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Predictors of response following standardized education and self-management recommendations for low back pain stratified by dominant pain location

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ABSTRACT

Background: Low back pain (LBP) is a leading cause of disability globally. Risk-stratification systems (e.g. STarT Back) have been proposed to guide treatment, but with varying success. We investigated factors associated with poor response to standardized LBP education and self-management recommendations stratified by dominant pain location (back or leg).

Methods: LBP patients underwent a standardized primary care model of care of education and self-management recommendations. Poor response was defined as an Oswestry Disability Index (ODI) change score <10 units by 6 months. Multivariable logistic regression was used to identify poor response risk factors, stratified by back-dominant and leg-dominant back pain. Baseline factors: age, sex, body mass index, ODI, LBP/leg-pain intensity, LBP/leg-pain duration, STarT Back chronicity-risk, smoking, comorbidity count, and self-efficacy.

Results: The sample consisted of 767 patients (443 back-dominant, 324 leg-dominant). Mean age was 53 years, and 59% were female. Females accounted for 66% of back-dominant and 50% of leg-dominant patients. Chronicity risk was 'high' for 18% of back-dominant and 29% of leg-dominant patients. Poor response was higher in back- (57%) compared to leg-dominant (42%) patients. Adjusted stratified analyses: female sex, moderate or high chronicity-risk, and increasing age were associated with increased risk of poor response, and greater self-efficacy with favourable response, in leg-dominant patients; these were not the cases among back-dominant patients. Increased comorbidity count was associated with poor response in back dominant patients. In both patient groups, higher baseline ODI score was associated with favorable response, and smoking and longer pain duration with poor response.

Conclusions: Differences in the influence of sex and chronicity risk in particular on outcome by dominant pain location suggests that considering these patients as a single group may not be appropriate. Furthermore, findings suggest that stratification by pain dominance may enhance the use of established risk stratification tools such as the STarT Back.

Introduction

Low back pain (LBP) is a common and poorly managed health condition associated with significant health, social, and economic burden.[1–6] Several studies have reported that up to two-thirds of individuals with LBP may have recurring LBP at one year following onset,[7] and nearly one-quarter of prevalent LBP cases are chronic. Chronic LBP cases disproportionately contribute to total disability, accounting for more than three-quarters of years lived with disability due to LBP.[2] It is not surprising, therefore, that determining which individuals will develop chronic LBP and developing strategies to mitigate this risk has garnered broad attention and interest.[8–10]

Several risk factors associated with disabling chronic LBP have been identified, such as previous LBP episodes, greater pain intensity, leg pain, depression, low self-efficacy, smoking, and lower socioeconomic status.[7, 11, 12] Education and self-management recommendations to

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remain physically active, exercise therapy, and, when appropriate, cognitive behavioral therapy, are recommended in the treatment of chronic LBP.[9] Evidence also suggests that stratified management approaches lead to improved outcomes. Hall et al. used a classification system based on dominant mechanical patterns of symptoms to stratify management.[13] A screening tool that has received considerable attention,[14] the STarT Back separates patients into low, moderate, and high risk for persistent disabling LBP, has been used for stratified management centred around psychosocial factors.[15] Others have recommended stratification by severity of pain and disability.[16] However, there remains significant variability in treatment responses across LBP patient groups.

In a cross-sectional study assessing primary care LBP patient characteristics, dominant mechanical LBP symptom (i.e. back- or leg-dominant) stratification resulted in discrimination of distinct chronic LBP patients not otherwise differentiated by the StarT Back chronicity risk stratification, or degree of disability, alone.[17] The aim of the current study was to identify baseline factors associated with 6-month disability-related response to first-line non-surgical LBP treatment (education and self-management recommendations) within a standardized primary care LBP model of care. The focus was on determining whether the influence of patient characteristics, disability and chronicity risk on treatment outcome differed for patients stratified by mechanical LBP pattern, namely back- versus leg-dominant pain symptoms.

Methods

This is a prospective, observational study of patients recruited from 2013 to 2016 with follow-up to 2017. The study was approved by the University Health Network Research Ethics Board (14-7776-BE/16-5826).

