

**TREATMENT- AND COST-EFFECTIVENESS OF EARLY INTERVENTION FOR
ACUTE LOW BACK PATIENTS: A ONE-YEAR PROSPECTIVE STUDY***

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ABSTRACT

In an attempt to prevent acute low back pain from becoming a chronic disability problem, an earlier study developed a statistical algorithm which accurately identified those acute low back pain patients who were at high risk for developing such chronicity. The major goal of the present study was to evaluate the clinical effectiveness of employing an early intervention program with these high-risk patients in order to prevent the development of chronic disability at a one-year follow-up. Approximately 700 acute low back pain patients were screened for their high-risk versus low-risk status. On the basis of this screening, high-risk patients were then randomly assigned to one of two groups: a functional restoration early intervention group (n=22), or a non-intervention group (n=48). A group of low-risk subjects (n=54) who did not receive any early intervention was also evaluated. All these subjects were prospectively tracked at 3-month intervals starting from the date of their initial evaluation, culminating in a 12-month follow-up. During these follow-up evaluations, pain disability and socioeconomic outcomes (such as return-to-work and healthcare utilization) were assessed. Results clearly indicated that the high-risk subjects who received early intervention displayed statistically significant fewer indices of chronic pain disability on a wide range of work, healthcare utilization, medication use, and self-report pain variables, relative to the high-risk subjects who do not receive such early intervention. In addition, the high-risk non-intervention group displayed significantly more symptoms of chronic pain disability on these variables relative to the initially low risk subjects. Cost-comparison savings data

were also evaluated. These data revealed that there were greater cost savings associated with the early intervention group versus the no early intervention group. The overall results of this study clearly demonstrate the treatment- and cost-effectiveness of an early intervention program for acute low back pain patients. The study represents the first of its type and clearly demonstrates the therapeutic and financial advantages of an early intervention approach to acute low back pain disability.

KEY WORDS: acute low back pain; cost effectiveness; early intervention; functional restoration; treatment effectiveness;

Approximately 70% to 80% of all individuals in industrialized countries will suffer from low back pain at some point during their lives (1). As originally reviewed by Mayer and Gatchel (2), low back pain is the number one cause of disability of persons under age 45. Over this age, it is the third leading cause of disability, becoming progressively less of a factor during later years when function and productivity become of less concern than survival. It should also be noted that back-related disorders present the most prevalent source of disability in the U.S. military (3). It has been estimated that, in any one year, about 3-4% of the population in all industrialized countries has a temporarily disabling low back pain episode, and that more than 1% of the working age population is “totally and permanently disabled” by this problem. From a financial point of view, it is one of the most costly problems in the North American workplace (4). The critical nature of this disability is further highlighted by the fact that, in 1998, the National Institutes of Health requested the National Academy of Sciences/National Research Council to convene a panel of experts to carefully examine some major questions raised by the U.S. Congress concerning occupational musculoskeletal disorders (5). One of the important issues raised by Congress was: “Does the research literature reveal any specific guidance to prevent the development of chronic conditions?”

A need for early prevention of chronic low back pain disabilities is further highlighted by additional epidemiological studies that continue to show that low back pain is a serious problem resulting in immeasurable suffering, work loss, and high cost (e.g., 6). There is now a call for early intervention methods to prevent acute low back

pain (ALBP) from becoming a chronic disability problem (e.g., 5, 7). As a first step in this process, Gatchel, Polatin and Mayer (8) conducted a prospective, longitudinal study to identify predictors of when ALBP incidents are likely to develop into chronic disability problems. In this study, 421 patients presenting with ALBP were systematically evaluated in order to assess the predictive power of a comprehensive assessment of biopsychosocial factors using a standard test battery. All patients had been symptomatic with lumbar pain for six weeks or less. Subjects were tracked every three months, culminating in a structured telephone interview conducted one year after initial evaluation in order to document return-to-work status. The results of this study clearly isolated some significant psychosocial risk factors that successfully predicted the development of chronicity, with a 90.7% accuracy rate. Using a receiver-operator characteristic (ROC) curve analysis which was based on the probabilities estimated from the logistic regression model developed on this cohort of patients, a statistical algorithm was subsequently developed that could be used to identify “high risk” ALBP who are prime candidates for early intervention in order to prevent chronicity. This algorithm formed the basis in the current study for classifying patients presenting with ALBP who are at risk for developing chronic pain disability problems. The major goal of the present study was to evaluate the clinical effectiveness of employing an early intervention program with high risk ALBP patients in order to prevent the development of chronic disability at a one-year follow-up. It should also be noted that, as investigators such as Linton and Bradley (9) have pointed out, although cost reduction is often used as an argument for early intervention programs, there has been a paucity of adequate analyses reported in the literature. Therefore, an additional goal of the

present study was to evaluate the relative cost savings of such an early intervention program.

