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Randomized Controlled Trial of Neural Mobilization After Spinal Surgery

[Randomized Trial]

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Outline

Graphics

Abstract^

Study Design. Randomized controlled trial with 12-month follow-up.

Objectives. To determine whether the addition of neural mobilization to standard postoperative care improved the outcome of lumbar spinal surgery.

Summary of Background Data. It has been suggested that neural mobilization should be performed after spinal surgery to prevent nerve root adhesions and improve outcome. However, to date, there is no convincing evidence of the value of neural mobilization.

Methods. Eighty-one patients undergoing lumbar discectomy, fusion, or laminectomy at a private hospital in Sydney were randomly allocated to standard postoperative care or standard care plus neural mobilization. Neural mobilization included passive movements and active exercises designed to mobilize the lumbosacral nerve roots and sciatic tract. Primary outcome measures were global perceived effect measured on a 7-point scale, pain measured using visual analogue scales and the McGill Pain Questionnaire, and disability measured with the Quebec Disability Scale.

Results. All patients received the treatment as allocated with 12-month follow-up data available for 76 patients (94% of those randomized). There were no statistically significant or clinically significant benefits provided by the neural mobilization treatment for any outcome.

Conclusions. The neural mobilization protocol evaluated in this study did not provide an additional benefit to standard postoperative care for patients undergoing spinal surgery. The authors advocate that this protocol not be used in clinical

practice.

It is common for patients who undergo lumbar spinal surgery to receive physical therapy as part of their rehabilitation. Before surgery patients may receive advice on back care, [8] immediately after surgery assistance with ambulation and guidance on resuming daily activities, [8] and later a graded physical activity program designed to increase the patient's capacity for home and work duties. [3,8] Although these are the common elements to most programs, additional treatments such as electrical methods and joint mobilization, [13] braces and corsets, [15] and massage may also be used. [10]

As with many other health care providers, there is now a growing acceptance by physical therapists of the need to provide evidence-based health care. Physical therapists managing patients with nonspecific low back pain (LBP; of unknown origin) can be guided by the large amount of information from evidence-based clinical practice guidelines, systematic reviews, and randomized controlled trials. However, there is less information available on the physical therapy management of patients who have undergone spinal surgery.

There is clinical trial evidence to support the use of physical activity after spinal surgery. Four randomized controlled trials [3,6,8,12] have compared various physical activity programs for patients who have undergone lumbar discectomy. The benefits of the physical activity programs included less pain and disability, improved range of motion, and greater satisfaction with care. Physical activity programs were more effective when they were intensive rather than mild [3 12,8] and did not limit the program according to the patient's pain, [12] a result that has also been reported for the management of nonspecific LBP. [9] One study found that home training provided similar results to supervised care. [8]

One approach to treatment that has not been well investigated is "neural mobilization" treatment. In the physical therapy literature there are whole textbooks devoted to the topic of neural mobilization [1] with the technique used for a range of orthopedic conditions. After lumbar spine surgery physical therapists may use passive and active movements to ". . .maintain interplane mobility of the neural structures by stimulating gliding surfaces. . ." (p. 2346). [8] An example movement, designed to mobilize the lumbosacral plexus, is knee extension with the hip in 90° of hip flexion. Neural mobilization treatment of patients after lumbar spine surgery has its origins in Fahrni's hypothesis [5] that one cause of poor outcome after spinal surgery is the formation of nerve root adhesions. To prevent the formation of adhesions, Fahrni [5] suggested that immediately post surgery the nerve root should be gently mobilized with straight leg raising.

To date, the effect of neural mobilization has only been evaluated in one trial [7] studying patients who had undergone lumbar decompressive surgery. In this randomized trial patients performed auto-assisted straight leg raise exercises using a rope-and-pulley system. The study reported the treatment to be ineffective in improving pain or disability. However, there were only six subjects in each group and patients were only followed for 6 weeks. So the trial does not provide convincing evidence on the

efficacy of neural mobilizations. Additionally, there is little evidence to evaluate Fahrni's hypothesized mechanism of action of this therapy.

The current study addressed the deficits of the earlier trial by providing long-term follow-up and by being designed to have sufficient statistical power to detect even a small benefit of neural mobilization. The aim of the current study was to establish whether, for patients who had undergone lumbar spinal surgery, neural mobilization provides an additional benefit to standard postoperative care. Subjects were followed for 12 months and outcome was assessed in terms of global perceived effect (GPE), disability, pain, return to work/normal activity, and straight leg raise range. The study was not designed to evaluate the hypothesized mechanism of action of this therapy, only whether the therapy was clinically effective.