Patients

Data are from patients who sought care from their primary care provider for persistent (>6 weeks to 12 months) first time or recurrent (i.e. episodic) LBP and were referred to the Inter-professional Spine Assessment and Education Clinics (ISAEC: www.ISAEC.org) pilot program. ISAEC uses an interdisciplinary shared-care model to provide a standardized multidimensional risk assessment (Hall mechanical patterns of LBP [13], Psychological profile (StarT Back) [15], Inflammatory [18] and surgical criteria) and provides stratified, guideline-based education and self-management recommendations. Other than demonstration of self-management exercises, the program does not deliver treatment.

Education and individualized self-management recommendations are based on risk stratification and pattern of pain (i.e. type of exercise). Demonstration of recommended home exercise are provided, as is specific education regarding best-evidence for non-operative treatment recommendations (as per Cochrane reviews) for those engaged in or considering treatment, however, the program does not provide any hands-on treatment. Based out of three initial pilot project cities in Ontario, Canada (Toronto, Hamilton, and Thunder Bay), 493 primary care providers participated in the shared-care model of care program and referred patients to ISAEC networked providers.

Referred patients were evaluated by community-based, inter-professionally trained, regionally networked advanced practice clinicians (Physiotherapist or Chiropractor with specific standardized ISAEC program training) who are linked to networked spine specialists for additional evaluation and support when needed. Based on positive patient, provider and system (reduced LBP related imaging) outcomes, the ISAEC pilot program has now transitioned to a provincial program (2018) with 14 integrated regionally networked, centrally managed hub-and-spoke programs (www.lowbackrac.ca) supporting over 6000 primary care providers.

Using shared-care model principles, patients' networked primary care provider (including Nurse Practitioners (25%)) would refer the patient on to the nearest ISAEC provider if they were not responding to the management they provided. Patient eligibility included 18+ years of age and experiencing persistent LBP-related symptoms lasting 6 weeks to 12 months or recurrent LBP (thus excluding incident acute LBP episodes and chronic long-term pain disorders). Patients with emergent or urgent 'red flag presentation' such as diagnoses or symptom presentations such as myelopathy, progressive neurological deficit, associated trauma, or known associated diagnosis of tumor, infection, or inflammatory conditions are excluded and redirected to emergency care or urgent specialist referrals. Other exclusions included patients with work-based insurance claims, pain related to motor vehicle accidents, established narcotic dependency (i.e. in active treatment), involvement in active litigation, pregnancy or postpartum <1 year, emergent spinal presentations, or an established pain disorder (i.e. already assessed and/or treated in multidisciplinary pain clinic).

From among the intake clinical cohort, the leg dominant patterns of pain presentation are possible surgical candidates. As part of program protocol, these patients underwent a secondary assessment to determine surgical candidacy to enable patients to have a more fully informed shared decision-making process regarding management preferences. For the specific purpose of this study, patients that underwent or were scheduled for back surgery during the 6-month follow-up period were also excluded from analysis.

At their initial ISAEC visit, patients completed a standardized health intake and risk assessment questionnaire and received a standardized history and physical assessment. A follow-up questionnaire was completed at 6-months post-treatment. The study received ethics approval and patients provided informed consent for enrollment.

Dominant mechanical LBP pattern

For this study, patients' LBP symptoms were stratified into one of two clinical pain patterns,[13, 19] back-dominant or leg-dominant LBP symptoms. Patterns and location of dominant LBP were determined by each patient's history and physical examination.

Study outcome

The Oswestry Disability Index (ODI) [20] is the most widely used patient-reported and validated outcome measure for LBP patients.[21] The questionnaire consists of 10 items assessing the level of pain and interference with physical activities, sleeping, self-care, work, social life, and travel. The sum of the ten items is expressed as a percentage, with higher scores representing greater disability. Poor response to stratified education and self-management recommendations was defined as an improvement of <10 units in the ODI by 6-months post-treatment compared to the baseline score. Response was defined as an improvement of 10 units or greater, which has been deemed a clinically important improvement for ODI in LBP.[22] For individuals beginning with a baseline ODI score below 10, response was defined as reporting no pain-related disability (ODI=0) at 6 months.

