ORIGINAL ARTICLE

The Role of the *Back Rx* Exercise Program in Diskogenic Low Back Pain: A Prospective Randomized Trial

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ABSTRACT. Vad VB, Bhat AL, Tarabichi Y. The role of the *Back Rx* exercise program in diskogenic low back pain: a prospective randomized trial. Arch Phys Med Rehabil 2007;88: 577-82.

Objective: To determine the efficacy of the *Back Rx* program in patients with diskogenic low back pain (LBP).

Design: Prospective, randomized study.

Setting: Outpatient setting of a major university teaching hospital.

Participants: Subjects with LBP greater than leg pain for at least 3 months duration and magnetic resonance imaging evidence of disk pathology. Fifty of 87 eligible patients consented and were randomized into age- and sex-matched groups.

Interventions: Group I participated in the *Back Rx* program for 15 minutes a day, 3 times a week. All patients, from both groups, received celecoxib (200mg) and hydrocodone (5mg) with acetaminophen (500mg) as needed, and wore a lumbar cryobrace for 15 minutes before bedtime.

Main Outcome Measures: Roland-Morris Disability Questionnaire score, numeric pain rating score, patient satisfaction score, measured forward flexion, use of celecoxib, hydrocodone, and acetaminophen, time off work, and rate of symptom recurrence.

Results: At minimal 12-month follow-up, 70% of group I reported over 50% pain reduction with good or better patient satisfaction, compared with 33% in group II ($P=.001$). Average daily hydrocodone and acetaminophen use and time off work were less for group I (all, $P<.05$). Recurrence of symptoms at the end of the year was less for group I ($P=.001$).

Conclusions: *Back Rx* exercises, combined with use of a lumbar cryobrace and oral medications, yielded superior therapeutic results than with use of medications and cryobrace alone. Also significant was the reduced rate of recurrence in these patients.

Key Words: Exercise; Intervertebral disk; Low back pain; Rehabilitation.

LOW BACK PAIN (LBP) usually is considered to be a self-limiting condition that tends to improve over time.[1-4] It also is among the leading causes of disability. A large variety of therapeutic interventions are available for the treatment of patients with LBP. The effectiveness of most of these interventions has not been shown beyond doubt, however. Consequently, the therapeutic management of these patients varies widely. Exercise is one therapy that is frequently prescribed for patients with LBP.[5-23] It encompasses a wide array of interventions ranging from general physical fitness or aerobic exercise, flexibility, and stretching exercises, to strength training. Despite its frequent application, exercise therapy has not been shown to be more efficacious than other treatment modalities, especially in patients with acute LBP. In 1991, Koes et al[8] sought to address the efficacy of exercise in LBP with a systematic review of 16 randomized controlled trials, most of which were considered to be of poor methodologic quality. No conclusions regarding the efficacy of exercise therapy compared with other conservative treatments could be drawn from this review and little evidence was found in favor of a specific type of exercise. In 1996, Faas[19] published his own review of the matter in which he conducted a Medline search for randomized trials concerning exercise therapy in patients with back pain published from 1991 to 1995. Faas concluded that in acute back pain, exercise therapy is ineffective, whereas in subacute back pain, exercises with a graded activity program deserved attention, and in the case of chronic back pain, intense exercises may be promising. These equivocal findings prompted another systematic review of the literature by van Tulder et al[20] to assess the effectiveness of exercise therapy for LBP with regard to pain intensity, functional status, overall improvement, and return to work. Their conclusions did not indicate that specific exercises are effective for the treatment of acute LBP, but rather that exercise may help patients with chronic LBP accelerate their return to normal daily activities and work. In subacute LBP populations, some evidence suggests that a graded-activity program improves absenteeism outcomes in occupational settings, although evidence for other types of exercise is unclear.[24]

It has been postulated that the degenerative process of the intervertebral disk evolves through 3 stages, namely, dysfunction, instability, and stabilization.[25-30] Though each has distinct clinical and radiologic findings, any stage may coexist independently of another at any point along the entire lumbar axial skeleton. The initial or dysfunction stage is characterized by circumferential and radial tears within the annulus and synovitis of the zygapophyseal joints and typically presents in a younger age group. Diskogenic LBP constitutes a subgroup within the broad category of patients with LBP and these patients usually fall within the stage of dysfunction more than the stage of instability.

