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Derivation of a Preliminary Clinical Prediction Rule for Identifying a Subgroup of Patients With Low Back Pain Likely to Benefit From Pilates-Based Exercise

STUDY DESIGN: Prospective cohort study.

OBJECTIVE: To derive a preliminary clinical prediction rule for identifying a subgroup of patients with low back pain (LBP) likely to benefit from Pilates-based exercise.

BACKGROUND: Pilates-based exercise has been shown to be effective for patients with LBP. However, no previous work has characterized patient attributes for those most likely to have a successful outcome from treatment.

METHODS: Ninety-six individuals with nonspecific LBP participated in the study. Treatment response was categorized based on changes in the Oswestry Disability Questionnaire scores after 8 weeks. An improvement of 50% or greater was categorized as achieving a successful outcome. Thirty-seven variables measured at baseline were analyzed with univariate and multivariate methods to derive a clinical prediction rule for successful outcome with Pilates exercise. Accuracy statistics, receiver-operator curves, and regression analyses were used to determine the association between standardized examination variables and treatment response status.

RESULTS: Ninety-five of 96 participants completed the study, with 51 (53.7%) achieving a successful outcome. A preliminary clinical prediction rule with 5 variables was identified: total trunk flexion range of motion of 70° or less, duration of current symptoms of 6 months or less, no leg symptoms in the last week, body mass index of 25 kg/m^2 or greater, and left or right hip average rotation range of motion of 25° or greater. If 3 or more of the 5 attributes were present (positive likelihood ratio, 10.64), the probability of experiencing a successful outcome increased from 54% to 93%.

CONCLUSION: These data provide preliminary evidence to suggest that the response to Pilates-based exercise in patients with LBP can be predicted from variables collected from the clinical examination. If subsequently validated in a randomized clinical trial, this prediction rule may be useful to improve clinical decision making in determining which patients are most likely to benefit from Pilates-based exercise. *J Orthop Sports Phys Ther 2012;42(5):425-436. doi:10.2519/jospt.2012.3826*

KEY WORDS: *classification, lumbar spine, Pilates-based exercise, stabilization*

Low back pain (LBP) is a primary cause of disability in modern society,[65] yet the pathoanatomic cause of LBP cannot be identified in the majority of individuals.[32,61] Attempts to identify effective interventions for LBP have been mitigated by the low methodological rigor of many of these studies.[45,75] Many researchers suggest that patients with LBP are not a homogeneous group and should be classified into subgroups of individuals who share similar clinical characteristics.[13,54] This type of classification system could guide diagnosis and treatment and improve overall decision making in the management of patients with LBP.[23] It may also improve research by denoting homogeneous subgroups for treatment outcomes studies.[12]

Clinical prediction rules (CPRs) consist of combinations of variables obtained from self-report measures and historical and clinical examinations. One purpose is to assist with subgrouping patients into specific treatment-based classifications. Recently, CPRs have been shown to be useful in classifying patients with LBP who are likely to benefit from a particular treatment approach, such as spine manipulation and lumbar stabilization.[17,27,36] An advantage of CPRs is that they use the diagnostic properties of sensitivity, specificity, and likelihood ratios, so their interpretations can be readily applied to

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individual patients.[53] Because CPRs are designed to improve decision making, it is important they be developed and validated according to rigorous methodological standards. McGinn et al[53] have suggested a 3-step process for developing and testing a CPR prior to widespread implementation of the rule in clinical practice. Once a CPR has been derived, validated, and shown to positively impact clinical behavior, it can be helpful in selecting the most effective treatment for an individual patient.

Exercise therapy has been shown to be effective in decreasing pain and improving function in populations with chronic LBP.[34,75] Research has shown that specific exercise programs can be designed to be effective in certain subgroups of patients with LBP.[38,59] Evidence is emerging[14,47] in support of the belief popularized by McKenzie[54] that some patients with LBP respond to direction-specific exercise interventions that include end-range movements. Direction-specific exercises and stabilization exercises are 2 recognized treatment approaches for LBP outlined in the treatment-based classification system introduced by Delitto et al,[23] which aims to match treatments to specific patient categories. Some researchers support stabilization exercise regimens that improve strength of larger spinal muscles (erector spinae, oblique abdominals, and quadratus lumborum),[36,51,52] while others[38,44] have focused on the deep muscles of the spine (ie, multifidus, transversus abdominis), which have been shown to become neurologically inhibited with pain.[39,40] This has increased attention on stabilization programs that emphasize motor control and specific low-threshold training of these muscles.[38,59] Current studies, however, have questioned whether specific muscle retraining may be the most effective approach to stabilization.[15,43]

The Pilates method of exercise is a unique mind-body exercise program developed by Joseph Pilates in the early 1900s. Pilates called his method *Contrology*,[64] and it became popular in the dance community and in dance medicine. The Pilates method incorporates movement principles that include both physical and cognitive elements: whole-body movement, attention to breath, balanced muscle development, concentration, control, centering, precision, and rhythm.[6] Clinical applications of the Pilates movement principles[3] (**APPENDIX A**) and exercises based on the Pilates method are being implemented by physical therapists as a therapeutic intervention. Pilates-based exercise uses movement enhancement techniques such as tactile and imagery cuing to reinforce the movement principles. The Pilates Reformer is an apparatus that provides an assisted environment through its pulley system and springs, grading movement from assistive to resistive and allowing nonpainful movement to begin early in the rehabilitation phase. Graded movement may be helpful in the treatment of fear-avoidance,[30,46] which can cause faulty motor patterns[7] and has been linked to chronic LBP.[21,63] Pilates-based exercises progress from basic gravity-eliminated movements to complex and functional movements requiring coordination and balance against gravity. It has been postulated that spine rehabilitation may need to focus more on coordination and less on actual strength or muscle torque, suggesting that isolated volitional strength of postural muscles is not as valuable as their coordinated integration.[66]