Baseline factors – questionnaire-based

Based on literature findings,[7, 11, 23, 24] several characteristics were considered as potentially influencing 6-month ODI disability outcome. Age was self-reported and operationalized as a continuous variable. Sex was self-reported as male or female. Body mass index (BMI; kg/m^2) was calculated using measured weight and height. Current smoking status was self-reported as yes/no. Pain intensity was measured on a numeric pain rating scale (0-10) and was reported for back pain at rest and back pain with activity, and for leg pain at rest and leg pain with activity. Baseline back and leg pain intensity scores were defined as the worst (highest) score of the respective two questions. Self-efficacy refers to the level of confidence a person has regarding their own ability to perform a particular behavior. The Self-Efficacy for Managing Chronic

Table 1
Baseline sample characteristics, overall and by dominant symptom group.

	Overall (n=767, 100%)	Back Dominant (n=443, 57.8%)	Leg Dominant (n=324, 42.2%)	
	Mean (± SD)			t-test p-value
Age (years)	53.1 ± 15.3	50.8 ± 15.5	56.1 ± 14.6	<0.001
BMI (kg/m^2)	27.3 ± 5.3	26.8 ± 5.4	27.8 ± 5.6	0.010
LBP Intensity	6.5 ± 2.7	6.7 ± 2.2	6.2 ± 3.1	0.007
Leg pain intensity	5.6 ± 3.4	4.2 ± 3.4	7.6 ± 2.1	<0.001
Comorbidity count	1.6 ± 1.6	1.5 ± 1.5	1.7 ± 1.6	0.043
Self-efficacy score	6.4 ± 2.0	6.7 ±2.0	6.1 ± 2.1	<0.001
Baseline ODI	35.6 ± 17.3	31.7 ± 16.6	41.1 ± 16.9	<0.001
6-month ODI	24.6 ± 19.0	22.6 ±17.5	27.4 ± 20.5	0.001
Change in ODI	11.0 ± 17.5	9.0 ± 15.5	13.7 ± 19.7	0.001
	n (%)			X^2 test p-value
Gender				<0.001
Male	314 (40.9)	153 (33.5)	161 (49.7)	
Female	453 (59.1)	290 (65.5)	163 (50.3)	
Chronicity Risk				<0.001
Low Risk	322 (42.0)	222 (50.1)	100 (30.9)	
Medium Risk	272 (35.5)	141 (31.8)	131 (40.4)	
High Risk	173 (22.6)	80 (18.1)	93 (28.7)	
LBP Duration				<0.001
Not applicable	17 (2.2)	-	17 (5.4)	
<3 months	176 (23.2)	99 (22.3)	77 (24.4)	
3-6 months	179 (23.6)	95 (21.4)	84 (26.6)	
6+ months	387 (51.0)	249 (56.2)	138 (43.7)	
Leg pain Duration				<0.001
Not applicable	116 (15.9)	116 (15.9)	-	
<3 months	202 (27.7)	88 (21.7)	114 (35.2)	
3-6 months	151 (20.7)	73 (18.0)	78 (24.1)	
6+ months	261 (35.7)	129 (31.8)	132 (40.7)	
Smoking				0.792
Non Smoker	647 (84.3)	375 (84.6)	272 (83.9)	
Smoker	120 (15.6)	68 (15.3)	52 (16.0)	
Poor Response*				0.001
No	391 (51.0)	204 (46.0)	187 (57.7)	
Yes	376 (49.0)	239 (57.0)	137 (42.3)	

*Poor response represents <10-unit improvement in ODI score over the 6-month period

Disease 6-item Scale was used.[25, 26] A self-efficacy score was calculated by averaging patients' answers to the 6 validated questions (each rated 0-10), with higher scores indicating greater self-efficacy.

Degree of disability was based on the ODI. Chronicity risk was assessed with the Keele STarT Back questionnaire,[15] a nine-item tool designed to measure severity in different domains, including dressing, walking, fear, worry, catastrophizing and mood, and bothersomeness. Patients were categorized by risk of persistent disabling symptoms - low, medium, or high risk.

