Special Interest Group

Preliminary Development of a Responder Index for Chronic Low Back Pain

LEE S. SIMON, CHRISTOPHER EVANS, NATHANIEL KATZ, CLAIRE BOMBARDIER, CHRISTINE WEST, JEFFERY ROBBINS, CATHERINE COPLEY-MERRIMAN, J. MARKMAN, and JOHN H. COOMBS

ABSTRACT. ***Objective.*** One of the greatest obstacles to identifying the most effective therapy for chronic low back pain (CLBP) is the lack of standardized outcome measures for assessing treatment effect in clinical trials. The aim of the OMERACT Special Interest Group was to discuss the development and validation of a preliminary responder index in CLBP.

Methods. Patient data from 5 clinical trials of celecoxib and valdecoxib use in CLBP were used to assess the reliability and validity of multiple items in the outcome domains of pain, functioning, and overall impression of health. Candidate preliminary responder indices were selected on the basis of effect size, high chi-square test values, and a placebo response rate ≤ 25%.

Results. Candidate indices comprised improvements in single outcome measures and combinations of improvements and/or avoidance of worsening in multiple measures. The preliminary choice for the responder index was at least 30% improvement in pain, with an improvement of at least 30% in patient global assessment and no worsening in function.

Conclusion. Further studies are needed to refine a responder index for CLBP trials that is clinically relevant, reliable, and easy to administer for standardizing assessments across clinical trials. (J Rheumatol 2007;34:1386–91)

Key Indexing Terms:
LOW BACK PAIN
CLINICAL RESPONDER CRITERIA
OUTCOME MEASURES
INSTRUMENTS

Nonspecific low back pain (LBP) is a major health and socioeconomic problem across the industrialized world[1-3]. About two-thirds of adults will suffer from LBP at some point in their lives, and at any one time 4% to 33% of a given population will be affected[4,5]. The majority of patients with LBP recover quickly, without longterm loss of function; however, if pain persists for more than 12 weeks, recovery is slow and uncertain[6]. Because a precise pathoanatomic diagnosis of CLBP is often not possible, the goal of nonsurgical treatment is reduction in pain intensity and pain related functional impairment[7]. These cases of chronic LBP (CLBP) impose a huge burden on healthcare systems, cause significant disability and absence from work, and account for a substantial proportion of medical consultations[1,2,5,6,8-11].

From Harvard Medical School, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; MAPI Values, Boston, Massachusetts, USA; Analgesic Research, Newton, Massachusetts, USA; University of Toronto, Toronto, Ontario, Canada; Pfizer Inc., Ann Arbor, Michigan, USA; and the University of Rochester School of Medicine and Dentistry, Rochester, New York, USA.

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L.S. Simon, MD, Harvard Medical School, Beth Israel Deaconess Medical Center; C. Evans, PhD, MAPI Values; N. Katz, MD, Analgesic Research; C. Bombardier, MD, University of Toronto; C. West, PhD; J. Robbins, MS; C. Copley–Merriman, MS, MBA; J. Markman, MD; J.H. Coombs, PharmD, Pfizer Inc.

Address reprint requests to Dr. L.S. Simon, Harvard Medical School, Beth Israel Deaconess Medical Center, 35 Oldham Road, West Newton, MA 02465. E-mail: lsimon@bidmc.harvard.edu

Early treatment, therefore, has the potential to reduce the social, economic, and medical effects of CLBP[9]. However, the efficacy of most therapeutic interventions has not yet been established beyond doubt, and there remains an urgent need to identify which treatment, if any, provides benefit for patients[12]. One of the greatest obstacles to achieving this goal lies in the varied measures used to interpret the effects of therapy in clinical trials of CLBP[13]. Response to treatment may be assessed using measures of disability [e.g., the Roland Morris Disability Questionnaire (RMDQ), Oswestry Disability Index[11,13,14], functional health status (e.g., Nottingham Health Profile)[15], pain (e.g., Aberdeen Back Pain Questionnaire)[14], visual analog scale (VAS)[12,16], and verbal rating scale[17]]. However, many of these measures are highly subjective[18] and do not necessarily reflect improvements in quality of life[19]. Physiological measurements of muscle strength and range of motion are often considered to be objective; nonetheless, despite their frequent use in clinical trials, these measures correlate poorly with behavior and symptoms[18].

