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A Population-Based, Randomized Clinical Trial on Back Pain Management

[Clinical Studies - Treatment]

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Outline

Graphics

Abstract^

Study Design. Population-based randomized clinical trial.

Objectives. To develop and test a model of management of subacute back pain, to prevent prolonged disability.

Summary of Background Data. The present management of back pain seems inadequate, and development of innovative models has been urged.

Methods. A model for the treatment of subacute work-related back pain has been developed and evaluated in a population-based randomized clinical trial. Workers (n = 130) from eligible workplaces in the Sherbrooke area (N = 31), who had been absent from work for more than 4 weeks for back pain, were randomized, based on their workplace, in one of four treatment groups: usual care, clinical intervention, occupational intervention, and full intervention (a combination of the last two). The duration of absence from regular work and from any work was evaluated using survival analysis. Functional status and pain were compared at study entry and after 1 year of follow-up.

Results. The full intervention group returned to regular work 2.41 times faster than the usual care intervention group (95% confidence interval 1.19-4.89; $P = 0.01$). The specific effect of the occupational intervention accounted for the most important part of this result, with a rate ratio of return to regular work of 1.91 (95% confidence interval = 1.18-3.10; $P < 0.01$). Pain and disability scales demonstrated either a statistically significant reduction or a trend toward reduction in the three intervention groups, compared with the trend in the usual care intervention group.

Conclusions. Close association of occupational intervention with clinical care is of primary importance in impeding progression toward chronicity of low back pain.

Back pain is a common, frequently self-limiting condition that causes major disability and considerable financial cost in a minority of cases. It has been shown that a small number of low back pain patients, those who are absent from work for more than 6 months, are responsible for most of the costs related to this disease.[1,10,16] Many factors prolong back pain: Some are related to the patient,[19] whereas others are related to the workplace [8] or to Worker's Compensation Board (WCB) regulations.[6] Although many treatment regimens have been applied to subacute back pain, few have

been beneficial. This has provided the rationale for developing, applying, and validating a clinical-occupational model (incorporating the worker and the workplace) of back pain management.

The Québec Task Force on Spinal Disorders recommended early intervention to reduce chronicity, early evaluation of cases by a back pain medical specialist, early implementation of rehabilitation measures, and early return to work with light duties.[2] However, these recommendations have never been tested scientifically. Also, since the Task Force report, ergonomic approaches to improve the safety of worksites in a participatory way have been developed.[17] On the basis of these reports, a model for the treatment of subacute work-related back pain has been developed and evaluated in a population-based, randomized clinical trial.

Methods^

The Sherbrooke Model. A precise description of the Sherbrooke model and of the methods for its evaluation has been published.[12] The model includes surveillance in participating worksites to detect incoming cases, followed by an occupational medicine and ergonomic intervention (henceforth, called occupational intervention) and a clinical and rehabilitation intervention (called clinical intervention). In the current study, these two interventions were tested separately and jointly.

The occupational intervention began after 6 weeks of absence from work and included patients' visits to an occupational physician and a participatory ergonomics evaluation conducted by an ergonomist. The occupational physician could recommend investigation or treatment or could try to set up light duties to help the patient return to usual tasks. The ergonomic intervention was a worksite evaluation that included union and employer representatives in determining the need for job modifications. For each incident case, a group was formed that included the ergonomist (leader), the injured worker, the worker's supervisor, and representatives of management and unions. After observation of the worker's tasks, a meeting of the group allowed for a specific ergonomic "diagnosis," and precise solutions to improve the worksite were submitted to the employer. Implementation of these recommended solutions remained the employer's responsibility and were directed toward the stable return of the worker to the worksite.