Statistical analysis

Descriptive statistics were produced for the overall sample and separately by dominant symptom. Multivariable logistic regression models were used to assess associations between response (model outcome) and baseline factors, stratified by dominant symptom groups (back-dominant and leg-dominant). Based on the logistic regression models, graphs of predicted probabilities of poor response were developed. All analyses were performed using SAS version 9.4.

Results

Study sample

The sample consisted of 767 patients and Table 1 presents the baseline characteristics of the sample, overall and by dominant symptom group. Mean age overall was 53 years, with 314 males (41%) and 453 females (59%). Fifty-eight percent of patients were classified as having back-dominant (n=443) and 42% as leg-dominant (n=324) symptoms. Back-dominant patients were more frequently female than leg-dominant patients, and 18% were deemed to be at 'high' chronicity risk compared to 29% among leg-dominant patients. As expected, LBP intensity was greater for the back-dominant group, and leg pain intensity greater for the leg-dominant group. Among back-dominant symptom patients, 56% reported LBP duration of 6+ months, while 41% among leg-dominant patients reported leg pain duration of 6+ months.

Baseline ODI scores were worse among those with leg-dominant compared to back-dominant symptoms. The average change in ODI score over the 6-month period was an improvement of 11 units overall, and specifically 9 units among the back-dominant compared to nearly 14 units among the leg-dominant symptom patients. Accordingly, the leg-dominant group had a significantly lower rate of poor response (i.e. ODI improvement <10 units) than the back-dominant group (42% versus 57%).

Table 2 presents results from the logistic regression analyses. For both back and leg dominant pain groups, longer LBP/leg pain duration and smoking were significantly associated with an increased risk of poor response, while increasingly worse baseline ODI score was associated with a decreased risk poor response. Female sex, moderate and high chronicity risk, and a higher comorbidity count were associated with a significantly higher risk of poor response among leg-dominant symptom patients. These factors were not significantly associated with poor response among back-dominant symptom patients.

Results from the logistic regressions are presented, in part, graphically in Figures 1 and 2, focusing on two baseline factors which had the largest statistically significant difference in effect on treatment success

Table 2
Multivariable logistic regression examining the association between baseline factors and poor response (i.e. <10-unit improvement in ODI by 6-months).

	Back Dominant Group			Leg Dominant Group			
Baseline Factor	Odds Ratio	95% CI	*p*-value	Odds Ratio	95% CI	*p*-value	
Age	**1.02**	1.00, 1.03	**0.035**	1.00	0.98, 1.02	0.686	
Female vs Male	1.17	0.74, 1.84	0.506	**2.58**	1.50, 4.46	**0.001**	*
Body Mass Index	0.99	0.95, 1.03	0.626	0.98	0.93, 1.03	0.428	
Baseline ODI (0-100)	**0.94**	0.92, 0.96	**<0.001**	**0.92**	0.90, 0.95	**<0.001**	
LBP intensity (0-10)	1.02	0.91, 1.15	0.692	1.06	0.96, 1.18	0.256	
Leg pain intensity (0-10)	**1.09**	1.02, 1.17	**0.016**	1.04	0.90, 1.21	0.563	
LBP/Leg pain duration							
3-6 vs <3 months	0.91	0.48, 1.73	0.771	0.89	0.44, 1.83	0.760	
6+ vs <3 months	**2.45**	1.44, 4.18	**0.001**	**2.38**	1.26, 4.47	**0.007**	
STarT Back Chronicity Risk							*
Moderate vs Low	0.85	0.50, 1.44	0.546	**2.84**	1.39, 5.80	**0.004**	
High vs Low	1.32	0.65, 2.66	0.444	**3.70**	1.56, 8.76	**0.003**	
Smoker vs Non-smoker	**1.86**	1.00, 3.45	**0.049**	**3.76**	1.77, 7.99	**0.001**	
Comorbidity count	1.06	0.90, 1.25	0.481	**1.31**	1.08, 1.60	**0.006**	
Self-Efficacy score (0-10)	**0.82**	0.71, 0.93	**0.003**	0.89	0.76, 1.04	0.140	

*statistically significant interaction with back/leg dominant symptoms (sex: p=0.030; STarT Back: p=0.025).

