PROSPECTIVE RANDOMIZED CONTROLLED STUDY OF VAX-D AND TENS FOR THE TREATMENT OF CHRONIC LOW BACK PAIN

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Abstract Low back pain is one of the most significant medical and socioeconomic problems in modern society. The purpose of this randomised controlled trial is to address the question of efficacy and appropriateness of VAX-D (Vertebral Axial Decompression) Therapy, a new technology that has been shown in clinical research to create negative intradiscal pressures, and has been shown to be effective in treating patients presenting with chronic low back pain (>3 months duration) with associated leg pain. Successful outcome was defined as a 50% reduction in pain utilising a 10cm Visual Analogue Pain Scale and an improvement in the level of functioning as measured by patient-nominated disability ratings. Patients were randomly assigned to VAX-D or to TENS which was used as a control treatment or placebo. The TENS treatment demonstrated a success rate of 0% while VAX-D demonstrated a success rate of 68.4% (P<0.001). A statistically significant reduction in pain and improvement in functional outcome was obtained in patients with chronic low back pain treated with VAX-D.

Summary Chronic low back pain is increasing faster than any other disability, and 5-7% of the population will report their back problems as being a chronic illness. Fifty percent of work loss caused by back pain is accounted for by duration of disability for longer than 4 weeks. Today's primary care practitioners have a comprehensive responsibility in the management of their patient's low back conditions, and they must be aware that recurrences after the presenting episode are likely.

If the disc is a major source of low back pain then applying specific target therapy for the treatment of disc pathology should improve patient outcomes. VAX-D is a primary, non-surgical treatment for the management of patients with disabling low-back pain and neurological symptoms associated with herniated and degenerative disc disease. Research has shown that the VAX-D table is a decompression device that is capable of reducing intradiscal pressures to negative levels.

Successful reduction of intradiscal pressures with VAX-D represents a technological advance that should provide a means of addressing compressive disc pathology. Creating negative intradiscal pressure is likely to affect both the biomechanical and biochemical causes of discogenic pain. Patients suffering from discogenic pain and/or associated sciatic pain are seeking conservative treatment without the risks associated with injections and surgical procedures.

VAX-D incorporates advanced technology that permits the application of distractive tensions without eliciting reflex muscle guarding. Conventional traction devices have not demonstrated this ability or the ability to reduce intradiscal pressures to negative levels. Studies published in the medical literature report that intradiscal pressure either remains unchanged or increases during traction. It has also been demonstrated that paraspinal muscles are not able to fully relax during conventional traction.
The beneficial effects of VAX-D decompression in the relief of peripheral nerve dysfunction has been previously reported in the literature, and a multi-center outcome study reported that VAX-D treatment was successful in 71% of the 778 cases studied.

In association with Quintiles, the world's largest health care consultancy organization for data analysis in clinical trials, a protocol was developed and then approved by the Human Research Ethics Committee at the University of Wollongong, New South Wales, Australia. The instruments for determination of these outcomes were supplied by the National Musculoskeletal Initiative of Australia. The study itself was to be conducted in the medical clinics of the VAX-D Spinal Institute and so to prevent bias in the data collection Quintiles were engaged to collect and analyse the data. TENS was selected as an appropriate placebo treatment as a means of establishing a plausible but ineffective control for an unblinded treatment.

Forty-four patients with chronic low back pain greater than 3 months in duration, with associated leg pain, and a confirmed disc protrusion or herniation on CT Scan or MRI were selected and randomised into the two treatment methods, either VAX-D or TENS. The patients were randomised in sequential order and treatments were determined by a predefined central randomisation list. The average duration of pain in the patient population was 7.3 years.

Successful reduction of intradiscal pressures with VAX-D therapy represents a technological advance in lumbar spinal treatment and is likely to affect both the biomechanical and biochemical causes of discogenic pain.

The results from this study demonstrate that VAX-D is an effective treatment for the management of patients with chronic low back pain and is significantly superior when compared to TENS therapy. Analysis of the data demonstrated an attributable success rate of 68.4% for VAX-D. These findings are consistent with earlier studies by Gose E, Naguszewski W, Naguszewski R. At six-month follow-up, of the 13 successful cases, 2 have been lost to follow-up, 1 case suffered a significant other injury and of the remaining 10, seven have shown sustained success (ie. they still meet the criteria for successful outcome).

The results of this prospective study demonstrated that VAX-D can achieve a statistically significant improvement in pain and functional outcome in managing patients suffering from disc related chronic low back pain.