Pilates-based exercise has characteristics of other exercise systems. It focuses on motor control of both global stabilizers and mobilizers as described by Comerford and Mottram[19] and could therefore be effective in the treatment of LBP for patients in both the stabilization and direction-specific categories outlined in the Treatment-Based Classification system.[23] It has been postulated that improved motor control that facilitates accurate anticipation of spinal loads may provide better protection to the intervertebral discs from the harmful effects of sudden loads.[59,60] Much like specific stabilization exercise therapy,[66] Pilates-based exercise emphasizes facilitation techniques, such as tactile cuing and imagery, to encourage skeletal alignment and breathing. Unlike specific stabilization exercise therapy, however, it does not attempt to facilitate conscious activation of any isolated muscle or muscle group. Some have incorporated conscious muscle activation techniques into a Pilates-based exercise program for a combined therapeutic intervention.[67] However, the automatic subconscious activation of low-threshold (local stabilizer[19]) muscles during a Pilates-based exercise intervention alone, using movement enhancement techniques, warrants further investigation.

Lim et al[45] concluded in a recently published systematic review that Pilates-based exercise is superior to minimal intervention for pain,[67] but that current evidence does not establish superiority of Pilates to other forms of exercise for patients with LBP. Despite early evidence to support the effectiveness of Pilates-based exercise, no studies to date have determined if there is a parsimonious set of physical, historical, and psychosocial characteristics that predict which patients may likely benefit from Pilates-based exercise. We hypothesized that a parsimonious set of factors would emerge from the clinical examination to identify patients with LBP who would be most likely to benefit from the Pilates-based exercise.

METHODS

Subjects

This was a prospective cohort study in which 96 subjects with LBP were sequentially enrolled. Informed consent was obtained, and the rights of subjects were protected. The protocol for this study was approved by The Institutional Review Board of the Rocky Mountain University of Health Professions. Inclusion criteria included (1) current LBP with or without prior history of LBP, (2) modified Oswestry Disability Questionnaire (ODQ) score of 20% or greater, (3) age of 18 years or greater, and (4) referral to physical therapy by a physician or self-referred. Subjects were excluded if any of the following were present: (1) third trimester of pregnancy; (2) 2 or more signs consistent with nerve root compression (positive straight leg raise test at an angle less than 45° or diminished lower extremity strength, sensory function, or deep tendon reflexes); (3) previous spinal fusion surgery; or (4) evidence of serious pathology (eg, acute spinal fracture, tumor, infection, etc).

The desired minimum number of 95 participants for this study was determined using the "rule of thumb" approach for regression studies,[71] which specifies the need for 15 subjects per predictor variable in the final prediction model. Prior published studies suggest anticipating a 4- or 5-level CPR[27,36] and, therefore, an enrollment of 75 participants. Subsequently, a 15% dropout rate was estimated and added to the sample size, leading to the desired 95 participants.

Study Setting

The study was conducted primarily at the Steadman Hawkins Clinic in Denver, CO, where 92 subjects were recruited. Two subjects were recruited at Select Physical Therapy Center in Denver and 2 were recruited at Pinnacle Performance in Salt Lake City, UT.

Physical Therapists

Four licensed physical therapists participated in the examination and treatment of subjects in this study. All therapists had been trained in a comprehensive Pilates training program through Polestar Education (www.polestarpilates.com). All therapists received specific training and written instructions in the evaluation and Pilates intervention protocols. Each therapist had at least 2 years of individual experience in using Pilates-based exercise with patients. The primary researcher had 17 years of experience with this exercise approach.

Examination Procedure

Physical therapists administered a baseline standardized physical examination and collected data including demographic information. Pain at baseline was assessed using an 11-point (0-10) visual analog scale, with 0 representing no pain and 10 representing emergency-room pain. The subjects also completed a pain diagram and the Fear-Avoidance Belief Questionnaire (FABQ). The FABQ has 2 subscales that measure fear-avoidance beliefs about work (7-item scale) and physical activity (4-item scale). The ODQ assesses disability related to LBP. The ODQ was administered at baseline and after 8 weeks of treatment, and served as the reference standard for determining the success of the treatment program. The health history intake included questions concerning mechanism of injury, nature of current symptoms, and prior episodes of LBP. Subjects were also asked about the distribution of symptoms for their current episode.

The physical examination included measurement of lumbar spine range of motion (ROM) and total trunk flexion ROM using an inclinometer.[77] Aberrant motions during lumbar ROM were noted, including instability catch,[57] painful arc of motion,[22] Gowers' sign, or a reversal of lumbopelvic rhythm.[23] Supine straight leg raise and prone hip rotation ROM were measured using a single inclinometer.[77] Generalized ligamentous laxity was assessed on a 9-point scale described by Beighton and Horan.[8] Two special tests

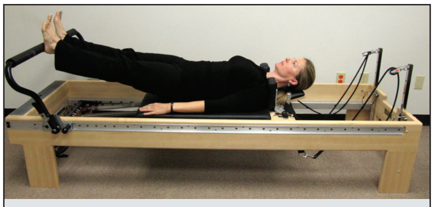

FIGURE 1. Supine hip and knee extension on the Pilates Reformer.

FIGURE 2. Standing hip extension on the Pilates Reformer.