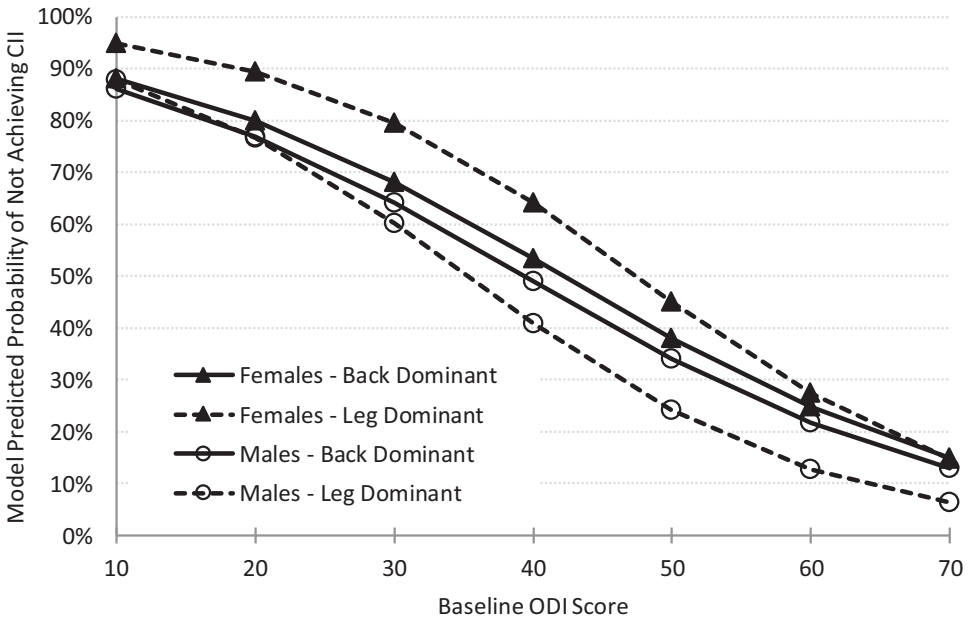

Fig. 1. Predicted probability of poor response (i.e. failing to achieve a clinically important improvement (CII) (<10-unit improvement in ODI by 6-months)) based on the multivariable logistic regression analysis, by pain pattern and sex.

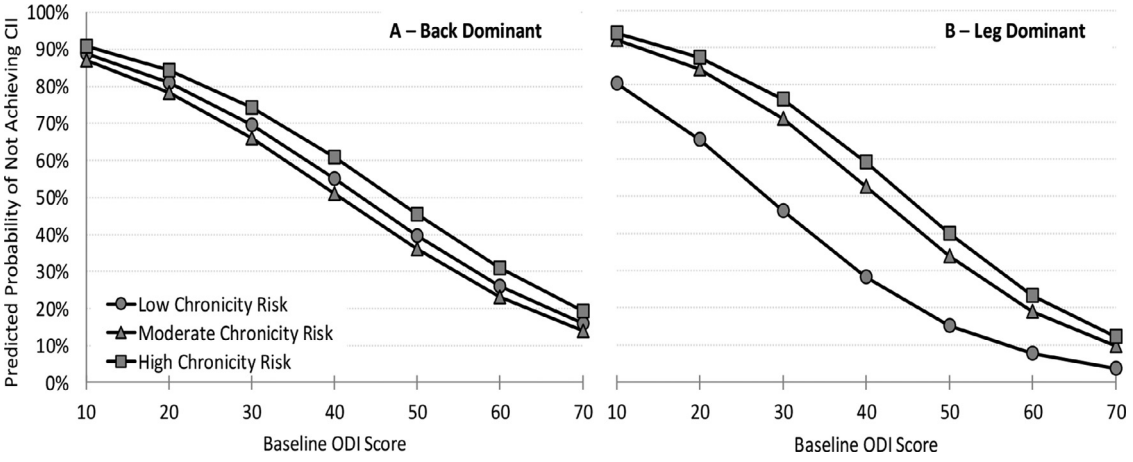

Fig. 2. Predicted probability of poor response (i.e. failing to achieve a clinically important improvement (CII) (<10-unit improvement in ODI by 6-months)) for patients with back dominant (A) and leg dominant (B) pain by chronicity risk.