The clinical intervention included, after 8 weeks' absence from work, a visit to a back pain specialist and a school for back care education (back care school) and, after 12 weeks' absence, a multidisciplinary work rehabilitation intervention. The medical specialist was consulted to exclude a serious or very specific disease (malignant tumor or severe, persisting sciatica with proven herniated nucleus pulposus requiring surgery). If no serious condition was detected, attendance at a back school was prescribed. If return to work did not occur after the school session (after approximately 12 weeks of absence from work), functional rehabilitation therapy was proposed to the practicing physician. The rehabilitation plan was a modified Mayer's intervention,[14] including fitness development and work hardening with a cognitive-behavioral approach. It ended with a progressive return to work, called therapeutic return to work, alternating days at the original job with progressively increased tasks and days receiving functional therapy.

All described interventions were provided by a multidisciplinary medical, ergonomic, and rehabilitation staff at the Sherbrooke University Hospital (Centre Universitaire de Santé de l'Estrie) back pain clinic.

Study Population. All workplaces in the Sherbrooke area (Québec, Canada) meeting inclusion and exclusion criteria, were invited to participate in the trial. Collaboration from employers, unions and the WCB were required. The city of Sherbrooke and surroundings has a population of 120,000.

Inclusion criteria for workplaces to participate in the study were: to have more than 175 employees and to be located within 30 km of the study site. Inclusion criteria for workers from these workplaces were: thoracic or lumbar back pain incurred at work that had caused an absence from work (or an assignment to light duties) for more than 4 weeks and less than 3 months, age from 18 to 65 years, and back pain accepted for compensation by the Québec WCB. Pregnant workers and workers with spinal fracture, significant degenerative spinal disease (spondylolisthesis, Grade 2 or more), a nonmechanical spinal disease (tumor or infection), or a major comorbid condition that might limit participation were excluded.

Randomization. To avoid possible contamination between cases randomized to receive the occupational intervention, a cluster randomization design was chosen (Figure 1). All eligible workplaces were first randomized to sites where affected workers would or would not undergo occupational intervention. This first randomization was stratified according to activity sector (manufacturing, services, health care) and according to the number of employees (less than or more than 500). Randomization was carried out during a meeting of the oversight committee (see Organization of the Study, later in the article). The eligible workers from all workplaces (with or without the occupational intervention) were successively randomized to receive, or not, the clinical intervention. For this randomization, 500 random numbers were generated by a computer and were given the status yes or no for clinical and rehabilitation intervention. Each random number, along with the intervention status, was placed, in order of generation, into envelopes numbered from 1 to 500. Envelopes were sealed, and the first 250 were distributed in successive order to the incoming eligible workers from the workplaces receiving the occupational intervention, and the other 250 to the incoming eligible workers from the workplaces not receiving the occupational intervention. This randomization process resulted in four groups of patients: usual care only, clinical intervention only, occupational intervention only, and the full intervention that combined clinical and occupational interventions (Sherbrooke model). Table 1 shows the schedule of the specific interventions delivered to the patients according to their randomization group. Patients in the usual care group received treatment from their attending physician, who was at liberty to prescribe any test, treatment, or referral to a specialist for care. Patients in the other three groups received their specific interventions at the study site, but remained free to seek additional treatment in the community. All clinical recommendations made by the back pain clinic staff were addressed to the patient's attending physician who was at liberty to prescribe the advice or not to and who determined the timing of the patient's return to work. Ergonomic recommendations were addressed to the employer, who was at liberty to implement them or not to. To limit the Hawthorne effect,[7] minimum clinical-like and occupational-like interventions

were given to all participant patients and workplaces: An educational videotape on back protection in daily activities was shown to all study participants, and supervisors at the worksites of all participants received a questionnaire assessing job difficulties.

Figure 1. Cluster randomization design used to compare the effectiveness of the clinical and rehabilitation intervention alone (clinical), the occupational medicine and ergonomic intervention alone (occupational), and both interventions combined (full) to usual care provided by the worker's physician. Worksites have been randomized to receive or not to receive the occupational intervention, to avoid contamination between cases that receive this intervention.