Methods^

Selection of Patients.^

All patients undergoing lumbar spinal surgery (discectomy, laminectomy, and fusion) at Dalcross Private Hospital from July 1997 to March 1998 were invited to participate. Subjects who had undergone microdiscectomy, had malignant disease, or were unable to read English were excluded. Microdiscectomy cases were not included because at Dalcross Hospital microdiscectomy is mainly performed by a surgeon who does not request postoperative physical therapy for his patients. All subjects signed a consent form before admission to the study. The University of Sydney Human Ethics Committee approved the study protocol.

Randomization.^

Subjects were stratified into three groups (discectomy, laminectomy, and fusion) and then randomly allocated to treatment group using a separate allocation schedule for each stratum. The allocation schedules were developed from a random numbers table. The first author was responsible for determining whether subjects were eligible to participate and for allocating subjects to group.

Interventions.^

The operations were performed by four neurosurgeons. With discectomies the disc was exposed with either an interspinous approach or an interlaminar approach, and loose disc fragments or a part of the disc was removed if necessary. Laminectomies entailed dissection of paraspinal muscles and removal of spinous processes at the appropriate level as well as removal of the ligamentum flavum and the lamina to give good decompression of the affected nerve roots. Three fusion techniques were used: 1) posterior lumbar interbody fusion with pedicle screw fixation and posterior joint fusion; 2) anterior interbody fusion, segmental fusion with a Brantigan cage and translaminar screws, and then posterior fusion; and 3) posterior fusion with translaminar screws.

Both groups received the same standard postoperative care. Patients who had undergone discectomy or laminectomy returned to the surgical word after operation and received injections or oral analgesia

as required. Drains were removed 1 day after surgery and the patients were allowed out of bed. The wound dressings were changed daily and kept dry for 1 week. The patients who underwent fusion received epidural pain relief and were nursed in a high dependency ward for 2 days. On day 3 the drains and epidural were removed and the patient was transferred to the surgical ward where they used patient-controlled analgesia for pain relief. On day 4 patients were allowed out of bed wearing a corset. The wound was dressed every day and kept dry. On day 10 sutures were removed.

The physiotherapy treatment consisted of isometric and dynamic exercises for the lower limb and trunk. A smaller subset of the exercises was commenced on day 1 with extra exercises added as tolerated, so that by discharge patients performed the whole set of exercises. Patients were encouraged to do the exercises every 2 hours while on bed rest. The therapist visited the patient twice each day to supervise and progress exercises. Once out of bed patients were encouraged to do their exercises two or three times daily, with the therapist continuing to progress their exercises. At discharge the patient was given an exercise sheet and encouraged to continue exercises for at least 6 weeks.

The neural mobilization group received, in addition to standard care, active and passive exercises that were designed to mobilize the neural tissues. The physiotherapist performed neural mobilizations twice daily as set out below.

Laminectomy and Discectomy.^

Day 1–6
Through-range straight leg raises on each leg
6 straight leg raise with dorsi/plantar flexion to onset of pain on each leg
6 passive neck flexion (active if able)
Day 2
Progress to 10 through-range straight leg raise on each leg
10 straight leg raise with dorsi/plantar flexion on each leg
10 active neck flexion in supine

Fusion.^

Day 1
6 repetitions of passive hip and knee range of movement exercises on each leg
6 repetitions of passive neck flexion
6 repetitions of knee extension–flexion, with hip in some flexion, on each leg
Day 2
Progress to 10 passive neck flexion
10 through-range straight leg raise on each leg to onset of pain
10 knee extension–flexion, with hip in some flexion, on each leg
Day 3
Progress to 10 through-range straight leg raise on each leg to onset of pain
10 straight leg raise with dorsi/plantar flexion on each leg active neck flexion
As with the standard therapy group, the neural mobilization group was given an exercise sheet at discharge and encouraged to continue exercises for at least 6 weeks. The neural mobilization exercise

sheet included additional exercises designed to mobilize the lumbosacral nerve roots and sciatic tract.

The physiotherapist who performed the treatments (S.V.S.) was not blind to group allocation. At 6 weeks the physiotherapist questioned the patient to ascertain compliance with the exercise protocol.