METHOD

Subjects

Subjects were recruited from a number of orthopedic practices situated in close proximity to The University of Texas Southwestern Medical Center at Dallas. All patients ages 18 to 65 with ALBP (defined as less than 10 weeks since injury) were included in the study, unless they had some other significant pain-exacerbating physical condition (such as cancer or fibromyalgia), six or more DSM-IV Axis I diagnoses, or current psychosis or suicidal ideation. Of the approximately 700 individuals screened for participation (see Procedures section), 124 subjects (54 low risk and 70 high risk) participated in the current study. In order to be eligible for the study, subjects had to meet the following criteria: a) no more than two months since ALBP onset; b) constant daily pain when performing activities, from initial onset to current evaluation; c) decreased ability to perform normal job requirements because of the pain; d) no history of chronic episodic back pain (i.e., two or more disabling episodes at least four to six months apart during the past two years, with fluctuating low grade discomfort between episodes); e) no current need for surgery. This surgery determination was made according to appropriate orthopedic practice. Specifically, every patient had a complete orthopedic and neurological evaluation for back pain and underwent appropriate tests. If such evaluations were positive (e.g., neurological findings on examination suggested

a disc herniation; i.e., muscle weakness with particular pattern and hyposthesia), then they were referred on for possible surgical evaluations. Those who were not surgical candidates would then be eligible to be enrolled in the study; f) only those subjects who were fully employed at the time of their injury were selected for the study.

Procedure

When subjects arrived for their regularly scheduled appointment with their physician, they were offered \$20 to complete an initial evaluation packet. This packet contained an informed consent, a payment voucher, a patient information form, and a survey form which included information allowing us to classify subjects as “high risk” or “low risk” based upon our earlier developed screening algorithm (10). Specific details concerning this screening protocol can be found in Pulliam, Gatchel and Gardea (11). The high risk patients were randomly assigned to one of two groups: 1) a functional restoration early intervention group (n=22); or 2) a non-intervention group (n=48). The low risk subjects (n=54) did not receive any early intervention. These three groups were carefully matched for age, gender, race, and time since original injury based upon an urn randomization procedure (12, 13). There was no cost to patients assigned to the early intervention group.

Following completion of the initial evaluation, subjects were contacted by telephone and were offered \$50 to participate in the remainder of the evaluations (again, see 11). Subjects were then also contacted by telephone at 3-, 6-, 9-, and 12-month follow-up intervals, starting from the date of their initial evaluation. During the

follow-up calls, subjects were administered a structured telephone interview to evaluate pain disability and socioeconomic outcomes, such as return-to-work and healthcare utilization (14).

Functional Restoration Early Intervention. This early intervention program involved an interdisciplinary team approach consisting of four major components—psychology, physical therapy, occupational therapy, and case management—and which was guided by a supervising nurse-physician team. It is based upon the assumption that almost all patients suffering from spinal pain and disability can be returned to a productive lifestyle through appropriate re-conditioning and coping skills training. This functional restoration is accomplished through an aggressive, individualized psychosocial and physical reconditioning program, not through traditional passive physical treatment modalities. Treatment is initially guided by quantified measurement of function, which not only allows the reconditioning to proceed safely, but provides quantifiable documentation of compliance, effort, and eventual success. This functional restoration program is described in detail in a number of publications (e.g., 15, 16). Psychosocial issues and return-to-work issues are simultaneously addressed by the psychology, occupational therapy and case management components of the program. Such issues can be effectively dealt with using psychological approaches (cf 17).

This early intervention protocol consisted of a maximum of the following: 3 physician evaluations; 1 physical therapy evaluation lasting 1 hour; 9 physical therapy sessions, consisting of 15 minute individual exercise classes; 9 physical therapy

sessions, consisting of 30 minute group exercise classes; 9 biofeedback/pain management sessions; 9 group didactic sessions lasting 45 minutes; 9 case manager/occupational therapy sessions lasting 30 minutes; 3 interdisciplinary team conferences. The treatment was administered by professionals licensed in their prospective areas at the Eugene McDermott Center for Pain Management, The University of Texas Southwestern Medical Center at Dallas. The program is accredited by CARF. Treatments were ideally spaced over a three-week period, but modifications were made if necessary in order to accommodate the subjects' schedules. The number of sessions administered to patients was also tailored to their specific needs, with most patients not needing all of the aforementioned number of sessions.