Table 1. Type and Schedule of Interventions, Based on the Randomization Group

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Identification of Cases. The management of the participating workplaces identified workers filing claims for back pain. To ascertain unidentified cases, persons identified by management were compared with those in the WCB master files. After 4 weeks of absence from work (or assignment to light duties) had been accumulated during 1 year, the worker and attending physician were offered the opportunity to participate in the study. If absence from work was divided in several noncontiguous episodes, date of study entry was the first day of the last episode. Patients were recruited from September 1, 1991, to December 31, 1993.

Assessment. The first assessment (baseline) was scheduled at 4 weeks accumulated absence (study entry), and the final follow-up assessment 1 year after the initial absence from work. Two intermediate visits, 12 and 24 weeks after the initial absence, were scheduled to improve compliance with the study protocol.

Outcome Variables. The primary outcome variable was the duration of absence from regular work in the year after enrollment. Regular work was defined as work identical to that performed before the onset of the work-related back pain. Thus, workers returning to light duties were not considered to have returned to regular work until they resumed their normal jobs. The secondary outcome variable was the duration of absence from any work (regular work or light duties). At baseline, all workers were absent from their regular work.

In addition, data were collected on the functional status (the Oswestry questionnaire [4] and the Sickness Impact Profile [2]), and the pain level (McGill-Melzack questionnaire [13]). All three questionnaires had been validated and widely used in back pain research.[9] Data from a medical questionnaire and examination for back pain were collected (including neurologic examination of lower limbs) by a physician blinded to the subject's randomization status. Information on the presence of minor comorbid diseases and on satisfaction with family and work [5,3] was obtained, as potential

confounding variables.

Organization of the Study. The conduct of the study was overseen by a committee including investigators from the University of Sherbrooke, responsible for developing and implementing the study; investigators from McGill University, responsible for its evaluation; and representatives from the employers, the unions, and the WCB, responsible for ensuring participation. The McGill evaluation team had no contact with the study site, the worksites, or the participants. It organized the randomization process and was responsible for data analysis.

The study and consent form were approved by the ethics committee of the Sherbrooke University Hospital, and all participants provided written, informed consent.

Statistical Analysis. Data were entered into Acius 4th Dimension, version 2.1, (Acius Inc., Cupertino, CA) and then were transferred for analysis to SAS software version DOS 6.04 (SAS Institute [15]). Compared were baseline data from eligible and noneligible study subjects, from those completing the 1-year study, and from those who withdrew early.

The duration of absence from regular work and from any work during the 1-year follow-up (including possible recurrences) was analyzed with survival analysis. The Kaplan-Meier product-limit method was used to describe the distribution of the duration of absence from work in the intervention groups. Between-group comparisons of the duration of absence were tested with the log-rank test. Cox's proportional hazards model was used to derive rate (hazard) ratios (and 95% confidence intervals) for these outcomes. Rate ratios resemble relative risks. They were adjusted for age, gender, comorbidity, and body-mass index. For the Cox regression analyses BMDP/PC release 88.2 (SAS Institute Inc., Cary, NC) was used. Three comparisons were conducted: Comparison 1 was between results in the usual care and the full intervention groups. Comparison 2 extracted the independent effects of the occupational intervention (occupational effect) and of the clinical intervention (clinical effect). The evaluation of the occupational interventions effect was first performed in the product-limit analysis by comparing results in both groups that received the occupational intervention (the occupational intervention and the full intervention groups) with those in both groups that did not receive this intervention (the usual care intervention and the clinical intervention groups). The clinical interventions effect was determined by comparing results in both groups that received the clinical intervention (the clinical intervention and the full intervention groups) with those in both groups that did not receive this intervention (the usual care intervention and the occupational intervention groups). In the Cox regression analysis, the evaluation of the occupational effect and of the clinical effect were estimated within the same model. Comparison 3 was made among the four intervention groups. For the functional status and pain variables, the statistical analyses and effect estimations were conducted using analyses of covariance. Age, gender, comorbidity, and body-mass index were included in the analyses to adjust the estimation of the mean differences between groups. $P < 0.05$ was considered significant for all comparisons.