This lack of standardization of endpoints and interpretation in clinical trials hinders any attempt to assess or directly compare different studies[20], thus impeding the identification of optimal therapeutic strategies. Indeed, Roland and Morris have suggested that clinical trials of CLBP therapy have made a "disappointing contribution" to the management of back pain[21]. Several researchers have proposed core sets of out-

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come domains that can provide a framework for assessments in CLBP trials (Table 1)[18,22]; however, these recommendations are not specific enough to ensure that the most appropriate measures are used consistently across different trials. Further, their ability to detect clinically important differences between active and placebo arms is limited.

In view of these observations, it is important to consider whether a responder index in CLBP could alleviate any of the problems associated with currently used outcome measures. A responder index is a composite measure of clinically face-valid and nonredundant clinical endpoints. Response to treatment is measured by specific improvement criteria selected for the endpoints. These improvement criteria establish clinical efficacy and differentiate between placebo and active responses. To date, such improvement and response criteria have been developed and used in several different musculoskeletal disorders, including ankylosing spondylitis[23], rheumatoid arthritis[24], osteoarthritis (OA)[25], and juvenile arthritis[26]. In our report, we describe the preliminary development of a responder index in CLBP and summarize the OMERACT discussion and future research agenda.

METHODS

The study consisted of 4 stages that encompassed both qualitative and quantitative methods.

Stage 1: Literature review. The current literature on chronic pain outcome measures was reviewed in order to develop a list of potential component items for a responder index. This review highlighted 2 primary recommendations for chronic pain outcomes: the Initiative on Methods, Measurement, and Pain Assessment (IMMPACT)[22] and the 6-item outcome set for LBP proposed by Deyo, *et al* (Table 1)[27].

Three responder indices in other therapeutic areas were also examined: the ASsessment in Ankylosing Spondylitis (ASAS)[23], the American College of Rheumatology core set of outcome measures[24], and the OMERACT–OARSI criteria for OA in the hip and knee[25]. Following evaluation of those items that were common to all 3 indices and recommendations from the IMMPACT and Deyo publications, it was decided that a candidate responder index for CLBP should include measures of pain symptoms, physical function, overall patient global assessment, and patient satisfaction with treatment.

Table 1. Core measures for chronic pain and LBP trials.

IMMPACT[22] (chronic pain trials)	Deyo, et al[27] (CLBP)
• Pain • Physical function • Emotional functioning • Rating of improvement and satisfaction with treatment • Symptoms and adverse events • Participant disposition (adherence to treatment and premature withdrawal)	• Pain symptoms • Back-related function (RMDQ or Oswestry) • Generic well-being (SF-12/EQ-5D) • Disability (social role): absenteeism/productivity • Satisfaction with care

SF-12: 12-item Short Form Health Survey; EQ-5D: EuroQol, 5 dimensions.

Stage 2: CLBP focus groups. Three focus groups of patients with CLBP met to discuss the effect of this condition on pain, symptoms, daily activities, and quality of life. Two groups met in the United States (n = 6 and n = 9), and 1 group was established in the United Kingdom (n = 7). The overall objective of the groups was to confirm the findings of the literature review and elicit other concepts for the development of the responder index.

Participants of the focus groups were English-speaking individuals over age 18 years, diagnosed with mechanical (excluding neuropathic or neurologic etiology) CLBP of at least 3 months' duration and treated with nonselective nonsteroidal antiinflammatory drugs (NSAID) or cyclooxygenase-2 (COX-2) selective inhibitors. During the focus group discussions, patients were asked for their perspectives on the following issues: general feelings about CLBP, related symptoms and their impact, physical functioning and activities of daily living, pain associated with CLBP, experiences with CLBP treatment, side effects related to therapy, and compliance and satisfaction with treatment. From these discussions, the candidate responder index criteria for CLBP were refined to include primarily functional measures, along with more traditional measures of pain intensity.

Stages 3 and 4: development and validation databases. Following the literature review, focus group discussions, and input from clinical experts, the clinical trial data were quantitatively analyzed in 2 stages following a process similar to that used for the ASAS improvement criteria in which candidate improvement criteria were identified from an NSAID clinical trial database sample, and then validated in another related NSAID database sample[28]. The initial (development) analysis identified and tested potential indices using data from three 12-week, placebo controlled clinical trials of celecoxib therapy in CLBP. The findings of this analysis were then validated using data available from two 12-week, placebo-controlled trials of valdecoxib therapy. All 5 trials were reviewed to ensure that they captured all information relevant to the construction of a responder index in CLBP. The main elements of these trials are shown in Table 2.