Successful treatment of subjects with the so called "diskogenic LBP" depends on making the specific diagnosis and merging of the biochemical and biomechanic etiologic constructs—again, for which there is no criterion standard treatment modality.

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Back Rx[31] is specifically designed as a lumbar stabilization program that restores flexibility, strength, and endurance while eliminating positions such as sitting and forward flexion that may increase intradiskal pressure and in turn lead to diskogenic LBP.

The purpose of the present study is to assess the efficacy of the *Back Rx*[31] exercise program when coupled with oral medication and a back brace, as compared with the use of medication and a lumbar brace alone in patients with axial, diskogenic LBP. The hypothesis the authors set out to test was that the *Back Rx* exercise regimen can decrease pain as well as reduce recurrence of pain in patients with subacute or chronic diskogenic LBP.

METHODS

Approval for this study was obtained from the institutional review board of the Hospital for Special Surgery. Inclusion criteria included: symptoms of LBP greater than leg pain of at least a 3-month duration, exacerbation of pain with sitting and alleviation with walking, and magnetic resonance imaging (MRI) documented evidence of disk pathology (eg, disk protrusion or extrusion on a T2-weighted sagittal image without any central and/or foraminal stenosis or degeneration of the facet joints). Patients were excluded if they had a recent history of trauma, prior history of lumbar spinal surgery, or had undergone any recent spinal interventional procedures. Similarly, subjects with pending legal claims or worker's compensation claims were excluded. Of the 87 patients assessed, 65 met the aforementioned criteria, and 50 consented to be enrolled in this prospective study. Fifteen of the 65 who met the inclusion criteria were unwilling to commit themselves to a regular home-exercise program and/or to come in for compliance monitoring.

We then randomized the patients into 2 groups matched for age and sex. Subjects from group I (n=25) participated in the *Back Rx* program for at least 15 minutes a day, 3 times a week. Exercises were done based on a real-time *Back Rx* DVD handed to patients and subjects were given a calendar to mark the days so as to monitor self-compliance. Further compliance was monitored by the principal author at timely intervals of 3 weeks, 6 weeks, 3 months, 6 months, and at the end of 12 months. This was undertaken by means of a face-to-face interview of at least 20 minutes duration. The overall compliance rate was 91%.

Patients from both groups used a lumbar cryobrace for 15 minutes before bedtime daily. Medications permitted in both groups included up to 200mg of celecoxib per day, as well as 5mg of hydrocodone with 500mg of acetaminophen for breakthrough pain as needed.

The *Back Rx* program progresses through series A, B, and C, all of which develop flexibility, strength, and endurance with elements of physical therapy and rehabilitation, yoga, and Pilates. The yoga- and Pilates-based elements in the program were modified to exclude exercises that may easily traumatize a weak back. Positions that increase intradiskal pressures by forcing patients to sit and bend forward, for instance, were either modified or ruled out. Patients in group I underwent 6 months of the series A exercise regimen, followed by at least 6 months of series B.

Series A emphasizes isometric muscle work derived mostly from physical therapy. Series B builds on series A by including more dynamic muscle movements, as well as more yoga-based exercises that intensify the isometric loading of the core muscles of the back. Other targeted areas in both series include: chest, shoulder, abdominal, thigh, and full hip musculature.

We monitored patients for a minimum of 12 months. Outcome measures included Roland-Morris Disability Questionnaire (RMDQ) score, numeric pain rating score, patient satisfaction score, and the finger-to-floor distance during forward flexion with knees extended. Time taken off from work, medication usage, and the recurrence of symptoms between both groups were monitored as well. A successful outcome was defined as greater than 50% pain reduction with good or better patient satisfaction.