FIGURE 3. Prone spine extension on the Pilates Reformer.

for lumbar spine instability were performed: the prone instability test[37] and the passive lumbar extension test.[1,42] A posterior/anterior lumbar spring test[48] was performed at each spinal level. Two strength tests, the active sit-up and active bilateral straight leg raise tests, were administered.[77] The extensor endurance test and the side support test[50] were performed to determine muscle endurance of the spinal extensors and lateral flexors. Operational definitions for components of the physical exam are provided in **APPENDIX B**. A total of 37 potential predictor variables were measured at the baseline assessment session.

Treatment

Treatment consisted of a standardized Pilates-based exercise program utilizing a Balanced Body Pilates Reformer (Balanced Body Inc, Sacramento, CA) (**FIGURES 1** through **3**), with emphasis on tactile and imagery cuing. The Pilates-based exercises are listed in **APPENDIX A** and include modifications and progressions. One set of 8 to 10 repetitions per exercise was performed during each session. Therapists were instructed to use clinical reasoning skills to omit exercises entirely or to apply the appropriate regression or progression to an exercise. Criteria for exercise omission and modification included movement-direction preference[14,54] and subjective irritability levels. Modification or elimination of an exercise was applied if the subject was unable to perform the exercise in proper form or the subject's pain level increased by performing the exercise. The exercise was resumed at a later stage in the treatment if these difficulties were overcome. The

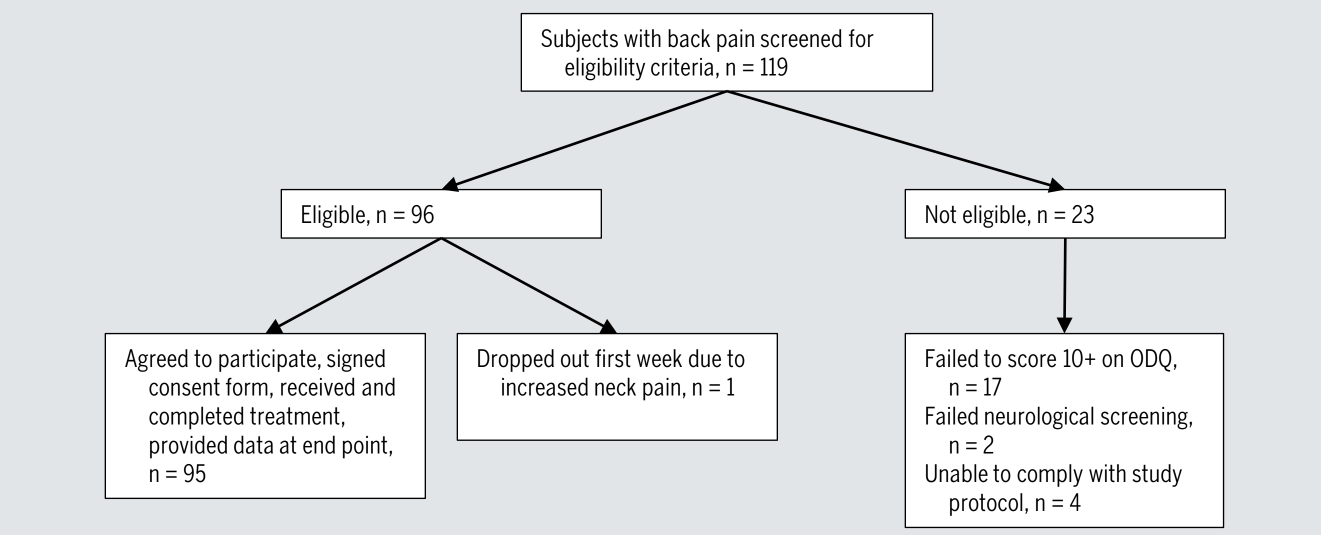

FIGURE 4. Flow diagram showing recruitment and retention.

exercises consisted of a combination of spine stability and mobility movements. Subjects were seen twice per week for 8 weeks. Supplemental instructions were given to each subject, reinforcing the basic Pilates principles of breathing, skeletal alignment, and self-awareness in various relationships to gravity. Subjects were encouraged to practice finding neutral postures in supine, quadruped, sitting, and standing, especially as they encountered these postures in daily activities, and to pay attention to their breathing patterns. The supplemental instructions are described in **APPENDIX C**. After 8 weeks, a posttest ODQ was administered.

Data Analysis

Descriptive statistics were calculated to summarize the data. Individual variables from the self-report measures, history, and physical examination were tested for their univariate association with success using independent sample *t* tests for continuous variables and chi-square tests for categorical variables. Continuous predictor variables were dichotomized by establishing a cut score with receiver-operator curve analysis. This process computes sensitivity and specificity for multiple cut scores along the continuum of the scale, yielding coordinates for a plot so that the characteristics of the scale can be observed graphically.[33] Area under the receiver-operator curve was used as 1 measure of how well each continuous scale predictor performed in this respect.[24]

Subjects were grouped according to success or nonsuccess with respect to treatment. Success with treatment was determined by percent change in disability scores on the ODQ after 8 weeks of Pilates-based exercise. Patients who experienced at least a 50% improvement were categorized as having a successful outcome. Those not achieving at least a 50% improvement were classified as having a nonsuccessful outcome. The minimum clinically important difference in ODQ score has been calculated as 5 to 6 points (10%-12% change).[10,23,29,56]

Binary logistic regression analysis was used to filter the set of predictor variables further and to derive a multivariate model (CPR) that eliminated redundant or substantially correlated predictors. Potential predictors yielding *P* values less than or equal to .10 from the *t* tests and chi-square tests were entered into the logistic regression analysis using a forward stepwise procedure. The predictor variables were chosen for retention by the forward stepwise method if they had significant changes ($P \leq .05$) in −2 log likelihood of the model, when added from the previous step of model development. For continuous scale variables and categorical scale variables with more than 2 levels, the raw (nondichotomized) variables were entered into the logistic regression analysis. Predictor variables that met the statistical criteria were ultimately accepted, based on their clinical plausibility.