For the development analysis, the following celecoxib dose groups were analyzed separately: 200 mg once daily (qd) pooled across 3 trials, and 200 mg twice daily (bid). For the validation analysis, the following valdecoxib dose groups were analyzed separately: 10 mg qd, 20 mg qd pooled across 2 trials, and 40 mg qd. Two patient populations were identified for analysis in the development and validation databases: the overall population and the patients who had a history of NSAID use prior to enrollment in the trials (NSAID users).

The items for testing and possible inclusion in candidate responder indices were obtained from the following measures available in the clinical trial database: LBP intensity, Patient

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Table 2. Development and validation trials used to construct a preliminary responder index in CLBP.

Outcome Measure	Outcome	Development Analysis (Celecoxib) Assessments			Validation Analysis (Valdecoxib) Assessments	
		Study 1 (200 mg qd)	Study 2 (200 mg qd)	Study 3 (200 mg qd/bid)	Study 4 (20 and 40 mg qd)	Study 5 (10 and 20 mg qd)
LBP intensity (VAS)	Pain	√	√	√	√	√
PGA	Global	√	√	√	√	√
PhyGA	Global	√	√	√	√	√
PGESM	Medication effect	√	√	√	√	√
mBPI-sf	Pain/function	√	√	√	√	√
Productivity	Productivity	√	√	ND	√	√
RMDQ	Physical function	√	√	√	√	√
Q-LES-QSF	Satisfaction	√	√	ND	√	√
SF-36	Health status	ND	ND	√	ND	ND

VAS: visual analog scale; PGA: Patient Global Assessment; PhyGA: Physician Global Assessment; PGESM: Patient's Global Evaluation of Study Medication; mBPI-sf: Modified Brief Pain Inventory-Short Form; RMDQ: Roland-Morris Disability Questionnaire; Q-LES-QSF: Quality of Life Enjoyment and Satisfaction Questionnaire Short Form; SF-36: Medical Outcomes Study 36-item short form health survey; ND: not done.

Global Assessment (PGA), Physician Global Assessment (PhyGA), Patient's Global Evaluation of Study Medication (PGE), modified Brief Pain Inventory-Short Form (mBPI-SF), the RMDQ, and the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-QSF). Candidate responder indices were selected from the development database on the basis of effect size, high chi-square test values, and a placebo response rate ≤ 25%. This analysis was replicated in the validation database. Effect sizes were calculated for each item from the measures collected in the celecoxib trials as follows:

$$ES = \frac{\Delta_{treated} - \Delta_{placebo}}{STD_{BL_common}}$$

where Δ = mean change in score between baseline and 12 weeks; and STD_{BL_common} = standard deviation of the baseline scores in both treated and placebo groups.

RESULTS

Initial selection of candidate items. Based on the results of the effect size calculations in the pooled 200 mg qd NSAID user population (Table 3), the following items were considered for inclusion in candidate responder indices: LBP VAS, PGA, PhyGA, pain right now (mBPI-SF), satisfaction with economic status (Q-LES-QSF), satisfaction with ability to do work and hobbies (Q-LES-QSF), satisfaction with well-being (Q-LES-QSF), satisfaction with medication (Q-LES-QSF), and overall life satisfaction (Q-LES-QSF).

Although the PGA and the PhyGA were associated with similar effect sizes, PhyGA was not considered for reasons of parsimony (highly correlated with other measures) and slightly better face validity for PGA. Only 1 of the 5 satisfaction measures was retained (satisfaction with medication), as this measure broadly covered the area of satisfaction and exhibited the largest effect size of the satisfaction measures.

Table 3. Effect size calculation of variables in the development database, prior NSAID users.

Change in Variable	Effect Size	
	Pooled qd (Studies 1, 2, 3)	Range Across Studies
LBP intensity	–0.25	–0.32, –0.13
PGA	–0.20	–0.48, –0.06
PhyGA	–0.19	–0.42, 0.05
Pain right now†	–0.31	–0.32, –0.29
Total RMDQ score	–0.08*	–0.13, –0.07
Satisfaction with economic status†	0.19	0.14, 0.23
Satisfaction with ability to do work or hobbies†	0.14	0.12, 0.16
Satisfaction with overall sense of well-being†	0.15	0.11, 0.18
Satisfaction with medication†	0.28	0.15, 0.41
Overall life satisfaction†	0.22	0.15, 0.28

* Not significant; † not available from Study 3.

Inclusion of a single satisfaction measure also worked towards the goal of developing a simple, easy to use index. The RMDQ failed to achieve significance in the pooled 200 mg qd prior NSAID-user pooled dataset calculations (Table 3); however, it was retained for further testing, as the focus groups had emphasized the importance of this measure. In addition, it was found to be significant when the overall population results were examined (effect size –0.12, p = 0.0360).