RESULTS

Two patients from group I and 4 from group II received spinal epidural injections during the study duration, and were subsequently excluded from the final data analysis. After 1 year, group I (n=23) was composed of 11 men and 12 women, and group II (n=21) had 10 men and 11 women (fig 1). The average age was 31.4 years for group I and 30.9 for group II. Patients from both groups were younger and almost all had sedentary jobs with excessive sitting, which may explain early onset of diskogenic pain. The subjects had isolated diskogenic etiology without any associated disk degeneration or lumbar facet arthritis. None had a history of trauma to the lumbar spine. Comparisons of RMDQ scores, pain scores, forward flexion, and patient satisfaction at different time periods are shown in tables 1 through 4, respectively. The Wilcoxon signed-rank test was used for statistical analysis. At the minimal 12-month follow-up period (range, 12−15mo), 70% of the patients in group I reported a successful outcome, as compared with only 33% in group II ($P=.001$). During this 12-month duration, 48% of the subjects in group II reported a recurrence of acute symptoms lasting for more than 3 days, as compared with only 17% in group I ($P=.001$). The overall average daily use of hydrocodone with acetaminophen and time off work for group I were statistically less (all, $P<.05$) when compared with

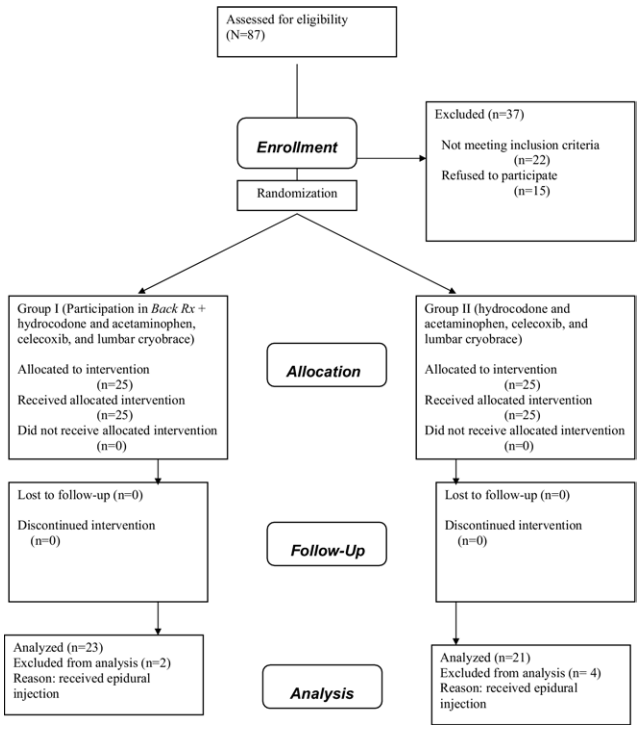

Fig 1. CONSORT flow diagram of subjects through the trial.

Table 1: Comparison of RMDQ Scores Throughout the Study Period in Groups I and II

Study Period	Group I	Group II
Onset	11.2±1.3	11.4±1.4
3 weeks	11.8±1.4	12.1±1.3
6 weeks	12.7±1.6	12.8±1.4
3 month	14.6±1.3	13.4±1.3
6 month	20.1±1.6	15.1±1.3
12 month	22.3±1.4	15.7±1.4
*P**	.008	.04

NOTE. Values are mean ± standard deviation (SD).
*For differences between the score at treatment onset and at 12 months for each group.

Table 3: Comparison of Forward Flexion Throughout the Study Period for Groups I and II

Study Period	Group I	Group II
Onset	62±1.4	64±1.3
3 weeks	63±1.3	59±1.5
6 weeks	52±1.4	50±1.3
3 month	35±1.3	44±1.4
6 month	24±1.6	35±1.3
12 month	25±1.5	30±1.4
*P**	.02	.007

NOTE. Values are mean centimeters ± SD.
*For differences between the distance at treatment onset and at 12 months for each group.

group II (tables 5, 6). There was no statistically significant difference between the groups for the average usage of celecoxib (table 7). This portion of the intervention (medication usage) is treated as a dependent measure in the statistical analysis as it was left at the discretion of the subjects themselves.