Sensitivity, specificity, and positive likelihood ratios (LRs) were calculated for all potential predictor variables. Once the number of predictor variables was determined, the CPR was developed by examining the accuracy statistics for various combinations of the retained variables.[68] Treatment success was defined as a 50% or greater reduction in ODQ score from baseline to completion of treatment. The goal for the final derivation of the CPR was to maximize the positive LR with a clinically sensible set of predictors at a level that yielded a viable proportion of subjects who were positive at that level.

RESULTS

Ninety-six subjects were enrolled in the study between February 2009 and September 2010. One subject dropped out after 1 week, due to increased neck symptoms, and these data

TABLE 1 History and Demographic Variables Assessed at Baseline*

Demographic Variable	All Subjects (n = 95)	Success (n = 51)	Nonsuccess (n = 44)	*P* Value
Age, y	56.0 ± 11.3	57.5 ± 10.0	54.2 ± 12.7	.15
Body mass index, kg/m^2	24.8 ± 4.1	26.2 ± 4.4	23.3 ± 3.2	<.001
Sex (women), %	81.1	74.5	88.6	.14
Duration of symptoms, d†	386 (12-16,842)	267 (12-16,842)	559 (38-15,167)	.003
Duration of symptoms, %				.003
≤6 mo	27	22	5	
>6 mo	68	29	39	
Number of prior episodes‡	3.3 ± 1.3	0.2± 1.4	3.6 ± 1.1	.063
Distribution of symptoms				
Lumbar spine, %	90.5	86.3	95.5	.24
Buttock, %	68.4	68.6	68.2	.86
Thigh, %	55.8	45.1	68.2	.04
Lower leg/foot, %	32.6	25.5	40.9	.17
Prior history of LBP (yes), %	75.8	78.4	72.7	.83
No leg symptoms last week, %	64.2	82.4	43.2	.02

Abbreviation: LBP, low back pain.
**Data are mean ± SD, except where specified for continuous variables, and percents for categorical variables. P values represent a 2-independent samples t test for continuous variables, where groups are defined as success and nonsuccess, and a chi-square test of association for categorical variables (success/nonsuccess is used as the reference criterion).*
†Median and range.
‡Missing data for this variable: total sample, n = 73; success, n = 39; nonsuccess, n = 34.

TABLE 2 Self-Report Variables*

Self-Report Variable	All Subjects (n = 95)	Success (n = 51)	Nonsuccess (n = 44)	*P* Value
Pain rating	5.3 ± 1.8	5.2 ± 1.8	5.4 ± 1.8	.55
FABQ work subscale (0-42)†	14.7 ± 13.8	11.6 ± 11.5	18.9 ± 15.6	.02
FABQ physical activity subscale (0-24)	16.1 ± 5.8	16.2 ± 6.0	16.0 ± 5.7	.86
Baseline ODQ score (0-50)	16.3 ± 4.6	15.4 ± 5.2	17.3 ± 3.7	.04
Change in ODQ score (0-50)	7.3 ± 6.7	12.0 ± 4.8	1.8 ± 3.6	<.001

Abbreviations: FABQ, Fear-Avoidance Belief Questionnaire (subscales where a higher score reflects a greater fear of movement and a greater avoidance of activities); ODQ, modified Oswestry Disability Questionnaire (where a higher score reflects greater disability).
**Data are mean ± SD. P values represent 2 independent-samples t tests, where groups are defined as success and nonsuccess.*
†Missing data for this variable: n = 84 for all subjects, n = 46 for success, n = 38 for nonsuccess.

were excluded from the analysis. **FIGURE 4** provides a flow diagram of subject recruitment and retention. Of the 95 subjects for which data were collected, 15 had prior physical therapy for their symptoms and 6 had previous Pilates exercise experience. Among the 95 subjects completing the study, 89 (93.7%) attended all 16 scheduled treatment sessions, while the remaining 6 subjects attended at least 13 of the 16 sessions. Fifty-one (53.7%) subjects who completed the study experienced a 50% or greater improvement in their ODQ scores over 8 weeks. **TABLE 1** provides subject descriptive information.

TABLE 2 summarizes results for self-report variables. Pain rating averaged a mean ± SD of 5.3 ± 1.8 on a 0-to-10-point scale, and the FABQ work and physical activity subscales averaged 14.7 ± 13.8 and 16.1 ± 5.8, respectively.

Eleven demographic, self-report, and physical exam variables (**TABLE 3**) were significantly associated with success and thus further analyzed as potential predictors (**TABLE 4**): FABQW less than or equal to 10, body mass index (BMI) of 25 kg/m^2 or greater, total trunk flexion ROM of 70° or less, positive prone instability test, positive active sit-up test, duration of symptoms of 6 months or less, number of prior episodes of LBP less than or equal to 3, left- or right-side support of 30 seconds or longer, right or left hip average rotation of 25° or greater, and 2 variables from the self-report indicating that subjects currently experienced no lower extremity symptoms or that these symptoms were not currently bothersome.