Outcome Measures

In addition to assessing self-reported pain using the Characteristic Pain Inventory (18), various important socioeconomic outcomes were also collected. In keeping with the suggestions of Mayer, Prescott, and Gatchel (14), the following socioeconomic outcomes were collected by a structured telephone interview at 3, 6, 9 and 12-months follow-up evaluations: return-to-work status; average number of healthcare visits regardless of the reason; average number of healthcare visits related to the original low back pain; average number of disability days due to low back pain; injury recurrence; medication use. In addition, cost-comparison data were collected by using unit cost multipliers obtained from the Bureau of Labor Statistics for compensation costs due to disability days (19), from the Medical Fees in the United States 2002 for healthcare costs (20), and from the Drug Topics Redbook 2002 for medication costs (21).

RESULTS

As expected, on the basis of the urn randomization procedure, there were no significant differences among the groups based upon analyses of variance (for the continuous variables) and chi-square analyses (for the categorical variables). The average age of the cohort was 38.2 (SD=11.0), with 65% male and 35% female. The average number of weeks since the original ALBP injury was 3.8 (SD=2.4)

Table I presents the 12-month follow-up outcome results for the three groups of subjects. Analyses of variance and chi-square tests were used to analyze these continuous variable and categorical variables, respectively. As can be seen, the high-risk ALBP subjects who received early intervention (the HR-I group) displayed statistically significant fewer indices of chronic pain disability on a wide range of work, healthcare utilization, medication use and self-reported pain variables, relative to the high-risk ALBP subjects who did not receive such early intervention (the HR-NI group). Compared to the HR-NI group, the HR-I group was much more likely to have returned to work (odds ratio=4.55), less likely to be currently taking narcotic analgesics (odds ratio=0.44), and also less likely to be taking psychotropic medication (odds ratio=0.24). In addition, the HR-NI group displayed significantly more symptoms of chronic pain disability on these variables relative to the initially low-risk ALBP subjects (the LR group).

INSERT TABLE I ABOUT HERE

The cost-comparison savings data were also quite impressive. Table II lists these costs associated with the HR-I and HR-NI groups. As can be seen, the average overall cost per patient over the one-year follow-up period (even taking into account the average \$3,885/patient cost of the early intervention for the HR-I group) was significantly higher for the HR-NI group. An independent t -test found the difference to be statistically significant, $t(68)=-1.20$, $p < .05$ (two-tailed).

INSERT TABLE II ABOUT HERE

DISCUSSION

The results of this study clearly demonstrate the treatment- and cost-effectiveness of an early intervention program for ALBP patients. As noted earlier, even though investigators such as Linton and Bradley (9) have indicated that cost reduction is often used as an argument for early intervention programs, there has been a paucity of adequate analyses reported in the literature. For example, Goosens and Evers (22) have noted this shortage in the area of low back pain. However, the few that have been

reported have clearly suggested such savings (as cited by Linton and Bradley, (9). Mitchell and Carmen (23, 24) presented preliminary findings from a multicenter trial (involving over 3,000 patients with acute soft-tissue and back injuries). Two groups of patients were compared: those who received early intensive intervention, and those who received standard treatments at other facilities. During a 5-month follow-up period, it was found that there was a savings each month of roughly \$1-1.5 million in wage-loss and healthcare costs. In a follow-up evaluation of 542 patients, Mitchell and Carmen (25) found that the early intensive intervention produced a projected savings of \$5,000 per patient. Unfortunately, this series of studies was multi-center in nature, and a standardized intervention program was not used for all subjects. The advantage of the current study was the use of a well recognized and standardized functional restoration early intervention program.

The other major contribution of the present study was the clear demonstration that appropriate early intervention can successfully prevent the development of chronic low back pain disability. Such results have major implications for effective intervention and significant healthcare cost savings for this prevalent disability problem. Low back pain carries a very high cost to society. Over the past several decades, there has been an increase in particularly work-related back pain. It has been estimated that low back injuries constitute 16% of all workers' compensation claims, but consume 33% of all claim costs (26).

