge, and (iii) total treatment sessions. VAS pain rating was determined on an 11-point scale (0 = no pain, 10 = worst possible pain). VAS pain rating was determined only for the dominant symptom (either back pain or leg pain). Secondary outcome measures were: (i) change in medication usage from assessment to discharge, and (ii) subjective global pain rating at discharge (pain is: gone, decreased, same, increased). Since no psychosocial conditions were assessed, no psychosocial outcomes were evaluated.

Logistic regression analysis was used to model the relationship between the binary response variable (comorbidity present yes/no) and the individual outcome measures for the two groups. Univariate logistic regression analysis was used to identify any significant associations between each independent variable and the dichotomous outcome. Multivariable analysis was used to adjust for covariates. An alpha level of 0.05 (two sided) was used as the criterion for statistical significance. All analyses were conducted with SPSS for Windows release 15.0.1, November 22, 2006. Minimal clinically important difference was a 2-point difference on the 11-point numeric scale for pain rating and a 30% change in questionnaire score for function (22,23).

Results

The mean age of the cohort was 41.7 years (SD = 10.9, range = 18–65) with 60% males. The mean symptom duration was 177.1 days or 5.8 months (SD = 72.7, range = 90–365 days), with a median of 160 days (5.25 months). The mean number of treatment sessions was 28.2 (SD = 22.7, range = 2–173) conducted across a median of 51 calendar days. Prior to treatment, constant pain was reported by 52% of the cohort and 68.4% reported daily medication use for their back pain. Of the 2777 patients treated over the 20-month period, 32.3% (n = 898) reported at least one comorbidity. For those in the workforce, 30% received workers' compensation-type benefits.

For within group differences, the magnitude of change was a 12.2% reduction in pain rating ($p < 0.001$) and 14.3% improvement in functional score ($p < 0.001$) for the Comorbidity Group; there was a 12.5% reduction in pain rating ($p < 0.001$) and 14.6% improvement in functional score ($p < 0.001$) for the Back Pain Group. While these changes showed statistically significant improvements, the results were not clinically significant.

For between group differences, Table II reveals that there were no baseline statistically significant differences in VAS pain rating, questionnaire score, symptom duration, percent in constant pain, medication use or LBP sub-classification between groups. The Comorbidity Group was significantly older by approximately 5 years (45.5 vs 39.9, $p < 0.0001$) and had significantly more females (45.5% vs 37.4%, $p < 0.0001$). To account for these statistically significant differences between groups, odds ratios were adjusted for age and sex.

Table II. Baseline differences between groups.

	Comorbidity Group, $n = 898$	Back Pain Group, $n = 1879$	SSD
Sex, % male	54.5	62.6	*
Age, mean (SD)	45.5 (11.1)	39.9 (10.3)	*
VAS, mean (SD)	5.56 (2.2)	5.53 (2.23)	NS
Q Score, mean (SD)	36.5 (10.3)	36.8 (10.8)	NS
Symptom duration, mean (SD)	178.4 (75.1)	176.5 (71.7)	NS
Constancy, % constant pain	53.3	52.5	NS
Medication use, % not using	10.9	11.4	NS
Back pain classification			
% Pattern 1 and 2	89.7	85.9	NS
% Pattern 3 and 4	6.3	7.1	
No pattern	3.9	7.02	

SD, standard deviation; SSD, statistically significant difference; NS, not significant; *$p < 0.0001$.

Table III displays the logistic regression analysis and reveals no statistically significant difference for change in functional score (odds ratio (OR) = 0.996), change in VAS pain rating (OR = 1.013), and number of treatment sessions (OR = 0.997), between groups. Chi-square analysis revealed that there were no statistically significant differences in global pain rating and 'never' using medication, between groups (Table IV).