Outcome Measurements and Follow-Up.^

The primary outcome measures were GPE, pain, and disability. GPE at the 12-month follow-up was rated by the patient on a 7-point scale (completely recovered to vastly worsened). Pain was measured at baseline, discharge, 6 weeks, 6 months, and 12 months after baseline using two 100-mm visual analogue scales (VAS) (one for current pain and the other for pain over the past 24 hours) and the pain rating index of the McGill Pain Questionnaire (range, 0–78). Disability was measured using the Quebec Disability Scale (range, 0–100) at baseline, 6 weeks, 6 months, and 12 months.

Secondary outcome measures were straight leg raise and return to work or normal activities. Maximum tolerated straight leg raise was measured using an inclinometer [14] before surgery, day 1 post operation, at discharge, and at 6 weeks post baseline. The research assistant who measured the straight leg raise outcome was blind to group allocation.

At 6 weeks, 6 months, and 12 months, subjects were asked if they had returned to work (yes/no). Alternatively, if subjects were retired at trial commencement, they were asked if they had returned to normal activities. At 12 months subjects who were employed at trial commencement were asked to report whether they had returned to more hours, the same number of hours, less hours, or had not returned to work. Their replies were recorded as follows: more hours = 4; same hours = 3; less hours = 2; not returned to work (NRTW) = 1 and considered as ordinal data. Subjects were also asked to report how many weeks after surgery they returned to work. At 12 months all subjects were asked if they had returned to normal activities (yes/no) and, if so, the percentage of normal activities they had returned to (0–100%). Subjects who considered that they had resumed normal activities were also asked to report how many weeks after surgery before normal activities had been resumed.

Data Analysis.^

Pain, disability, and straight leg raise data were analyzed using two-way (group × time) repeated-measures analysis of variance with repeated-measures on the time factor. The 12-month GPE data and data describing the extent to which subjects returned to work were analyzed using a Mann-Whitney U test. The percentage of activities returned to at 12 months and length of time to return to work and normal activity were analyzed using unpaired *t* tests. The proportion of subjects who had returned to work or normal activities at 6 weeks, 6 months, and 12 months was analyzed using $[chi]^2$ tests. For all analyses, [alpha] was set at 0.05. Because all subjects completed the treatment protocol as allocated, the single analysis represented both a per-protocol and an intention-to-treat analysis.

Power Analysis.^

Sample size was determined using the procedures described by Cohen. [2] Estimates of variability were

obtained from the first 20 patients recruited in the trial. We aimed to recruit 36 subjects to each group, a sample size that would provide at least 80% probability of detecting clinically worthwhile effects (reported as 1.0 Units on the GPE scale, 20 mm on the VAS measures, 10 Units on the McGill Pain Questionnaire, and 20 Units on the Quebec Disability Scale) if such effects existed. The study was not designed with sufficient power to investigate whether the effect of neural mobilization treatment depended on the type of surgery performed, and so this type of subgroup analysis was not undertaken.

Results^

The trial flow diagram is shown in Figure 1. Ninety-five subjects were approached to join the clinical trial; 10 declined to participate, and four were excluded. Consequently, 81 subjects were randomized. Of the 81 subjects, all received treatment as allocated. Eighty subjects (99%) were followed-up at 6 weeks, 77 (95%) at 6 months, and 76 (94%) at 12 months. One subject withdrew without reason, one because she was too busy attending medical appointments and tests for her LBP, and three withdrew because of illness (metastatic cancer, below-knee amputation, and motor neuron disease requiring respirator support in hospital).

Figure 1. Flow chart describing patients' progress through trial.

Patient Characteristics^

Patient characteristics at baseline are provided in Table 1. Randomization achieved comparable groups at baseline.

Table 1. Patient Characteristics at Baseline

Exercise Compliance^

At 6 weeks 37 of 46 of the control group and 28 of 34 of the neural mobilization group reported that they had been compliant with the home exercise program.

Outcome^

The median GPE ratings at the 12-month follow-up for the neural mobilization group and control groups were both 2.0 (neural mobilization interquartile range 1.0–3.0, control interquartile range 1.0–2.25). The Mann Whitney U test revealed no significant difference between the groups ($P = 0.56$).

The repeated-measures analysis of variance on the pain, disability, and straight leg raise data all revealed no group × time interaction, indicating that the subject's recovery did not differ across

treatment groups (*P* ranged from 0.15 to 0.72). The 95% confidence interval for the difference between the means (Table 2) did not include the prespecified clinically significant effect, confirming that the nonsignificant result was not because of low power.

