Short and Long-Term Outcomes Following Treatment with VAX-D For Patients With Chronic, Activity-Limiting Low Back Pain

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Abstract

One hundred and eighteen patients treated with the VAX-D Therapy protocol were examined for pain reduction and activity modifications at end of treatment (discharge date), at one month and at six months, using the Roland Morris Questionnaire methods. All subjects exhibited radiological evidence of herniated intervertebral disc at one or more levels, and had chronic activity-limiting pain that was refractory to previous non-operative procedures. Statistically significant improvements in pain and activity scores were recorded at short and long term follow-up for patients with unfavorable prognosis for recovery from chronic activity-limiting low back pain.

Introduction

This study was done to determine outcomes following treatment with the VAX-D protocol from a sample of patients with chronic low back pain that had been refractory to at least two (2) previous non-operative procedures.

Number of Subjects

One hundred and eighteen subjects with chronic, activity-limiting low back pain enrolled in the study. All subjects had radiological or spinal imaging findings of a herniated intervertebral disc at one (1) or more levels of the lumbar spine.

Materials and Methods

Reports of pain (numeric rating scale 0-10) and activity-limitation (Roland Morris Questionnaire 0-24) were used as primary outcome measures. Subjects received an eight (8) week course of VAX-D treatment consisting of five thirty-minute sessions per week for four (4) weeks, followed by one thirty-minute session per week for four additional weeks. Follow-up measures were obtained at discharge and at thirty (30) and one hundred and eighty (180) days following discharge.

Results

Ninety-six (96) subjects completed the entire treatment protocol. Complete follow-up data were available for sixty-seven (67) subjects. An intention-to-treat analysis was used to account for those subjects lost to follow-up. Significant improvements were noted for both dependent variables at discharge, and thirty (30) and one hundred and eighty (180) post-discharge. The pre-intervention group mean for average pain intensity (N=118) was 6.03/10. At one hundred and eighty (180) days following intervention the mean score improved by –1.51 [95% Confidence Interval = (1.05-1.98)], P = .00, effect size 0.88). The pre-intervention

group mean for the Roland Morris Questionnaire (N=118) was 13.18. At one hundred and eighty (180) day follow-up the mean score improved by – 5.41 [95% Confidence interval = (3.83- 6.23), P=.00, effect size 1.07].

Conclusions

Following a conservative intention to treat analysis, statistically significant improvements were noted in average pain and the Roland Morris scores at short and long-term follow-up, although for the Roland Morris questionnaire the minimal detectable change score was within the 95% confidence interval for mean improvement at one hundred and eighty (180) days.

Clinical Relevance

The VAX-D is a low risk, non-invasive form of pelvic distraction that is administered with the patient in the prone position. Although its utilization in clinical settings has been growing, we need more evidence that describes outcomes following this intervention.

This study provides preliminary evidence that the VAX-D protocol is associated with improvements in pain and activity-limitation in a sample of patients with unfavorable prognosis for recovery from chronic activity-limiting low back pain. Further study is needed using randomized comparison groups.

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