No comparison analyses were conducted before the study's end of follow up. The closure of the

recruitment was decided on before the planned recruitment number had been obtained and was determined by the implementation by the Québec WCB of a new policy focused on an earlier detection of prolonged cases of sick-listed workers. This policy was likely to make a cointervention, possibly modifying the control arm of the study.

Results^

Forty workplaces, identified from the Québec WCB files, met the inclusion criteria and were randomized to receive or not to receive the occupational intervention. All sites were visited by the principal investigator. On detailed review, 5 did not meet the inclusion criteria. An additional 4 workplaces refused to participate. Therefore, 31 workplaces (management and unions) signed an agreement to participate. After 1 year, 1 workplace withdrew.

The population in the 31 participating workplaces was approximately 20,000 workers. Of these, 587 had 1 day or more of absence from work related to back pain. They were offered the opportunity to be recommended as potential cases to the study team. Fifty-five (9%) refused participation. Out of the 532 who agreed to participate in principle, 130 finally accumulated 4 weeks of absence from regular work, and all agreed to take part in the study and were randomized. Fourteen out of the 130 randomized workers (11%) failed to meet the inclusion criteria (noncases). This retrospective ineligibility was because of premature inclusion (less than 28 days of absence: 2 cases, a clerical error) or late inclusion (more than 90 days of absence: 12 cases, late declaration by the employer) of the patients in the study. These cases were distributed in the four randomization groups. Twelve workers (9%) did not respond to any follow-up visit (nonparticipants) and were also distributed in the four groups. Hence, the comparative analyses were performed on 104 participants. The participants did not differ from the nonparticipants in gender, duration of absence from regular work, or clinical data, but the participants were older. At baseline, the participants had a mean of 41.4 days of absence from their regular work.

Analysis of the baseline characteristics among the intervention groups showed statistically significant differences in age, gender, and the presence of comorbid diseases (Table 2). There were no significant differences among the four groups in the duration of absence from regular work, the body-mass index, the functional status, the pain score, or the level of satisfaction with family and work (Table 2). The groups did not differ in the findings on the medical questionnaire and examination at baseline (data not shown).

Table 2. Baseline Characteristics of Participants Based on Intervention Group

The results of the comparisons between groups, applied to the primary outcome (duration of absence from regular work), using survival analyses, appear in Table 3. Using the Kaplan-Meier analysis, the median duration of absence from regular work for the full intervention group was 60 days, compared

with 120.5 days in the usual care intervention group. The survival curves for these two groups differed significantly ($P = 0.02$; Figure 2). These results are in agreement with those of the Cox regression analysis that demonstrate a rate of return to regular work (when adjusted for age, gender, comorbidity, and body-mass index) that was 2.23 times greater (95% confidence interval from 1.04 to 4.80; $P = 0.04$) in the occupational intervention group than the rate in the usual care intervention group.

Table 3. Results of the Survival Analyses (Kaplan-Meier and Cox Regression) Comparing the Four Groups of Randomization and Testing for the Clinical and the Occupational Effects on Return to Regular Work

Figure 2. Survival curves of absence from regular work, comparing full and usual care interventions. The difference between the curves is significant (log-rank test; $P = 0.022$).

In the Kaplan-Meier analysis, the median duration of absence from regular work for the combination of the two groups that received the occupational intervention (occupational effect) was 67 days compared with 131 days in the two groups that did not ($P = 0.01$). The Cox proportional hazards model analysis (adjusted for age, gender, comorbidity and body-mass index) confirmed this result. The return to regular work was 1.91 times faster in the occupational effect groups than in the two groups without this intervention (95% confidence interval from 1.18 to 3.1; $P < 0.01$).

Results of the same analyses applied to the two groups that received the clinical intervention (clinical effect) did not demonstrate a statistically significant benefit when compared with the effect in the two groups without this intervention.

