Prospective Randomized Study of VAX-D Therapy for Acute Low Back Distress

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Abstract

This study is a randomized control trial designed to assess the efficacy of VAX-D Therapy to significantly abbreviate the disability period in patients with acute incapacitating low back pain. Patients included in the study were those with acute distress with pain and/or spasm, unable to functionally bear weight or partake in the activities of daily living [ADL's]. One hundred and ten [110] patients were randomly assigned to either VAX-D or standard medical therapy groups.
Patients were initially assigned to VAX-D Therapy or a sham-treatment (VAX-D Therapy without application of distraction tensions). However, this approach was discontinued due to the failure of patient compliance in the sham group. Sixty-eight percent [68%] of the fifty-five patients treated with VAX-D therapy achieve success according to the study parameters.

Key words: Low Back Pain; Intervertebral Disc; Lumbar spine.

Introduction

Low back pain is the second commonest cause of disability in North America. In uncontrolled studies the VAX-D Table has been shown to alleviate both acute facet and disc disease related back pain. The potential value of this apparently benign procedure should have a great impact on the epidemiology of chronic lumbar pain. A variety of devices have been designed and utilized to apply tractive forces in novel ways, such as tilt tables, gravity inversion devices, bed traction with weights, electronic motor winches etc. in order to relieve the compressive forces sustained by the spine and the resultant pain and disability. The successful application of lumbar distractive forces has been limited by the technological design of mechanical devices and by patient tolerance.

Technological advances have now led to the development of equipment, the VAX-D Treatment Table and Console. The equipment allows controlled, effective axial distraction tensions to be applied to the lumbar vertebral column. Distractive forces are applied in a gradual, progressive logarithmic fashion that does not elicit reactive reflex muscular resistance.

Clinical studies were initiated in benign but disabling forms of low back pain of varied etiologies.

Aims of the Study

In patients with acute recent disabling low back pain, to compare the efficacy of VAX-D treatment to a sham control, where both treatment groups receive concurrent best available medical therapy. The primary parameters of efficacy are severity and duration of both pain and disability, including analgesic requirements. A secondary parameter of efficacy is presence and degree of neurological involvement. Radiologic changes, as measured by non-contrast CT scan of the lumbosacral spine, will also be studied.

Material and Methods

1. Definitions Pain, Disability, Analgesic use and Neurological Scales:

The level of disease will be measured for all patients in four categories: Pain, Disability, Analgesic Use and Neurological Deficit. The first three of these will be considered on a scale from 0-5, and Neurological Deficit will be recorded as 0,2 or 4, according to the following definitions:

Pain: Each patient will record their own subjective assessment of their level of pain daily, using the following guidelines:

0-no pain
1-slight pain or discomfort
2-mild pain
3-moderate pain
4-severe pain
5-worst possible pain

Analgesics: Each patient's daily use of analgesics will be recorded on the following scale:

0-no analgesics used
1-non-narcotic analgesics used less than q 4 hours
2- non-narcotic analgesics used at least q 4 hours
3- narcotic analgesics used less than q 8 hours
4- narcotic analgesics used q 8 hours to q 4 hours
5- narcotic analgesics used at least q 4 hours

Disability: The level of disability of each patient will be recorded daily according to the following scale

0-independent activities of daily living [ADL] and work or retirement
1-independent ADL and most work or retirement activities
2- ADL, without assistance, no work or retirement activities
3-ADL, with assistance, no work or retirement activities
4-minor activities possible, with assistance
5-bedridden, no activity possible

Neurological Deficit: The level of neurological deficit will be recorded at each assessment by the Neurological Coordinator, using the following criteria:

0-no neurological deficit
2-any combination of; new patchy or dermal sensory deficit; diminished deep tendon reflex; minor motor impairment
4-moderate to severe motor impairment; new sphincter dysfunction

Daily Scale:

The patient will be supplied with a diary and will record each day his/her score in pain, disability and analgesic use. The first two scores will be added to make an aggregate score which is the primary outcome of interest. The analgesic use will be noted in terms of possible influence on the aggregate scores for pain and disability.

Study Design:

This study will be a two parallel group design, double-blind randomized controlled clinical trial. Patients who meet the eligibility criteria will be randomized to receive either a sham treatment or the VAX-D treatment. Patients will not know which of the two treatments they receive. Although the nurse/physician assistant who gives the treatment will know whether it is a sham control or actual, this will not be disclosed to either the patient or Neurological Coordinator, who will assess the outcome of therapy. Al patients will receive best standard therapy.

A. Sample size:

One hundred and ten [110] patients in total were randomly assigned to either VAX-D Therapy or standard medical therapy groups. Patients were initially assigned to VAX-D Therapy or a sham-treatment (VAX-D Therapy without application of distraction tensions). The treatment will be considered a success if the baseline aggregate score for pain and disability is reduced to 50% by therapy. Whereas many patient's pain will resolve given sufficient time and standard therapy, it is anticipated that the VAX-D therapy will significantly reduce the amount of time required to reach a 50% reduction. Therefore, the primary outcome variable is the time to achieve a 50% reduction in the baseline score. Assuming that 25% of the patients will not achieve a 50% pain reduction by the end of the study, the number of patients required in each group to detect halving of the median time to 50% reduction at X= .05 and 90% power is 48. For example, if the median time to 50% reduction is three (3) weeks in the control treated group, 48 patients per group will give 90% power to detect at the .05 level, a reduction of this median time to 1 1/2 weeks.