DISCUSSION

LBP is a multifactorial disorder with many possible etiologies. Its lifetime prevalence ranges from 65% to 85%, despite all efforts expanded into its prevention, treatment, and rehabilitation.[32] Though the majority of patients with acute LBP improve over time, a few continue to experience symptoms that can lead to absenteeism from work, extra expenses, and disability.[1-4] Published findings indicate that this condition tends to relapse, with 28% to 75% of patients experiencing multiple episodes with persistent pain.[33-42]

Diskogenic etiology has been implied in 26% to 39% of patients with LBP.[43-46] In the past 15 years, the treatment options for axial diskogenic LBP have almost reversed, progressing from lumbar fusion for eliminating motion to an artificial disk replacement aimed at maintaining maximal intersegmental flexibility to physiologic loads.[47-51] The precariousness of clinical treatment preferences and practices with respect to LBP is obvious from the limited quantity and quality of scientific evidence, for example, the scarcity of conclusive studies addressing the efficacy of exercise.

The *Back Rx* program was structured in a way that allows patients to gradually and comfortably develop flexibility, strength, and endurance. As already mentioned, many Pilates- and yoga-based elements in the program that may easily traumatize a weak back were modified accordingly. The program starts off in an accessible manner: patients conduct the first portion of series A lying flat on their backs, allowing them to minimize pressures on potentially deconditioned and injured muscles and disks. Exercises in the first series consist of isometric work derived predominantly from physical therapy, allowing patients to lay a foundation of core muscle flexibility and prepare their body for increased strength and endurance training. When ready, patients may progress to the slightly more challenging yet potentially more therapeutic series B. Series B consists of more yoga-based work that intensifies the isometric loading of the core muscles, as well as more dynamic muscle work that builds strength through concentric, eccentric, and plyometric contractions. Throughout all 3 series in the program, patients are asked to focus on their breathing—an essential aspect of both yoga and Pilates. By doing so, patients can pace themselves appropriately as well as potentially modulate their pain to make the exercises both easier to do and more therapeutic.

The overall efficacy of the *Back Rx* program was evident in the finding that, at 1 year, 70% of the group that had participated in the therapy reported a successful outcome, as compared with only 33% in the other group ($P=.001$). Furthermore, the average time off from work and daily medication usage were both significantly lower in the patients that participated in the exercise program (all, $P=.005$).

Perhaps the most noteworthy outcome in our trial, however, is the statistically lower rate of recurrence of acute symptoms in the group that enrolled in the *Back Rx* program ($P=.001$). Only 17% of these patients experienced a recurrence of symptoms, compared with 48% in our second group and 28% to 75% previously reported in the literature.[33-42] The aforementioned are all welcomed outcomes with regard to a health condition that has taken a significant toll on the health care system, with disability from LBP rising exponentially over the past 5 decades.[52]

Table 2: Comparison of Pain Scores Throughout the Study Period for Groups I and II

Study Period	Group I	Group II
Onset	8.7±1.6	8.4±1.5
3 weeks	8.8±1.7	8.0±1.5
6 weeks	7.7±1.6	7.8±1.3
3 month	6.4±1.3	7.1±1.5
6 month	4.3±1.3	5.2±1.3
12 month	1.8±1.3	4.1±1.6
*P**	.001	.01

NOTE. Values are mean ± SD.
*For differences between the score at treatment onset and at 12 months for each group.

Table 4: Comparison of Average Patient Satisfaction Score Throughout the Study Period in Group I and Group II

Study Period	Group I	Group II
Onset	0.9±1.2	0.8±1.2
3 weeks	0.9±1.4	1.1±1.3
6 weeks	1.3±1.2	1.4±1.3
3 month	1.8±1.4	1.6±1.3
6 month	2.3±1.5	1.7±1.2
12 month	2.8±1.3	1.8±1.4
*P**	.008	.006

NOTE. Values are mean ± SD. Rating scale: 0, poor; 1, fair; 2, good; 3, very good; 4, excellent.
*For differences between usage on treatment onset and at 12 months for each group.