The cost of providing medical and surgical treatment for low back pain is staggering. However, there is a weak relationship between clinical and economic outcomes, because common methodologies are lacking to enable comparison of existing studies (27). The availability of new technology drives up cost (28); (29), but does not necessarily improve outcomes. Back pain is treated by different categories of healthcare professionals. While results may be similar, expenditures are not. Chiropractors and orthopedists are associated with higher treatment costs, while primary care physicians and Health Maintenance Organizations have the lower costs, though not necessarily the highest patient satisfaction (30).

It is now agreed that, except under the circumstances of obvious structural pathology amenable to surgical intervention, conservative care is the initial treatment of choice for low back pain (31). Indeed, 85% of patients recover within a few months and do not really require even diagnostic imaging (32). Programs incorporating exercise seem to have better outcomes (33). Injured workers who stopped exercising after a back injury had longer periods of disability than those who remained more physically active (34). Medical exercise therapy and conventional physical therapy reduce the cost of low back pain, even in chronic cases (35). However, intensive multidisciplinary treatment is not necessarily more effective than a less intensive exercise program (36). It has been shown, for example, that low impact aerobics, which can be administered in large groups, is cheaper and easier for treating low back pain patients than conventional physical therapy or muscle reconditioning on training devices (37).

Indirect costs (indemnity) exceed direct costs of medical care by 2:1 or more (38). It is primarily psychosocioeconomic factors that are associated with more lost work days (39) and higher impairments (40). Low back disability is on the rise as well, so that while the total average cost of a claim may have come down in the last ten years, the median cost of a claim has gone up secondary to the skew of those claims with long term disability (41, 42).

It is also the psychosocial barriers which make back pain patients more difficult to treat. Typically, these cases have higher numbers of disability days, and are associated with receiving care from multiple providers (43). These patients are best treated by multidisciplinary physicians and support staff functioning as a unified team with common goals (44).

The average clinician is far more aware of psychosocial barriers leading to treatment failure and chronic disability now than he or she might have been even ten years ago. Health care cost containment is so focused on curbing overzealous treatment that an early intervention which aims to address psychosocial factors is frequently turned down in deference to more conventional physically oriented therapies, which usually fail in these complicated patients. Only when a patient is truly chronic (i.e., in excess of 6 or 12 months since injury) will an authorizing agency consider an integrated bio-behaviorally oriented program. We are of the opinion that such a patient should be identified early and treated before becoming chronic and more treatment refractory. The analogy would be with a condition such as post-traumatic stress disorder, previously overlooked, ignored, or neglected. Current algorithms of care for PTSD now stipulate that the sooner a patient is in active treatment, the better the

prognosis. And so it should be with back pain complicated by psychosocial barriers.

The present study made a significant stride in demonstrating the effectiveness of such early intervention with ALBP patients.

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Table I. Long-Term Outcome Results at 12-Month Follow-up

OUTCOME MEASURE	HR-I	HR-NI	LR	
	<u>(n=22)</u>	<u>(n=48)</u>	<u>(n=54)</u>	p value
% Return-to-Work at Follow-up*	91%	69%	87%	.027
Average # Healthcare Visits Regardless of Reason**	25.6	28.8	12.4	.004
Average # Healthcare Visits Related to LBP**	17.0	27.3	9.3	.004
Average # of Disability Days Due to Back Pain**	38.2	102.4	20.8	.001
Average of Self-Rated Most “Intense Pain” at 12-Month Follow-Up (0-100 scale)**	46.4	67.3	44.8	.001
Average of Self-Rated Pain Over Last 3 Months (0-100 scale)**	26.8	43.1	25.7	.001
% Currently Taking Narcotic Analgesics*	27.3%	43.8%	18.5%	.020
% Currently Taking Psychotropic Medication	4.5%	16.7%	1.9%	.019

* Chi-square analysis ** ANOVA

Table II. Cost-Comparison Results (Average Cost Per Patient/YEAR)

<u>COST VARIABLE</u>	<u>HR-I</u> (n=22)	<u>HR-NI</u> (n=48)
Healthcare Visits Related to LBP	\$1,670	\$2,677
Narcotic Analgesic Medication	\$70	\$160
Psychotropic Medication	\$24	\$55
Work Disability Days/Lost Wages	\$7,072	\$18,951
Early Intervention Program	\$3,885	NA
TOTALS	\$12,721	\$21,843