These variables were entered into the logistic regression modeling. Stepwise methods used in the modeling resulted in 5 predictors of success that were considered for the multivariate CPR (**TABLE 5**). The final model was statistically significant (P<.001), with reasonable goodness of fit (Hosmer-Lemeshow chi-square, 4.21; df = 8; P = .838). The best rule for predicting success (**TABLE 6**) was the presence of 3 or more of the 5 attributes (positive LR, 10.64; 95% confidence interval [CI]: 3.52, 32.14). Thirty-two of 35 subjects who were positive on 3 or more of the 5 criteria were in the successful-outcome group (**TABLE 5**). Accuracy statistics were calculated for each threshold for number of attributes present (**TABLE 6**). A patient exhibiting 4 or more of the 5 attributes would have a 96% (95% CI: 61%, 100%) posttest probability of success and a positive LR of 23.37. A patient exhibiting 3 or more of the 5 attributes would have a 93% (95% CI: 81%, 97%) posttest probability of success, and a positive LR of 10.64 (95% CI: 3.52, 32.14). If a subject met fewer than 3 variables, the posttest probability of success was no greater than chance and did not inform the decision making about the use of the Pilates-based exercise.

TABLE 3 Physical Exam Variables Assessed at Baseline*

Physical Exam Variable	All Subjects (n = 95)	Success (n = 51)	Nonsuccess (n = 44)	*P* Value
Total trunk flexion ROM, deg	88.8 ± 20.3	84.8 ± 19.0	93.5 ± 21.0	.04
Pelvic flexion ROM	61.3 ± 18.0	58.6 ± 19.2	64.4 ± 16.3	.12
Lumbar flexion ROM	26.6 ± 16.1	24.8 ± 14.1	28.7 ± 18.1	.12
Total trunk extension ROM, deg	19.8 ± 8.7	18.5 ± 8.6	21.4 ± 8.6	.12
Left sidebending ROM, deg	18.8 ± 7.0	17.7 ± 5.6	20.1 ± 8.1	.10
Right sidebending ROM, deg	19.7 ± 6.8	18.7 ± 6.4	20.9 ± 7.2	.12
Average sidebending ROM left and right, deg	19.2 ± 6.1	18.2 ± 5.3	20.5 ± 6.8	.07
SLR left lower extremity, deg	69.5 ± 11.7	69.3 ± 11.9	69.6 ± 11.6	.90
SLR right lower extremity, deg	68.5 ± 11.5	68.4 ± 11.3	68.6 ± 11.8	.93
Average hip rotation ROM right, deg†	30.3 ± 6.3	31.1 ± 5.2	29.3 ± 7.4	.16
Average hip rotation ROM left, deg†	29.2 ± 6.3	30.2 ± 5.9	27.9 ± 6.5	.08
Painful arc on return of trunk flexion, %	4.2	4.2	0.0	<.001
Status change in symptoms with trunk movement (yes), %	38.9	43.1	34.1	.49
Beighton and Horan test (0-9)	0.3 ± 1.1	0.3 ± 1.0	0.4 ± 1.3	.70
Prone instability test, %				.07
No pain with PA pressure	40.0	41.2	38.6	
Pain with no relief (negative test)	10.5	3.9	18.2	
Pain with relief (positive test)	49.5	54.9	43.2	
Passive lumbar extension test (positive), %	27.4	27.5	27.3	.83
Lumbar segmental spring test (positive), %	33.7	27.5	40.9	.24
Active sit-up test (positive), %	24.2	33.3	13.6	.05
Active bilateral SLR (positive), %	7.4	3.9	11.4	.25
Extensor endurance test, s	82.4 ± 81.2	75.1 ± 67.2	90.9 ± 95.1	.35
Side support test left, s	25.0 ± 23.5	22.1 ± 22.2	28.3 ± 24.9	.20
Side support test right, s	21.6 ± 21.5	16.7 ± 17.2	27.1 ± 24.6	.02

Abbreviations: PA, posterior to anterior; ROM, range of motion; SLR, straight leg raise.
**Data are mean ± SD for continuous variables and percents for categorical variables. P values represent a 2-independent sample t test for continuous variables, where groups are defined as success and nonsuccess, and a chi-square test of association for categorical variables (success/nonsuccess was used as the reference criterion).*
†Values are the average for hip internal and external rotation for the right hip and the left hip.

DISCUSSION

Though Pilates-based exercise has gained in popularity as an option for the conservative management of LBP, evidence for its effectiveness is sparse and inconclusive.[45] Lim et al[45] concluded that the relatively low quality of existing studies and the heterogeneity of studies they reviewed suggest that results should be interpreted with caution. However, the few studies that have examined homogeneous subgroups of patients with specific exercise programs have been promising.[36,44,59] Hicks et al[36] established a preliminary CPR for success with stabilization exercises. The purpose of our study was to derive a preliminary CPR for identifying a subgroup of patients with LBP likely to benefit from the Pilates-based exercise.

In this study, the 54% pretest probability of success shifted to 96% with a positive LR of 23.37 if a subject exhibited 4 or more of the 5 criteria in the preliminary prediction rule, and to 93% with a positive LR of 10.64 if a subject exhibited 3 or more of the 5 criteria in the CPR. However, the 4+ level of the CPR was so specific that a relatively small percentage of subjects in the study (14%) met that criterion. Therefore, we selected the 3+ level as a clinically sensible threshold, because 42% of subjects presented with 3 or more positive tests. If this CPR can be validated with a randomized controlled trial, it is anticipated that recommending the 3+ level may help select appropriate treatment for about 40% of patients presenting for treatment who are similar to the subjects with LBP who participated in this study.

Limitations

One limitation to this study is that 81.1% of subjects were female. While this proportion accurately reflects the gender bias in the industry,[70] the consequence of this demographic may be that this CPR applies more to women than to men.