Of the 898 patients with comorbid conditions, Hypertension ($n = 205$) and Diabetes ($n = 50$) were the most frequent conditions. Separate comparisons with the Back Pain Group were performed for these two comorbidity subgroups. Small sample sizes prevented subgroup analysis for the remaining conditions (coronary artery disease, rheumatoid arthritis, non-spinal malignancy, chronic obstructive pulmonary disease). Using the same logistic regression modeling techniques for Hypertension and Diabetes vs Back Pain, analysis revealed that there were no statistically significant differences between groups for functional score, VAS pain rating and treatment sessions.

For the Other category vs Back Pain, there were no statistically significant differences between groups for functional score, VAS pain rating and treatment sessions. For those with multiple conditions, there were no statistically significant differences between groups for functional score and treatment sessions; the Back Pain group had a statistically significant greater reduction in VAS pain rating (OR = 1.16, $p = 0.004$, 95% confidence intervals 1.05–1.27).

Table IV. Change in categorical outcomes by group.

Secondary outcomes	Comorbidity Group, $n = 898$	Back Pain Group, $n = 1879$	SSD
Medication use			NS
% Never	26.8	26.9	
% Daily/occasional	73.2	73.1	
Global pain rating			NS
Gone	10.9	13.8	
Decreased	66.6	62.9	
Same	17.3	19.1	
Increased	5.2	4.2	

SSD, statistically significant difference; NS, not significant.

Discussion

Nimgade et al. (2) believe it is beneficial to seek a more comprehensive picture of comorbid conditions and their collective influence rather than considering individual diseases in isolation. When considering all stated physical comorbidities as one entity, associated medical findings did not contribute to more pain, more medication usage or less function, post-treatment, in this cohort of chronic patients with mechanical low back pain all treated with the same active exercise approach. When comparing the Back Pain Group to the Comorbidity Group, odds ratios were approximately 1.00; thus, the differences in outcomes were not large enough to accept the research hypothesis. Those with a physical comorbid condition did not have poorer outcomes than those with back pain alone.

Conversely, combining different health conditions into one category for analysis can mask any potential associations for some conditions and not others. Different types of comorbid conditions interact with pain in different ways; this is particularly relevant for high blood pressure and coronary artery disease (24–26). Thus, a secondary analysis by individual comorbidity was conducted, but the results were similar; odds

Table III. Change in outcomes and odds ratios by group.

Primary outcomes	Comorbidity Group, $n = 898$	Back Pain Group, $n = 1879$	Odds ratio*	95% CI	p-value
Function (QS), mean (SD)	10.0 (11.9)	10.2 (12.1)	0.996	0.998–1.004	0.338
VAS, mean (SD)	−1.34 (2.44)	−1.37 (2.54)	1.013	0.963–1.065	0.62
Treatment sessions, mean (SD)	29.1 (21.9)	27.7 (23.2)	0.997	0.994–1.001	0.125

*Adjusted for age and sex. CI, confidence interval; VAS, visual analogue scale; SD, standard deviation; QS, questionnaire score (modified Low Back Outcome Score).

ratios were either not significant or marginally significant, indicating that outcomes were no worse by specific comorbidity type, particularly the Hypertension and Diabetes subgroups. For those with multiple comorbidities, the Back Pain Group had a greater reduction in pain but this result was not clinically significant.

These finding are similar to comorbidity research in acute low back (17) and even though Xuan et al. (5) suggest that comorbid conditions significantly affect generic quality of life scores and treatment effect, they conclude that comorbidity influence on disease-specific quality of life scores and treatment effect is considerably smaller.

However, the lack of differences in outcomes between groups in the current study is contrast to other comorbidity research. Schneider et al. (14) discovered that the morbidities they investigated were more common in subjects with back pain than in individuals without and concluded that it is important that physicians screen for comorbidities related to the back pain. Fanuele et al. (3) stated that the prevalence of non-spinal medical pathologies contributes to decreased functional status. Ritzwoller et al. (1) suggest that management approaches that are effective for physical and mental health comorbidities may prove beneficial for high-cost LBP patients. Sinikallio et al. (27) emphasize the importance of assessing and addressing the effect of coexisting medical conditions in any treatment program. IJzelenberg & Burdorf (28) state that comorbidity is important to consider when implementing workplace interventions because one musculoskeletal complaint may impact adversely on another musculoskeletal complaint. Differences in study populations and physical versus psychosocial comorbidities studies may account for the contrasting results. The methodology of the current study is also a principal difference.