The following items were therefore carried forward for additional testing as both single items and combinations: LBP VAS, PGA, pain right now (mBPI-SF), total RMDQ, and satisfaction with medication (Q-LES-QSF).

Improvement criteria and index construction. The following improvement criteria were used to construct the initial responder indices: 30% and 50% improvement in LBP VAS and pain right now, 30% improvement in PGA, 30% improvement in RMDQ, and 30% improvement in satisfaction with medica-

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tion. All items were tested as single items and in all possible multiple-item combinations (e.g., 30% improvement in LBP VAS + 30% improvement in PGA or 50% improvement in LBP VAS + 30% improvement in PGA + 30% improvement in RMDQ). All combinations had to include improvement in LBP VAS. Combinations with a "no worsening" criterion were permitted (e.g., 30% improvement in LBP VAS + no worsening in RMDQ); however, there were no combinations in which "no worsening" of LBP VAS was considered. The "no worsening" criteria were defined as changes of < 20% and ≤ 2 points on the PGA and RMDQ, respectively.

Development database. The results of the initial development database testing in all 4 patient populations (celecoxib 200 mg qd and 200 mg bid prior NSAID-user populations; 200 mg qd and 200 mg bid overall populations) identified 5 combinations as potentially sensitive responder indices, all including ≥ 30% improvement in LBP VAS, plus the following:

1. No worsening in PGA;
2. No worsening in PGA, and ≥ 30% improvement in total RMDQ score;
3. No worsening in RMDQ total score;
4. No worsening in RMDQ total score, and ≥ 30% improvement in PGA;
5. No worsening in RMDQ total score, and no worsening in PGA.

Validation database. The validation database used the same improvement/no worsening criteria and the same single-item and multi-item combinations as were used in the development database analysis. However, "satisfaction" and "≥ 50% improvement in LBP VAS" were excluded as a result of poor performance in the development database. The results of the validation database testing in both valdecoxib-treated patient groups (prior NSAID-users and overall population) highlighted 2 potentially sensitive indices: ≥ 30% improvement in LBP VAS and no worsening in PGA; and ≥ 30% improvement in LBP VAS, ≥ 30% improvement in PGA, and no worsening in RMDQ total score.

Selection of a preliminary responder index. Candidate responder indices were ranked according to chi-square values and the number of populations in which they achieved statistical significance. The items that scored highest in both categories were selected for the preliminary responder index (Table 4). Based on these criteria (highest chi-square values and statistically significant in ≥ 6 trials), 2 potential candidate responder indices were identified for final selection: ≥ 30% improvement in LBP VAS and no worsening in RMDQ total score; and ≥ 30% improvement in LBP VAS, ≥ 30% improvement in PGA, and no worsening in RMDQ total score. The 2 candidate indices are compared in Table 5.

Of the 2 potential indices, "≥ 30% improvement in LBP VAS, ≥ 30% improvement in PGA, and no worsening (≤ 20%) in RMDQ total score" was considered to be the most clinically meaningful, as it encompassed the patients' overall perspective on their health status. Further, it universally kept the placebo response < 25%, and is consistent with other indices that use a combination of criteria for determining a responder[23-26].

DISCUSSION

The clinical assessments used in LBP trials vary widely among different studies[13], correlate poorly with symptoms, and are often highly subjective[18]. Further, reliance on pain intensity measures precludes the possibility that there is a functional effect of LBP. The use of patient-reported outcome measures would appear to be an attractive solution to these problems, as they have multiple items and include information on functioning. However, recent increases in the number of questionnaires available, coupled with a lack of standardization of endpoints and interpretation, have hindered attempts to assess or directly compare the findings of different trials. A single outcome measure that provides a comprehensive, easy to interpret assessment without burdening the patient would be an ideal step toward standardization; such a measure should also mitigate the placebo effect and be sensitive to clinically meaningful treatment effects. These requirements suggest that a responder index might be beneficial.

We have developed a preliminary definition of a responder index for LBP patients, and initial testing and validation have yielded promising results. We believe that the final choice for the responder index (≥ 30% improvement in LBP VAS, ≥ 30% improvement in PGA, and no worsening in total RMDQ score) is clinically relevant and both reliable and appropriate for use in patients with LBP, as it includes the items that were considered important by participants of the focus groups. The development of this responder index closely followed the approach used to construct the ASAS[23]; however, our method differed from that described by Anderson, *et al* in that patient concerns, rather than the judgment of clinical experts, were the primary factor in guiding initial selection of candidate items. Thus, the index described here has a solid foundation in patients' perspectives and experiences of CLBP.

