dictive value—is important, but these results are useful until more information becomes available. Final decisions about screening for lead toxicity will depend on further evidence of the effectiveness of treatment, particularly for blood levels between 10 μg/dL and 15 μg/dL, and the prevalence of elevated blood levels in a particular community.

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BED REST, EXERCISES, OR ORDINARY ACTIVITY FOR ACUTE LOW BACK PAIN?

TITLE: The treatment of acute low back pain: bed rest, exercises or ordinary activity?
AUTHORS: Malmivaara A, Hakkinen U, Aro T, Heinrichs ML, Koskenniemi L, Kuosma E, et al.
JOURNAL: *The New England Journal of Medicine*
DATE: February 9, 1995; Volume 332:351–5.

Clinical question. Should we recommend bed rest, back exercises, or ordinary activity for patients with acute low back pain?

Background. Acute low back pain is extremely common in primary care practice, but what constitutes appropriate first-contact treatment is still unclear. Traditionally, primary care physicians have excluded neuropathy and serious disease, then treated nonspecifically with analgesics, bed rest, and/or a variety of back exercises. This study compares bed rest, back exercises, and ordinary activities.

Population studied. The study population consisted of 186 Helsinki city employees who presented to the city's occupational health centers with either acute low back pain or an exacerbation of chronic back pain lasting less than 3 weeks. All city employees were eligible, but those with neurologic deficits, pregnancy, fracture of the lumbar spine, or urinary tract disease were excluded. No information is available on the patients who refused to participate in the trial.

From a clinical perspective, these patients seem to be relatively similar to those we see, with relatively uncomplicated back pain of recent onset. Presumably, most have work-related injuries. Under the American system of workers' compensation, work-related injuries are a risk factor for chronicity. We do not know whether the same is true in Finland. In any case, the randomization process would probably control for this and other unmeasured potentially confounding variables. The lack of information on people refusing to participate in the study may be important because there may be some systematic differences between people entering the study and those staying out.

Study design and validity. The subjects were randomized to three types of advice: (1) 2 days of bed rest, with only essential walking, (2) written instruction in back extension and lateral bending exercises to be performed every 2 hours during the day until the pain subsided, together with a visit to a physical therapist, and (3) avoidance of bed rest and continuation of routine activity. Randomization succeeded in defining three groups with similar ages, sex ratio, body mass index, duration of pain, and disability. Over 90% of each group was treated with anti-inflammatory drugs or analgesics. All patients were reexamined by a physical therapist at 3 and 12 weeks and were given questionnaires to complete. This information was obtained from the medical record in which sick leave is recorded, as required by law. Patients who did not return for reexamination were contacted by telephone. To minimize bias of evaluators, patients reported their own symptoms and, at the beginning of the study, the staff were surveyed for their views about treatment.

This was a well-done study. The treatment arms reflect realistic options in our offices, although the specifics of exercise vary from physician to physician. A randomized trial is the best way to compare treatments, and follow-up is very good. Blinding was not possible in this study, but the authors made a sufficient attempt to address that and other potential biases.

Outcomes measured. The principal outcomes were duration of sick leave, patient report of the characteristics of pain, quality of life and functional assessment, physical examination, patient satisfaction, and cost of care at both 3 and 12 weeks.

Results. Randomization succeeded in identifying three similar groups. Patients advised to get back to their routine activity as soon as possible had significantly fewer sick days than did either of the other groups at both 3 and 12 weeks. The active group lost 4.7 days from work as compared with 7.2 days for the exercise group and 9.2 days for the bed-rest group. Although the total number of days away from work for all groups seems higher than American norms, the reduction in sick leave in the control group is clinically as well as statistically significant. At 3 weeks, there was also a nonsignificant trend toward less duration and intensity of pain, less disability, and higher quality of life in the control group, but at 12 weeks, there were no differences in these variables. Evaluator bias did not parallel these results, thus strengthening the finding. Patients in all groups were equally satisfied with treatment, and although there was a tendency for the control group to

have less expensive care, the difference was not statistically significant.

Recommendations for clinical practice. For uncomplicated acute low back pain, primary care clinicians need not encourage bed rest or back extension and lateral bending exercises. The two significant weaknesses of this study were its generalizability to patients living with our workers' compensation system and the somewhat low power to detect significant differences in, for example, patient satisfaction, but these weaknesses are relatively minor. It has been difficult to prove that any treatment regimen improves functional outcomes for patients with acute low back pain. Exercise prescriptions other than those included in this study may produce better results, and exercises and contact with physical therapists may eventually prove to be more effective in preventing recurrent low back pain, but these possibilities remain to be proved.

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QUININE AND LEG CRAMPS

TITLE: Meta-analysis of efficacy of quinine for treatment of nocturnal leg cramps in elderly people
AUTHORS: Man-Son-Hing M, Wells G
JOURNAL: *British Medical Journal*
DATE: January 7, 1995; Volume 310:13–7

Clinical question. Is quinine sulfate an effective treatment for nocturnal leg cramps in elderly patients?

Background. Nocturnal leg cramps are a common complaint among older patients. Quinine sulfate is a widely used therapy, but previous trials of its efficacy have been small and have had mixed results. Because of the drug's well-known and potentially serious side effects (pancytopenia, cinchonism, and visual toxicity), a meta-analysis was undertaken to determine whether quinine has any therapeutic benefit in the treatment of leg cramps.

Study design. The authors performed a meta-analysis of randomized, double-blinded, placebo-controlled, crossover trials of general ambulatory patients. The meta-analysis was well designed, with the following strengths: (1) the literature search was thorough and included a search for unpublished results; (2) review of the methods section of each article for the above inclusion criteria was blinded; (3) data on individual patients were obtained whenever possible; and (4) appropriate statistical tests were used. Sensitivity analyses, which made several worst-case assumptions, were performed to determine whether any identified treatment effect was the result of selection or publication biases. Publication bias refers to the greater likelihood that studies that show a benefit from treatment will be published compared with those that show no benefit. A recent article simulating the effects of publication bias and chance on the results of a meta-analysis nicely illustrates the methodology's pitfalls, and is recommended to interested readers.[1]

Outcomes measured. The following outcomes were measured: reduction in the total number of leg cramps and the number of nights during which leg cramps occurred; severity of leg cramps; duration of leg cramps; and the "cramp index" (the product of duration and severity).

Results. Of 11 potentially eligible trials, 6 with a total of 107 patients met the inclusion criteria. Individual patient data were available for all but one study. Patients taking quinine had a significant reduction of 8.83 (95% confidence interval [CI], 4.16 to 13.49) in the number of nocturnal leg cramps during a 4-week period, and a significant reduction of 27.5% (95% CI, 24.4 to 30.6) in the number of nights during which leg cramps occurred (although the latter outcome was reported by only two of the trials). No change was detected in the severity of cramps, their duration, or the cramp index. A variety of sensitivity analyses did not change these results. The authors discount the possibility of publication bias because of the "genuine uncertainty about the efficacy of quinine sulfate" among physicians, which I find reasonable. Nevertheless, it would have been helpful to calculate the theoretical number of unpublished negative trials needed to negate the results of the meta-analysis.[2]

Recommendations for clinical practice. Quinine sulfate in a dose of 200 mg to 300 mg given orally at bedtime appears to reduce the frequency but not the severity of nocturnal leg cramps in elderly patients. Patients should be treated daily for at least 4 weeks to determine individual benefit, and the possible risks of therapy, such as pancytopenia and cinchonism, must be balanced against any benefits. Since this study does not address the duration of benefit beyond 4 weeks, patients should be reevaluated regularly.

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