When comparing the four intervention groups, the median duration of absence from regular work was 60 days for the full intervention group, 67 days for the occupational intervention group, 131 days for the clinical intervention group, and 120.5 days for the usual care group ($P = 0.04$). Cox regression analysis showed a significant benefit on return to regular work in the full intervention group only. Those in the full intervention group returned to regular work 2.41 times faster than did those in the usual care intervention group (95% confidence interval from 1.19 to 4.89; $P = 0.01$).

When these same analyses were conducted with return to any work as the outcome, no statistically significant benefit was found in any group or combination of groups.

At the 1-year follow-up evaluation, the means of the Oswestry, Sickness impact profile (SIP), and McGill-Melzack scores were lower in the full intervention group compared with those in the usual care intervention group (Table 4). The difference was significant for the Oswestry score, and demonstrated a trend for the SIP and McGill-Melzack scores. The occupational effect was associated

with significant benefit on the SIP score, and the clinical effect had a similar effect on the pain level (Table 4).

Table 4. Difference Between the Full Intervention Group and the Usual Care Intervention Group and Evaluation of the Independent Effects of the Occupational Intervention (Occupational Effect) and the Clinical Intervention (Clinical Effect) at the Baseline and the 1 Year Follow-up Evaluations for the Oswestry Score, the Sickness Impact Profile Score, and the McGill-Melzack Pain Rating Index Score

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Discussion^

The current study was designed to determine whether a comprehensive clinical and occupational intervention could reduce progression to prolonged disability originating from back pain, by reducing the time away from regular work for affected workers. With occupational back pain, persistent disability is linked to prolonged absence from work or frequent recurrences of absence from work. Any intervention that reduces absence from regular work is likely to reduce long-term chronicity, with all of its personal and financial costs.

The results demonstrate that this integrated clinical-occupational model of management of back pain is effective in increasing the rate of return to regular work more than twofold, compared with the effectiveness of the usual medical care. But a finding of particular interest in the current study was that an occupational medicine and ergonomic intervention led to a significant reduction in the duration of absence from regular work compared with the rates recorded with usual care. Conversely, an intensive clinical and rehabilitation intervention, designed specifically for early low back disease, did not significantly reduce the time of absence from regular work, if applied separately.

In contrast to these benefits, none of the interventions had a significant effect on the time to or rate of return to any work (that is, assuming light duties). Light duties are increasingly used in industrial settings. Although the benefits of light duties for back pain patients have not been evaluated, the workers so assigned remain partially disabled, because they have not returned to their normal regular work. Moreover, decisions for such assignments may depend more on WCB regulations and the employer's policies than on the worker's back condition. Further study of the impact of return to light duties on the long-term outcome of low back pain, particularly persistent disability, are required.

Relatively few studies of therapeutic interventions for subacute and chronic back pain have used functional status as an outcome measure.[18] In the current study, the impact of the intervention on functional status and pain was less clear-cut than the beneficial effect on the rate of return to regular work. However, the results suggest a trend to improvement in pain and functional status, with full intervention.

This clinical trial on back pain management was applied in a general population of workers in a

geographic area in the province of Québec, Canada. The socioindustrial context, with a unique provincial WCB, has made its implementation more practicable. A severe control of bias has been exercised, and all randomized groups received some intervention and four complete medical examinations to compensate for a possible Hawthorne effect.

In selected situations, results of recent studies have shown that linking medical and worksite interventions may be efficacious.[11,20] Lindström's study was a randomized clinical trial, conducted in a large workplace, which had also linked early work rehabilitation interventions to job evaluations (but apparently without job modifications [19]). Their model of management of back pain and their results were similar to ours. However, the current study is thought to be the first population-based evaluation of a comprehensive model of management of occupational back pain. The study design enabled the finding that the occupational intervention was, by itself, highly effective, which raises questions about current medical care of patients with back pain.

The results of the current study indicate that closely associating an occupational intervention with clinical care is of primary importance if the individual and societal burdens of chronic low back pain are to be reduced.

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