between the dominant symptom groups, specifically sex and chronicity risk. As reflected in Figure 1, a significant sex difference was found in the leg-dominant group, whereas no sex difference was noted among the back-dominant group. For example, for the average male and female patient with a baseline ODI score of 40 and leg-dominant LBP, their predicted probability of treatment failure was 41% and 64%, respectively (23 percentage points difference), compared to their back-dominant counterparts at 49% and 53%, respectively (4 percentage points difference). Figure 2 reflects differences between dominant symptom groups based on Start Back chronicity risk. For example, for the average patient with a baseline ODI score of 40, their predicted probability of treatment failure varied between 51% and 60% (9 percentage points range) across the 3 categories of chronicity risk if they were a back-dominant patient (Figure 2A), compared to varying between 28% and 59% (31 percentage points range) if they were a leg-dominant patient (Figure 2B).

Discussion

Among patients receiving guideline concordant education and self-management LBP recommendations, this study found poor response at 6-months to be more frequent among those with back-dominant compared to leg-dominant symptoms. While some patient characteristics similarly influenced risk of poor response in both groups, notable dissimilarities were found. In particular, among individuals with leg-dominant symptoms, females and those with moderate or high chronicity risk were at higher risk of failure; this was not the case among back-dominant patients.

Individuals with chronic LBP can have a wide range of symptom and etiology profiles. As a consequence, classifications of LBP have been put forward in an attempt to derive more homogeneous subgroups.[27] Subgrouping LBP patients has been suggested as an intuitive approach, as many clinicians perceive LBP as a complex condition that should not be managed or analyzed as the commonly termed "non-specific" entity.[28, 29] Nonetheless, further research is needed to improve the identification of LBP subgroups with distinct prognostic or predictive characteristics. This would support the ability of primary care to optimize outcomes by providing tailored, subgroup-specific education, self-management and treatment approaches.[13, 15, 30]

In this evaluation, we postulated that the simplest place to start would be clinical stratification by dominance of pain location. We found that some of the same patient characteristics had different influences on 6-month outcomes following intervention depending on whether patients had back- or leg-dominant symptoms. This practical, simple stratification elucidates the potential hazards of aggregating chronic LBP patients, as key characteristics that influence patient outcomes may be missed, along with opportunities to improve those patient outcomes. Similar considerations for research within this broader clinical population equally apply.

Although our patients were undergoing a secondary assessment in a shared-care primary care model, our overall sample was remarkably similar to cohorts consulting primary care physicians for LBP that were recruited for the IMPaCT Back cohort study and the STarT Back trial.[15, 30] The current sample had a mean age of 53 years, 59% were female, and 23% were deemed to be at high chronicity risk (STarT Back tool), compared to 54 and 50 years, 58% and 59% female, and 21% and 27% high risk in the IMPaCT and STarT Back studies. These overall estimates, however, overlook differences that were observed in the current sample when characteristics were examined by dominant symptom group.

For example, among back- and leg-dominant symptom groups, females accounted for 66% and 50% of the sample, respectively, and 18% compared to 29% had STarT Back scores indicating high chronicity risk, respectively. If factors which may affect outcomes differ in proportion between comparative groups, adjustment in regression analyses typically resolves the problem. However, this assumes that an 'averaging' of effects is appropriate. Our findings suggest that aggregating back- and leg-dominant patients and averaging effects for males and females and for chronicity risk levels, which is not uncommon in primary care LBP studies, may mask important underlying differences in their influence on outcomes.

When aggregated (data not shown), the odds ratio for female versus male experiencing poor response was 1.7 (p=0.002), compared to 1.2 (p=0.506) and 2.6 (p=0.001) for back- and leg-dominant symptom groups, respectively. These differences may in part explain variability in findings with respect to the impact of sex on LBP outcomes.[31] They also suggest that females with leg-dominant symptoms in particular may require targeted education and/or other targeted intervention to increase the likelihood of a good outcome. Among LBP patients, there has been limited attention given to the potential impact of sex differences on clinical outcomes, [32–34] and the need to consider sex (and gender) within the context of LBP research and clinical care guidelines has been raised.[35] Our findings confirm evidence of this need.

