Conservative Therapy for Low Back Pain

Distinguishing Useful From Useless Therapy

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• **Conservative therapies for low back pain (LBP) entail expense, work loss, and risk of side effects. Because many competing modalities have been advocated, 59 therapeutic trials were examined for adherence to 11 methodological criteria. Common problems included failure to randomize subjects, use "blind" observers, measure compliance, and adequately describe co-interventions. Applicability of many studies was unclear because of inadequate descriptions of patients, interventions, and relevant outcomes. Flexion exercises, administration of each of three drugs, one traction method, and certain manipulations were each supported by single studies of reasonable validity, but the importance of the results and their applicability to particular types of LBP were unclear. Valid trials supporting use of corsets, bed rest, transcutaneous nerve stimulation, and conventional traction were not found. Better methodological rigor is possible with newer techniques for ensuring blindness to therapy, measuring compliance, and assessing outcomes.**

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Criteria

Several authors have recently suggested criteria for critical readers or investigators to use to evaluate the validity and applicability of therapeutic trials.[1-4] Following are the criteria chosen for this analysis and a brief rationale for each.

Criteria for Validity

1. Randomization.—This is the best way to eliminate many of the biases that can lead to false results. Because there is great heterogeneity in the type and prognosis of back problems in patients seen in different settings and at different times, and because improvement is part of the natural history of LBP (approximately 80% of patients with acute LBP experience improvement within two weeks),[5] the use of randomized concurrent control subjects was judged essential for validity. Since randomized studies of all these treatments are feasible and have been reported, nonrandomized studies were not considered further.

2. Minimal Patient Attrition.—The exclusion or loss of randomized patients may bias results, especially since those who do especially well or especially poorly may be more likely to be unavailable for follow-up. To meet this criterion, an article had to describe what attrition of randomized patients occurred and (arbitrarily) have less than 15% attrition.

3. Blind Outcome Assessment.—While it may be difficult or impossible to "blind" patients in a study of various physical treatments, every effort should be made to ensure that the investigator who assesses outcomes is unaware of the treatment assignments. A study was judged to meet this criterion only if specific mention was made of the observer's blindness to treatment assignment.

4. Equivalent Co-interventions.—Since many modalities are often prescribed simultaneously (eg, analgesic administration, exercises, bed rest, physical therapy), it is essential to know whether such co-interventions were comparable among study groups.

5. Compliance.—Especially for outpatient trials, some effort to ensure or measure patient compliance is essential. Anecdotal experience suggests that compliance with exercise regimens, bed rest, and many physical modalities is difficult to achieve.

6. Minimal Contamination.—In long-term follow-up studies, it is often likely that patients assigned to one treatment will also obtain other study treatments during the ensuing months, especially if initial results are suboptimal. These could be thought of as "unintended crossovers." For present purposes, simply a description of such contamination was judged adequate, and inpatient trials were assumed to have little, if any, contamination.

7. Adequate Statistical Power.—In studies that report no differences among treatment groups, it is essential to know whether the sample size used was adequate to detect clinically important differences.

Criteria for Applicability

8. Adequate Demographic Description of Patients.—To assess applicability of results, it was judged necessary to know, at a minimum, the mean or median age of patients, sex, and source of patients (type of clinic or specialty of admitting physician for inpatients).

9. Adequate Clinical Description of Patients.—Great heterogeneity of back pain syndromes exists, and it is often impossible to make a firm diagnosis as to the source of pain. To apply the results, it was judged necessary to have a description of pain duration; presence or absence of sciatica, neurological deficits, and previous surgery; and at least some additional description of inclusion and exclusion criteria. Clinical description was judged adequate if four of these five factors were included.

10. Adequate Description of the Intervention.—Dose, duration of therapy, frequency of treatments, and a reproducible description of treatments were judged to be necessary.

11. Reporting of Relevant Outcomes.—Since death or complete cure are rare events in LBP, other outcomes must be sought. A wide variety of outcomes was encountered, and these were divided into four general categories: (1) physiological (eg, pain, range of motion, straight leg raising, neurological changes, and roentgenographic changes); (2) functional (eg, work status, activities of daily living, and time to return to full activities); (3) cost (eg, dollars and use of services); and (4) perceptions (eg, patient satisfaction, opinion of efficacy, preferred therapy, and psychosocial measures). While it might be unfeasible for a single study to report all such outcomes, all may be important in this condition. Reporting of outcomes was judged to be adequate if at least one measure from at least three of these four groups was included.

RESULTS

Fifty-seven articles describing original research were identified. Among