There have been criticisms of CPR development[31] and suggestions for improving methodological quality.[9] This study incorporated research design elements intended to help ensure methodological quality for derivation of interventional CPRs. Our own assessment of the 18 quality criteria proposed by Beneciuk et al[9] resulted in a score of 67%, which was above the suggested threshold of 60% for a high-quality study.[9] Though our sample size was relatively small, we met the criterion of including at least 10 subjects with the outcome of interest for each predictor variable in the final model, a protection intended to avoid overfitting of multivariate models.[20]

One specific criticism of previous CPR derivation studies is that cause-effect relationships cannot be inferred from single-arm trials.[31] However, we make no inferences regarding the efficacy or effectiveness of Pilates-based exercise for patients with LBP based on evidence from this current study, as results could potentially be attributable to natural history (ie, passage of time). Rather, this study follows the publication of multiple randomized controlled trials that have established Pilates-based exercise as a viable treatment option for patients with LBP.[4,45,67] In the validation process for this CPR, researchers should consider the broader set of predictor variables used to develop this CPR rather than limiting specific attention to only the final variables retained for the rule. Additionally, a validation study should include a long-term follow-up and comparison group to further investigate the predictive value of the variables in the preliminary CPR. If the rule is validated, an impact analysis of implementation of the rule on clinical practice patterns, outcomes, and cost of care should be investigated. Future research should also consider whether similar predictors emerge if the Pilates-based exercise is delivered in a group setting versus an individual setting when considering cost of care.

TABLE 4 ACCURACY STATISTICS WITH 95% CONFIDENCE INTERVALS FOR INDIVIDUAL PREDICTOR VARIABLES

Variable	Sensitivity (95% CI)	Specificity (95% CI)	Positive Likelihood Ratio (95% CI)
FABQW* ≤10†	0.55 (0.41, 0.68)	0.64 (0.49, 0.76)	1.51 (0.95, 2.40)
Total trunk flexion ROM ≤70°	0.27 (0.17, 0.41)	0.95 (0.85, 0.99)	6.04 (1.45, 25.13)
Active sit-up test positive	0.33 (0.22, 0.47)	0.86 (0.73, 0.94)	2.44 (1.06, 5.66)
No leg symptoms in the last week	0.82 (0.70, 0.90)	0.57 (0.42, 0.70)	1.91 (1.33, 2.74)
No distribution of symptoms in thigh/leg	0.55 (0.41, 0.68)	0.68 (0.53, 0.80)	1.73 (1.05, 2.84)
BMI ≥25 kg/m^2	0.78 (0.65, 0.88)	0.59 (0.44, 0.72)	1.92 (1.31, 2.81)
Duration of symptoms ≤6 mo†	0.47 (0.34, 0.60)	0.82 (0.68, 0.90)	2.59 (1.30, 5.17)
Number of prior episodes ≤3†	0.33 (0.22, 0.47)	0.86 (0.73, 0.94)	2.44 (1.06, 5.66)
Prone instability test positive	0.55 (0.41, 0.68)	0.57 (0.42, 0.70)	1.27 (0.84, 1.94)
Side support test right or left ≥30 s‡	0.86 (0.60, 0.96)	0.60 (0.50, 0.70)	2.17 (1.54, 3.06)
Right or left hip average rotation ≥25°§	0.78 (0.45, 0.94)	0.57 (0.46, 0.87)	1.81 (1.18, 2.77)

Abbreviations: BMI, body mass index; CI, confidence interval; FABQW, Fear-Avoidance Belief Questionnaire work subscale; ROM, range of motion.
**Scores range from 0 to 42, with a higher score reflecting a greater fear of movement and a greater avoidance of activities with respect to work.*
†Missing data (combined total cases present, n = 66).
‡At least 1 side in the side support test is 30 s or longer.
§At least 1 hip with an average internal and external rotation of 25° or greater.

TABLE 5 THE VARIABLES FOR THE CLINICAL PREDICTION RULE* AND THE NUMBER OF SUBJECTS IN EACH GROUP AT EACH LEVEL†

Number of Predictor Variables Present ‡	Successful Outcome Group	Nonsuccessful Outcome Group
5	2	0
4+	13	0
3+	37	3
2+	49	28
1+	51	43

**No leg symptoms in the last week; body mass index ≥25 kg/m^2; total trunk flexion ≤70°; left or right hip average rotation ≥25° (at least 1 hip with an average internal and external rotation of 25° or greater); duration of symptoms ≤6 months.*
†Total cases present, n = 95 (1 subject had 0 criteria present).
‡Plus sign indicates "or more."

Predictor Variables

This CPR includes 5 predictor variables that would require minimal time to assess as part of a comprehensive patient evaluation. BMI is a value calculated based on height and weight measurements and is significantly correlated with body fat content.[55] A BMI equal to or greater than 25 kg/m^2 is considered overweight and was a strong predictor of success (P<.001) for subjects in this study. Research has demonstrated that high BMI has a strong association with LBP,[35,69] and that being very overweight can change static and dynamic spine mechanics, including increased anterior pelvic tilt and limited thoracic flexion during forward-bend activities.[76] Both of these mechanical changes could adversely affect the stresses placed on the lumbar spine.

Another predictor for success was total trunk flexion ROM of less than or equal to 70°. Although the use of end-range motion measurements for outcome determinants in patients with LBP has been questioned,[73] such measurements are often used in physical therapy initial assessments to screen for other impairments. Limited motion may reflect pain-related fear, which often results in avoidance behavior that specifically limits or restricts motion of the lumbar spine,[74] even in the presence of lower FABQ scores.

Evidence exists for a relationship between hip joint flexibility and LBP.[18,26] Hip joint ROM discrepancy was a variable in the preliminary CPR developed for spinal manipulation.[17,27] In our study, subjects who had a mean internal and external hip rotation ROM of less than or equal to 25° in either hip tended not to be successful with treatment. Restricted hip rotation ROM has been established as a clinical indicator of hip osteoarthritis[2,41] and may complicate the treatment of LBP in those with this comorbidity.