B. Inclusion Criteria:

1. Patient eligibility requires either

(i) a score of at least 3, in 2 or more assessment categories [pain, disability and analgesic use] with or without neurological deficits, or;

(ii) a neurological deficit of 2 and a score of at least 3 in one of the assessment categories.

2. Absence of exclusion criteria listed below

C. Exclusion Criteria

1. Inability or unwillingness to give informed consent
2. Age less that 18 or greater than 70
3. Neurogenic sphincter dysfunction by history
4. Major systemic illness including cancer, recent [less that 6 months MI]
5. Osteoporosis by history of spine X-ray
6. Chronic pain syndrome
7. Previous back surgery including laminectomy, prosthesis [eg. Harrington rods], vertical fusion
8. Clinical evidence for collagen vascular disease [rheumatoid arthritis, lupus, ankylosing spondylitis].
9. Exam evidence for myelopathy or severe progressing lower motor neuron distribution weakness.
10. Radiologic evidence of fracture, tumour, infection or other non-degenerative spine disease

Treatment

VAX-D Therapy:

Follow the VAX-D protocol and instructions as outlined in the VAX-D user manual. Distraction strengths for females was in the range of 50-60 pounds, and for males 70-80 pounds, which includes a baseline pretension level of approximately 15 pounds. The treatment session consisted of fifteen (15) cycles of distraction of one minute duration, alternated with fifteen (15) one minute rest cycles.

Concomitant Therapy:

All patients will receive standard medical therapy as needed, including bed rest, analgesics, non-steroidal anti-inflammatory drugs and muscle relaxants. All patients will agree to forego any other form of physical therapy, including chiropractic, physiotherapy etc. Concomitant medical therapy, although not restricted in any way will be carefully recorded and changes noted during the study. Admission to hospital is to be avoided if at all possible, since the patients are to be encouraged to increase activities as tolerated. Recognizing that travelling daily to the hospital for treatment may well add an unusual stress and discourage participation by some individuals.

General Treatment Conditions:

All patients will be followed and required to complete their daily record for 30 days past the initial treatment. Patients will receive the treatment daily for the first ten days. This treatment will not be interrupted unless the Neurological Coordinator determines that the

patient is unable to continue or the symptoms resolve completely. Assessments should be made by the Coordinator at two day intervals during the treatment period and weekly thereafter.

The therapy will be considered a success if the aggregate score for pain and disability is reduced by 50% from the starting baseline. A patient will be considered a failure if either the neurological deficit worsens or a 50% reduction in the aggregate score has not been achieved by the end of the 30 day observation period. If after resolution of the initial episode is discontinued, symptoms recur, the patient will be offered a further course of therapy.

Investigations

A: Baseline Investigations

1. History and physical examination.
2. Baseline assessment of pain, disability, analgesic use and neurological deficit scores.
3. Thoracic, lumbar and sacral spine films – AP, lateral, and oblique views.
4. CT scan [without contrast] of L3-L4, L4-L5, and L5-S1 levels.
5. CBC, differential and biochemistry group
6. Urinalysis.
7. Chest X-ray.

B: Follow-up Investigations

1,2 and 4 above to be performed at the exit of the study period.

C: Examination for Efficacy

Efficacy will be assessed using the scores recorded daily in the patient diaries and verified by the Neurological Coordinator at examination every two days during the therapy period and weekly thereafter. The Coordinator will also make an assessment of neurological deficit at each examination. Also at these examinations, any complications or changes in the daily activities of the patients will be assessed and noted.

D: Analytical Methods

The primary outcome, time to achieve a 50% reduction of the aggregate score for pain and disability will be compared between the groups using standard logrank analysis methods. Concomitant variables, such as initial extent of disease and type of disease, will be controlled for as necessary using multivariate Cox proportional hazards regression techniques.

Other outcomes such as delta determinations to nadir aggregate scores and end-therapy scores will be analysed using binomial methods and chi-squared techniques.

Results:

Report to the Clinical Study Coordinating Committee on Sham Treatment:

It was reported that after several weeks of attempting to conduct a sham treatment control that patient compliance suffered to such an extent that continuation was deemed impractical.

According to the requirements for clinical trials, all patients were advised before volunteering that some could be assigned to a control group. It was not possible to convince the sham-control patients that they were receiving a treatment and those assigned refused to continue to suffer the stress of travelling to the hospital each day unless assured they would be reassigned.

We found that the patients discussed their progress with each other and their general practitioners and it became obvious that a double-blind or even a single blind system could not be sustained. Consequently the purpose of the sham-control was not only subverted by group non-compliance but also threatened the ability to attract additional patients from the referring community physicians. This leg of the study (sham control) was aborted.