Table 5: Comparison of Hydrocodone (5mg) and Acetaminophen (500mg) Use in Average Number of Pills Throughout the Study Period for Groups I and II

Study Period	Group I	Group II
Onset	1.8±1.7	1.8±1.4
3 weeks	1.8±1.6	1.7±1.3
6 weeks	1.4±1.4	1.5±1.6
3 month	1.1±1.2	1.4±1.3
6 month	0.7±1.3	1.3±1.4
12 month	0.4±1.6	1.2±1.8
*P**	.006	.07

NOTE. Values are mean ± SD.
*For differences between the score at treatment onset and at 12 months for each group.

Table 7: Comparison of Celecoxib (200mg) Usage in Average Number of Pills for Groups I and II

Study Period	Group I	Group II
Onset	0.9±1.1	0.9±1.1
3 weeks	0.9±1.1	0.8±1.2
6 weeks	0.9±1.3	0.7±1.3
3 month	0.8±1.2	0.7±1.2
6 month	0.8±1.3	0.7±1.3
12 month	0.5±1.4	0.5±1.3
*P**	.05	.03

NOTE. Values are mean ± SD.
*For differences between usage on treatment onset and at 12 months for each group.

It should be noted, however, that patients in the program experienced mildly increased symptoms for the first 3 weeks after initiation of the *Back Rx* exercises (see table 2). Though this effect is transient, it is imperative that patients be warned that exercise therapies such as this one may slightly increase their discomfort before potentially having a long-term therapeutic effect.

Now to discuss the important aspect of reliability and validity issue surrounding the diagnosis of diskogenic pain. The ideal tool for the diagnosis of diskogenic LBP pain should have clear applications, produce valid and reproducible results, and be free of complications. It must be sensitive with a low false-positive rate and specific with a low false-negative rate. Some have found MRI to be as good as diskography and even preferable because of its noninvasive nature, whereas proponents of lumbar diskography contend that pain provocation by intradiskal injection is the only method that can determine which disk is responsible for a patient's symptoms. This group also maintains that the diskography image can show lesions not revealed by other methods.[53-55]

Study Limitations

One of the limitations of this study was that provocative lumbar diskography was not used to confirm the diagnosis of diskogenic LBP. Lumbar diskography serves the single purpose of identifying the painful disk and is a physiologic evaluation consisting of a volumetric, manometric, radiographic, and pain-provocative challenge. Throughout the literature, lumbar diskography has been found to be a useful diagnostic tool but at the same time has been criticized for its shortcomings. Patients with no history of lumbar pain who had undergone posterior iliac crest bone graft harvesting for nonlumbar procedures have often experienced a concordant painful sensation during lumbar diskography. Thus the ability of a patient to separate spinal from nonspinal sources of pain on diskography is questioned, and a response of concordant pain on diskography may be less meaningful than often assumed. The diskogram is a tool and does have certain clear limitations.[56,57] Because the procedure assesses a subjective complaint of pain, it may be subject to false-positive responses. Furthermore, diskography by itself is painful, because it is ideally performed without any sedation, to optimize the patient response. The limitations of diskography are its invasive nature, moderate radiation exposure during fluoroscopy, and the potential complications including the remote risk for disk-space infection. For these reasons, it was not included as a mandatory inclusion criterion for this study and we chose to presume the diagnosis of diskogenic LBP based on symptoms (back pain greater than leg pain), physical examination (forward flexion then extension recreated usual symptoms), and MRI.

Table 6: Average Time Off From Work in Days for Both Groups Over the Entire Study Period

Time Off	Group I	Group II
Time (d)	4.2±1.4	12.1±1.8

NOTE. Values are mean ± SD.

CONCLUSIONS

These preliminary results suggest that a well-designed exercise program combined with use of a back cryobrace and oral medications may yield superior results for patients with axial diskogenic LBP when compared with oral medications and back cryobrace alone supporting the hypothesis set forth. Such a program, when done routinely with monitoring of compliance, may lessen chances of recurrence of acute LBP episodes, medication use, and time off work. A large-scale multicenter controlled trial should be undertaken for the further evaluation of our findings.

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