We also found that the 'average' influence of pre-shared-care management chronicity risk on the likelihood of poor response at 6-months obscured a considerably greater negative impact for leg- compared to back-dominant LBP symptom patients. When aggregated (data not shown), no significant difference (p=0.680) was found between those with moderate and low chronicity risk, while those at high chronicity risk (vs. low) had an odds ratio for poor response of 1.7 (p=0.037). This is in stark contrast to finding no statistically significant effect of pre-shared-care management chronicity risk among back-dominant symptom patients, and odds ratios of 2.8 (p=0.004) and 3.7 (p=0.003) for poor response among those with leg-dominant symptoms.

Use of the STarT Back tool as a basis for stratified treatment has garnered interest, and has been shown to be associated with some improvement in outcomes and cost-effectiveness compared to usual care.[36–39] However, our findings suggest that provision of greater intensity of treatment and/or more complex treatment for patients at moderate/high LBP chronicity risk may be differentially appropriate only for a subgroup of these patients (i.e. leg-dominant pattern). This certainly warrants further research using further degree of stratification. What this also suggests is that the use of the STarT Back stratification tool, or any other stratification schema, on its own may not enable further individualized treatment, such as in cases of mechanical patterns of pain and more targeted initial medical management, and its ability to predict patient outcomes may be outcome-dependent.[40] A multidimensional combination of stratification tools may be required to better represent the complexities of chronic LBP.[27]

Consistent with what has previously been reported, we found worse baseline disability scores were associated with greater likelihood of response,[41–43] while smoking and longer pain duration were associated with poorer outcome.[12, 43-49] Longer pain duration (6+ months vs. <3 months) was similarly associated with poorer outcome for the back- and leg-dominant pain groups. However, since our study questionnaire documented duration by categories of months, we did not have the granularity necessary to determine the critical length of symptom duration at which point a poorer outcome becomes more probable, and whether this differs between the two subgroups. This is an area requiring further research.

The patient population the current sample was drawn from represents three cities in different regions of Ontario, Canada and from the practices of 493 primary care practitioners. The sample likely represents the general chronic LBP population seeking primary care in Canada's most populous province, and likely Canada generally. Even so, primary care practitioners who volunteered to participate in the ISAEC programme were the source of study patients, and it is possible this introduced an element of selection bias. In addition, Canadians have universal, publicly funded healthcare for institution and physician services, but not rehabilitation services such as physiotherapy/chiropractor care. Thus, the profile of patients seeking and accessing primary care in jurisdictions operating under different funding systems may differ from those in the current study.

While pain at other sites, and specific psychosocial and societal factors are known to influence outcomes in LBP,[6, 7, 12, 33, 50-52] data regarding such factors were limited in the current study. Therefore, additional studies with more comprehensive consideration of these factors is warranted to further explore the unique features of the dominant symptom subgroups we considered. In addition, the study focused exclusively on clinical outcomes and did not take into account imaging findings which, for a subgroup of patients, may ultimately be important for understanding non-response to education and self-management intervention. Our findings provide an important basis for further research in LBP subgrouping.

Our findings also confirm the heterogeneity of LBP patients and provide evidence that biopsychosocial factors interact in influencing LBP outcomes. This can have important implications for care and for developing prognostic and predictive models.[53] Stratifying LBP primary care, and potentially combining this with targeted stepped care, provides an opportunity for developing and delivering more effective and patient-centered care to improve treatment response and, where possible, reduce chronicity for this large clinical population.[52, 54]

Conclusion

While differences in patient characteristics across subgroups of LBP have been reported, we found that the influence of several factors, and in particular sex and chronicity risk, on disability outcome appear significantly dependent on dominant pain location. The averaging of predictor effects across back- and leg-dominant pain subgroups appears to run the risk of missing, or minimizing, important determinants of outcome. Clinically, stratification by pain dominance may enhance the use of established risk stratification tools.

Informed Patient Consent

The authors declare that informed patient consent was taken from all the patients.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Disclosures

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