We excluded subjects with signs of nerve root compression. However, subjects with distal symptoms in the absence

TABLE 6 ACCURACY STATISTICS WITH 95% CONFIDENCE INTERVALS FOR THE 5 LEVELS OF THE CLINICAL PREDICTION RULE*

Number of Predictor Variables Present †	Sensitivity	Specificity	Positive Likelihood Ratio	Probability of Success (%)
5	0.05 (0.01, 0.15)	0.99 (0.90, 1.00)	4.33 (0.21, 87.78)	84 (21-99)
4+	0.26 (0.15, 0.40)	0.99 (0.90, 1.00)	23.37 (1.43, 382.06)	96 (61-100)
3+	0.73 (0.58, 0.84)	0.93 (0.81, 0.99)	10.64 (3.52, 32.14)	93 (81-97)
2+	0.96 (0.87, 1.00)	0.36 (0.22, 0.52)	1.51 (1.20, 1.90)	64 (58-69)
1+	0.99 (0.91, 1.00)	0.03 (0.00, 0.14)	1.02 (0.96, 1.09)	54 (53-56)

Abbreviation: CI, confidence interval.
**The probability of success is calculated using the positive likelihood ratios and assumes a pretest probability of 54%; total cases present, n = 95.*
†Plus sign indicates "or more."

of positive neurologic signs were included in the study. Subjects who experienced leg symptoms within the week prior to enrollment tended not to succeed. This is consistent with studies demonstrating that up to 40% of patients with leg pain who are treated conservatively undergo delayed surgery.[58,62]

Symptom duration of less than or equal to 6 months was a predictor of treatment success, even though 72% of all subjects in this study reported having symptoms for more than 6 months. Duration of symptoms for more than 12 weeks may be classified as chronic LBP[11] and is often associated with physical disabilities, psychological distress, depression, and inability to work.[72] Of those who remain disabled with back pain for more than 6 months, fewer than half return to work,[5] and they tend to have poor expectations for their back pain outcome.[28] The results in this study may be explained by the natural history of acute back pain, which is favorable without treatment,[25] even though its incidence of recurrence is about 40% in 6 months.[16] In addition, those who were not successful with treatment also experienced on average more than 3 (mean ± SD, 3.62 ± 1.10) prior episodes of LBP. It is likely that the group in this study of those who had "persistent" pain of more than 6 months in duration is a combination of subjects with continuous pain and those who had multiple recurrences.

It is interesting to note that none of the variables testing trunk strength or stability were retained in the final model, given that they are theoretically key indications for a spine stabilization intervention. This suggests that the indication for the Pilates-based exercise may not be limited to those patients who have spine instability but may include a wider range of patients, such as those in whom reduced spine and extremity mobility is contributing to their LBP symptoms.

CONCLUSION

FIVE PREDICTORS COLLECTED FROM the clinical examination comprised a clinically sensible preliminary CPR to identify individuals with LBP who are likely to respond to treatment using Pilates-based exercise. These predictors were total trunk flexion ROM of 70° or less, duration of current symptoms of 6 months or less, no leg symptoms in the previous week, BMI of 25 kg/m^2 or greater, and left or right hip average rotation ROM of 25° or greater. If any 3 or more of the 5 attributes were present (which occurred in 42% of study subjects), the positive LR was 10.64, thus sufficient to yield a large shift from pretest to posttest probability for experiencing a successful treatment outcome. ◉

KEY POINTS

FINDINGS: A preliminary CPR with 5 variables was identified: total trunk flexion ROM less than or equal to 70°, duration of current symptoms for 6 months or less, no leg symptoms in the previous week, BMI greater than or equal to 25 kg/m^2, and left or right hip average rotation of 25° or greater. If 3 or more attributes were present (positive LR, 10.64), the probability of experiencing a successful outcome increased from 54% to 93%.

IMPLICATIONS: These data provide preliminary evidence to support the idea that the response to Pilates-based exercise in patients with LBP can be predicted from variables collected from the clinical examination.

CAUTION: These results must be validated in a randomized controlled trial before clinicians can be confident that the CPR will be useful to improve clinical decision making in determining which patients are most likely to benefit from Pilates-based exercise. Insofar as 81.1% of subjects in this study were female, this CPR may apply more to women than to men.

ACKNOWLEDGEMENTS: *We would like to acknowledge Brent D. Anderson, PT, PhD, OCS, President, Polestar Physical Therapy and Polestar Pilates Education, Coral Gables, FL, for his contribution to the concept and design of the Pilates protocol in this study and his guidance as subject expert for the dissertation committee.*

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APPENDIX A

PILATES REFORMER EXERCISES FOR LOW BACK PAIN

Exercise, Pilates Nomenclature[6]	Spine Position	Clinical Applications of the Pilates Principles[3]	Variations and Modifications
Supine hip and knee extension (**FIGURE 1**), footwork	Neutral	Breathing, axial elongation, core control	Vary hip, foot, and ankle positions