Table 2. Mean and 95% Confidence Intervals for Between-Group Differences in Improvement for Each Outcome at Each Follow-up OccasionA positive score means that the experimental group had a greater improvement than the control group.N/A = not applicable; VAS now = current pain measured using a 100 mm visual analogue scale; VAS 24 hr = pain over the previous 24 hours measured using a 100 mm visual analogue scale; McGill = pain over the previous 24 hours measured using the pain rating index of the McGill pain questionnaire (range 0–78); Quebec = disability measured using the Quebec disability scale (range 0–100); SLR = maximum tolerated straight leg raise range (°).

The return to work/normal activities data (Table 3) similarly revealed no difference in outcome for the two groups.

Table 3. Return to Work/Normal Activity DataRTW = returned to work; NRTW = not returned to work.

Discussion^

The trial provides clear evidence that the neural mobilization treatment did not provide additional benefit to standard care. A lack of benefit was observed consistently across the range of outcomes and at each follow-up occasion. We have confidence in this conclusion because subjects were randomized to treatment and control groups, all subjects received the treatment as allocated, and 94% of subjects completed all outcomes. Further, the range of outcomes we assessed (GPE, pain, disability, return to work/normal activity, and straight leg raise) sampled most of the domains contained in the recent "core set" of outcome measures for LBP research. 4 Lastly, the 95% confidence intervals for between-group differences in the primary outcome measures (Table 2) do not include a meaningful clinical benefit, and so the failure to detect a positive effect of treatment cannot be attributed to low statistical power.

The data provide less clear evidence that neural mobilization treatment might actually have a harmful effect. The 95% confidence interval for between-group differences in improvement for pain and disability and straight leg raise (Table 2) spans the range that includes a clinically significant harmful effect. For example, at the 1-year follow-up the VAS (24 hours) 95% confidence interval lower limit was -31.5 mm, a difference in improvement we regard as clinically important. This result is not isolated, as 13 of the 18 point estimates in Table 2 represent a harmful effect of neural mobilization.

Although we accept that our study did not have sufficient power to provide a clear answer on whether the treatment was harmful, we cannot see any justification for conducting a larger study because our study has shown clearly that there was no benefit of neural mobilization.

There is empirical evidence that trials that fail to conceal treatment allocation and/or fail to use double blinding will report larger treatment effects than trials that do include these methodologic features. [11] This potential for bias exists with the current study design because concealed allocation was not used and complete double blinding was not possible. This potential for bias would be a concern if the trial had rejected the null hypothesis; however, this was not the case. At the beginning of the trial the first author anticipated that the null hypothesis would be rejected, and so the trial was designed to include some level of blinding. The individual who made the straight leg raise measures was blinded to group allocation, and the subjects were blinded to the experimental hypothesis by telling them that the trial was evaluating two physiotherapy programs and that it was not known which of the two programs was more effective. The two programs were not described with words such as “experimental” or “control,” which would unblind a subject familiar with experimental design.

The results of this study provide clear evidence that the postoperative management of lumbar spinal surgery should not include the neural mobilization protocol used in this study. Whether other neural mobilization protocols would be effective is unclear. In discussing this result with colleagues we have received conflicting advice on the most effective dose of neural mobilization. Some colleagues are firmly of the opinion that the protocol failed because it was too vigorous, whereas a similar number are convinced that the protocol was too gentle.

Kitteringham’s trial [7] provides some evidence on the issue of treatment dose. In that study subjects performed auto-assisted straight leg raise exercises using a rope-and-pulley system. Subjects in the control group received a low, presumably subtherapeutic, dose of exercise, whereas the control group received the full dose. Subjects commenced the exercises immediately after surgery and performed either 10 straight leg raise exercises on each leg eight times a day at approximately 2-hour intervals (the experimental group) or the same exercises on only one occasion each day (the control group). There were no between-group differences in pain or straight leg raise range at week 1 or week 6 after operation. This result needs to be viewed with caution because of the low subject numbers, but it clearly does not provide evidence to support the premise that more neural mobilization will give a better therapeutic effect.

Conclusion^

The neural mobilization protocol used in this study should not be part of postoperative rehabilitation for patients who have undergone lumbar surgery.

Key Points^

* Neural mobilization is used in the physical therapy management of patients who have undergone lumbar spinal surgery.

* Neural mobilization has been suggested to improve outcome by preventing nerve root adhesions.
* This clinical trial found no benefit when neural mobilization was added to standard care.

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