Fifty Five (55) patients that were randomized to VAX-D Therapy had a reduction in their *Pain and Disability Grade* from an average level of 5.3 at the outset of the study to a level of 0.9 after ten (10) VAX-D Treatment sessions (See Graph Figure 1.) Sixty-three percent (63%) of the patients treated with VAX-D Therapy achieved success, obtaining a fifty (50%) reduction in their pain and disability score.

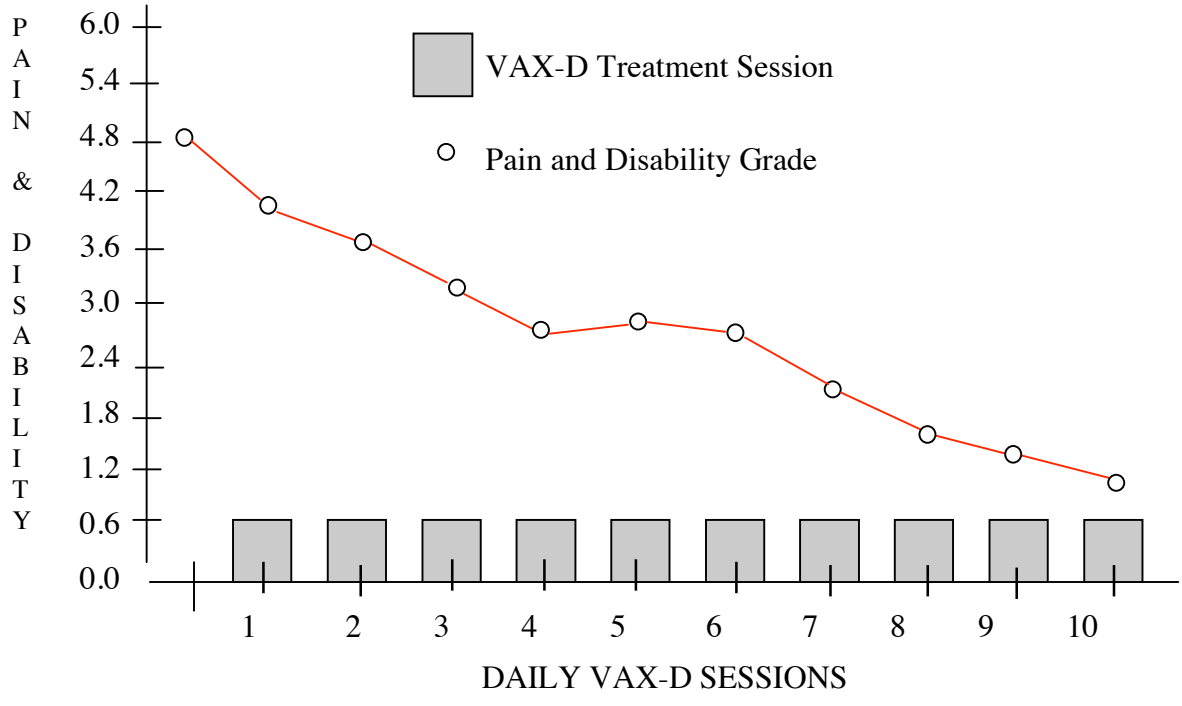

FIG. 1. AVERAGE RESPONSE RATE WITH VAX-D THERAPY

An initial control group of fifty-five (55) patients were randomized to VAX-D Sham treatment (VAX-D Therapy with no tension applied). This control leg was abandoned after two weeks of treatment due to non-compliance of the patients. At this point some of the patients dropped out of the study while others elected to continue. Those that continued were then given a regimen of medication and standard physical therapy.

Discussion

Low back problems affect almost everyone at some time during their lifetime. Acute low back problems are defined as activity intolerance due to lower back or back-related leg symptoms of less than 3 months' duration. The acute phase presents issues to be faced by first contact physicians during the first four to six weeks of evaluation and treatment of acute low back pain, not associated with trauma, infection or major neurological deficit.

Low back complaints that are potentially related to work are the most common problems presented to occupational health and primary care providers. They are the most common cause of reported occupational complaints and workers' compensation claims.

Despite the current statistics on the magnitude of this problem, the number of cases continues to grow, and the data on how well the problem is being managed is often incomplete.

Currently there is a movement to develop and evaluate evidence-based guidelines for the management of lumbar musculoskeletal pain disorders.

In this study one hundred and ten [110] patients were randomly assigned to either VAX-D or standard medical therapy groups. Patients were initially assigned to VAX-D Therapy or a sham-treatment (VAX-D Therapy without application of distraction tensions - as a control). However, this approach was discontinued due to the failure of patient compliance in the sham treatment group. This points up the inherent difficulties in randomization of patients to a sham control when a mechanical therapy is being applied and examined.

Sixty-three percent [63%] of the fifty-five (55) patients that were treated with VAX-D therapy achieved success according to the study parameters. VAX-D Therapy provides a primary treatment modality for the management of pain and disability for patients presenting in acute distress from low back pain.

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