APPENDIX A

Exercise, Pilates Nomenclature[6]	Spine Position	Clinical Applications of the Pilates Principles[3]	Variations and Modifications
Supine shoulder extension, hundred (prep)	Neutral, flexion	Breathing, core control, shoulder girdle organization	Increase (or decrease) knee and hip flexion, posterior pelvic tilt
Supine long-leg femur arcs, feet in straps and long spine	Neutral	Breathing, core control	Straps above knees, knees flexed, hip circumduction
Supine bridging, pelvic lift	Flexion	Breathing, spine articulation	Limit motion, neutral spine, single leg
Quadruped hip extension, knee stretch	Neutral	Breathing, core control, shoulder girdle organization	Modify spring tension, face head of Reformer to resist hip flexors
Tall kneeling shoulder extension, chest expansion	Neutral	Breathing, core control, shoulder girdle organization	Modify spring tension, seated on box
Z-sit lateral flexion and rotation, mermaid	Lateral flexion and rotation	Breathing, axial elongation, spine articulation, movement integration	Neutral hip position, limit range of motion
Prone spine extension (**FIGURE 3**)	Extension	Breathing, axial elongation, upper extremity alignment, spine articulation	Limit motion, adjust foot bar, adjust spring tension
Standing hip extension (**FIGURE 2**)	Neutral, extension	Breathing, lower extremity alignment, movement integration	Reduce lower and upper extremity assistance
Standing hip abduction, side splits	Neutral	Breathing, axial elongation, lower extremity alignment	Narrow stance, add support, flex hips and knees, adjust spring tension

APPENDIX B

OPERATIONAL DEFINITIONS FOR PHYSICAL MEASURES PROCEDURES

Physical Measures	Procedure
Range of motion (ROM)	
Total trunk flexion ROM[77]	The patient stands and an inclinometer is held at T12-L1. The patient is asked to reach down as far as possible toward the toes while keeping the knees straight.
Pelvic flexion ROM[77]	Same as above but inclinometer is placed at S2.
Lumbar flexion ROM[77]	Subtract pelvic flexion from total flexion.
Total trunk extension ROM[77]	The patient stands and an inclinometer is held at T12-L1. The patient is asked to arch backward as far as possible.
Right and left sidebending ROM[77]	The patient stands with an inclinometer aligned vertically in line with the spinous processes of T9 to T12. The patient is asked to lean over to 1 side as far as possible with the fingertips reaching down the side of the thigh.
Right and left straight leg raise (SLR) ROM[77]	The patient is supine. The inclinometer is positioned on the tibial crest just below the tibial tubercle. The lower extremity is raised passively by the examiner, whose other hand maintains the knee in extension. The lower extremity is raised slowly to the maximum tolerated SLR (not the onset of pain).
Hip passive rotation ROM test[77]	The patient is lying prone. The knee is flexed to 90° and the lower leg is placed in vertical alignment. The inclinometer is placed on the distal aspect of the fibula and set at 0°. Measurement of hip internal rotation and external rotation is recorded as the angle when the pelvis first begins to move.
Muscle performance tests	
Side support test[49]	The patient is sidelying with lower extremities extended and the top foot in front of the lower foot. While resting on the elbow in contact with the table for support, the patient lifts the hips off the table, with only the elbow and feet remaining in contact with the table. The patient is instructed to hold this position as long as possible. The test is done for both sides, and the performance time is recorded in seconds.

APPENDIX B

Physical Measures	Procedure
Muscle performance tests (continued)	
Extensor endurance test[45]	The patient is asked to lie prone while holding the sternum off the floor for as long as possible. A small pillow is placed under the lower abdomen to decrease the lumbar lordosis. The patient also needs to maintain maximum flexion of the cervical spine and pelvic stabilization through gluteal contraction. The patient is asked to hold this position as long as possible, not to exceed 5 minutes. The performance time is recorded in seconds.
Active sit-up test[77]	The patient is supine and is asked to flex the knees to 90° and place the soles of the feet flat on the surface of the table. The examiner holds both feet down with 1 hand. The patient is instructed to reach up with the fingertips of both hands to touch (not hold) both knees and hold the position for 5 seconds. If the patient cannot maintain this position for 5 seconds, the test is positive.
Active bilateral straight leg raise test[77]	The patient is supine and is asked to lift both legs together 6 inches (15.24 cm) off the examining surface and hold that position for 5 seconds. Both heels and calves should be cleared from the examining surface. If the patient cannot maintain this position for 5 seconds, the test is positive.
Special tests	
Prone instability test[50]	The patient lies prone with the body on the examining table and lower extremities over the edge and feet resting on the floor. While the patient rests in this position, the examiner applies posterior/anterior pressure to the lumbar spine. Any provocation of pain is reported. Then the patient lifts the lower extremities off the floor (the patient may hold table to maintain position) and a posterior/anterior compression is applied again to the lumbar spine. If pain is present in the resting position but subsides in the second position, the test is positive.
Lumbar segmental spring testing for mobility[48]	The patient is prone. The L1 spinous process is contacted with the examiner's thenar eminence, and a posterior/anterior-directed force is applied. The procedure is repeated at each lumbar level. Mobility is judged as hypermobile or hypomobile.
Passive lumbar extension test[38]	The subject is in the prone position; both lower extremities are elevated together to a height of about 30 cm from the bed while maintaining the knees extended and gently pulling the legs. The test was judged to be positive when, during elevation of both lower extremities, the subject complained of strong pain in the lumbar region, including "low back pain," "very heavy feeling on the low back," and "feeling as if the low back was coming off," and such pain disappeared when the lower extremities returned to the initial position.

APPENDIX C

SUPPLEMENTAL INSTRUCTIONS

Phase	Instruction	Clinical Application of the Pilates Principles[3]
Phase 1: neutral spine, diaphragmatic breathing	To be practiced in all functional positions, including: supine, hook-lying, prone, quadruped, sitting, and standing	Breathing, axial elongation, core control, shoulder girdle organization, lower and upper extremity alignment
Phase 2: doorway stretch	Stand in doorway, arms against doorframe, shoulders are abducted 90°, elbows are flexed 90°	Breathing, axial elongation, core control, shoulder girdle organization, lower and upper extremity alignment