The results do not allow for conclusions on all back pain patients. There were a few characteristics of this cohort that can influence external validity, namely gender and treatment type. The results are most generalizable to chronic, mechanical low back pain patients referred to active rehabilitation. This cohort had significantly more males than females, which is not common among chronic populations, but the percentages were not completely awry particularly in the Comorbidity Group; nevertheless, to account for this variation, odds ratios were adjusted for sex and for age. Only physical conditions occurring in conjunction with back pain were addressed; the inclusion of psychosocial factors would have allowed for a broader conclusion on the role of general comorbidity, but the study was limited to only physical comorbidities.

It is important to note that outcomes may be influenced by factors other than physical ability and/or symptom reduction. Motivation, job availability and satisfaction, economic imperatives, and levels of sickness or injury compensation may override simply comorbidity status in patient decisions. All stakeholders involved in the rehabilitation process have the potential to influence outcomes, particularly 'number of treatment sessions'. Patient, referral source and/or clinician, in either isolation or combination, all have a voice in treatment length. In the rehabilitation system of this study, treatment does not usually continue when: (i) patients announce that they feel ready to return to activities of daily living, (ii) patients reach the set number of treatments as dictated by payors, (iii) a clinician believes that further improvement is not likely, and it is in a patient's best interest to discontinue treatment. Thus, treatment termination is usually a negotiation between the three parties involved. Discharge occurs when the parties conclude that the goals and objectives set out in the treatment plan have been satisfactorily fulfilled. Unfortunately, in some cases, the maximum treatment length is determined by the number of treatments the payor agrees to fund, which is not standardized and varies from one payor to the next, but the wide range of treatment sessions shows that no one criterion dominates the discharge process. The short mean and median times suggest an intention to optimize therapy and avoid protracted interventions. Since the two groups showed similar frequency distributions and descriptive statistics, the decision process for discharge planning was similar for both groups.

Other limitations of this study include the potential for several biases (29). Determining physical comorbidity status was subjective. Since this was an observational cohort study, further verification clinically or with primary care physicians would have significantly increased costs and logistical planning of the study. The subjective nature of comorbidity determination may have lead to a reporting bias; however this approach has been used successfully in previous studies (3,17).

Since 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 towards this type of treatment. Similarly, since the treatment protocol was active, exercise-based rehabilitation, some 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, evidence from a pilot project involving rehabilitation providers (30) suggests that patient pain severity and functional status measures for this clinic system are similar to six other non-related physiotherapy facilities in Ontario Canada. There appears to be little, if any, selection bias specific to the clinic caseloads used for this analysis.

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. Using clinics that are fully integrated with the same centrally co-ordinated data collection tools and philosophy of treatment reduces the potential for inadequate data accumulation and unexpected treatment aberrations such as utilizing protocols outside the clinical syndrome identification method.

In conclusion, pain reduction, medication usage and functional outcomes all showed similar results for back pain patients enrolled in a rehabilitative program, which emphasizes active treatment and patient responsibility, regardless of whether or not comorbidities were present.

It is important to document coexisting medical conditions and ensure patients continue treatment for their comorbidity (if appropriate), but within the context of spine rehabilitation, therapeutic protocols can focus primarily on the assessment and treatment of low back pain.

The clinical approach to chronic low back patients with an associated comorbidity may seem more intimidating and/or more complicated at the start of treatment, but the potential for recovery is just as favourable as that for patients with uncomplicated mechanical back pain.

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