There are several weaknesses to this approach, and these should be addressed in future studies. The first potential problem is that the functioning items were derived exclusively from the RMDQ, and there can be no guarantee that this is the best CLBP functioning assessment of several patient-reported questionnaires available. However, this concern is mitigated somewhat by recent observations that the RMDQ is more sensitive to differences between groups than other generic and disease-specific measures[14]. There is also concern that the single item on sleep disturbance contained within the RMDQ may not be sufficient to capture all aspects of the sleep problems reported by the focus groups. Another limitation inherent in using the RMDQ is that all items are weighted equally in the scoring algorithm, whereas the focus group discussions indicated that some items are more important than others.

Finally, we must consider the possibility that the index is

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Table 4. Preliminary candidate responder indices.

Criterion	No. of Populations with Significance at $p < 0.05$	No. of Populations with Highest Chi-square Value
≥ 30% improvement in LBP VAS and no worsening in PGA	7	1
≥ 30% improvement in LBP VAS and no worsening in PGA and ≥ 30% improvement in RMDQ total score	2	1
≥ 30% improvement in LBP VAS and no worsening in RMDQ total score	6	4
≥ 30% improvement in LBP VAS and ≥ 30% improvement in PGA and no worsening RMDQ total score	8	4
≥ 30% improvement in LBP VAS and no worsening in PGA and no worsening in RMDQ	6	1
≥ 30% improvement in pain right now and no worsening in PGA and ≥ 30% improvement in RMDQ total score	1	0

Table 5. Comparison of candidate responder indices.

Trial	≥ 30% LBP VAS + No Worsening RMDQ		≥ 30% LBP VAS + ≥ 30% PGA + No Worsening RMDQ	
	% Placebo Responders	% Treatment Responders	% Placebo Responders	% Treatment Responders
Celecoxib 200 mg prior NSAID users	25.47	30.07*	19.68	23.98*
Celecoxib 200 mg bid prior NSAID users	17.65	44.04*	14.94	34.50*
Celecoxib 200 mg overall	26.77	29.71*	20.33	23.59*
Celecoxib 200 mg bid overall	18.48	42.41*	15.57	32.41
Valdecoxib 10 mg prior NSAID users	26.97	32.58	16.85	25.09*
Valdecoxib 20 mg prior NSAID users	27.61	30.18	19.53	23.87*
Valdecoxib 40 mg prior NSAID users	27.20	32.40*	21.60	26.80*
Valdecoxib 10 mg overall	27.45	32.35	17.65	24.51*
Valdecoxib 20 mg overall	27.78	30.47	20.20	23.91*
Valdecoxib 40 mg overall	27.18	33.22*	22.15	27.85*

* Statistically significant treatment effect over placebo ($p < 0.05$).

applicable only to trials assessing COX-2-selective inhibitors, and not to all LBP trials. However, it was necessary to start with clinical trial data, and the only data available were derived from celecoxib and valdecoxib trials. These trials were very comprehensive in terms of the measures used to develop the preliminary index, and contained information on many core domains assessed (i.e., pain, physician and patient global measures, functioning, and satisfaction). It must also be emphasized that the approach is based on a conceptual model of what constitutes a responder index, and we included all items that were important to patients. We recognize, however, that this preliminary recommendation should be evaluated in other clinical trial databases to ensure that the index is applicable to different drug classes and treatment settings.

Research agenda

The discussions of the Special Interest Group outlined a number of next steps for future work, including the following:

1. Seek clarity around diagnostic and classification criteria for CLBP (e.g., mechanical, inflammatory, neuropathic) and inclusion criteria for clinical trials;
2. Investigate domains for the responder index (Special Interest Group participants agreed that pain, patient global, and function should be included, but other domains may be warranted for consideration based on the patient focus group importance of sleep and other aspects that influence HRQOL);
3. Discuss applicability of available measurement tools for core CLBP domains;
4. Solicit additional feedback on potential responder indices from patients and clinicians;
5. Test the response criteria further in clinical trials (either retrospectively with existing trial datasets or prospectively in future clinical studies); and
6. Seek expanded participation in the CLBP Special Interest Group to advance the research agenda. Progress toward the above steps will be evaluated using the OMERACT filter of truth, discrimination, and feasibility.

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