

MTG Newsletter

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Special Report VAX-D

Eight out of ten adults will have a low back problem at some time in their life, and most will have more than one acute episode. Within the first two to three months of symptoms, surgery should be considered only when spinal pathology (or nerve root dysfunction) due to a herniated lumbar disc is demonstrated. Disc herniation is characterized by protrusion of the central nucleus pulposus through a defect in the outer annulus fibrosis. It may trap a nerve root causing irritation, leg symptoms and nerve root dysfunction. MRI's may show the presence of a herniated lumbar disc, but that does not imply nerve root dysfunction. Asymptomatic adults, when studied, commonly demonstrate intervertebral disc herniations that apparently do not entrap a nerve root or cause symptoms. These patients rarely benefit from a surgical consultation or surgery.

The human spine (or backbone) is made up of small bones called vertebrae which are stacked on top of each other to form a column. Between each vertebrae is a cushion known as a disc. The lower part of the back holds most of the body's weight and even a minor problem with the bones, muscles, ligaments, or tendons can cause pain when a person stands, bends, or moves around. A problem with a disc, however, can pinch or irritate a nerve from the spinal cord, causing pain that moves down the leg (sciatica). If sciatica is both severe and disabling, persists without improvement for longer than four weeks or with extreme progression and there is strong physiologic evidence of dysfunction of a specific nerve. The human spine (or backbone) is made up of small bones called vertebrae which are stacked on top of each other to form a column.

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Of the 80% of people with low back pain, 50% are working-age and this affliction is the most common cause of disability for persons under the age of 45. About one percent of the U.S. population is chronically disabled because of back problems at any given time, and another one percent are temporarily disabled.

Low back problems are expensive. It is difficult to assess or calculate the total cost to society, but there is strong evidence that both economic and psychosocial costs are substantial. For instance, low back problems are the second most common symptomatic reason expressed by patients for office visits to primary care physicians. They are the most

common reason for visits to orthopedic surgeons, neurosurgeons, and occupational medicine physicians. They rank third among the reasons for surgical procedures.

Although medical costs are astronomical, loss time from work as well as the disability payments for Worker's Compensation, can cost up to three times as much as medical treatment. Various estimates of the total annual societal cost of back pain in the United States range from \$30 to \$60 billion. The inability to function normally at work and in other daily activities has an impact on both patients and their families as well.

Diagnostic/treatment variations imply a lack of consensus about appropriate assessment and treatment of back problems, suggesting that some patients are receiving inappropriate or suboptimal care. Some patients appear to be more disabled after treatment than before (Failed Back Syndrome etc.) which is another indicator. The most obvious of these indicators is evidence of repeat surgical procedures that rarely lead to improved outcomes. There are documented examples of patients who have had as many as 20 spine operations. But surgery is not the only treatment that can lead to increased disability. Methods such as extended bed rest or extended use of high-dose opioids can prolong symptoms and further debilitate patients. Although the existing literature has shortcomings, there is sufficient scientific evidence for a number of conclusions about the efficacy and safety of current assessment and treatment methods.

Non interventional modalities used as standards of care are also used inappropriately for some low back problems. Manipulative techniques for mechanical low back pain associated with posterior facet syndrome or muscle strain have not been found as useful in the management of herniated or degenerated lumbar discs, according to the literature.

Similarly, other modalities including ultrasound, electrical stimulation, short-wave therapy, acupuncture, steroids, anti-inflammatory agents, and muscle relaxants can fall short of treating underlying problems associated with intervertebral disc lesions. None of these methods relieve the pain from neuro-compression or from the stimuli associated with a prolapsed nucleus pulposus.

Since MTG receives so many claims dealing with patients suffering from disc pathology, our Technology Assessment Division felt it prudent to study the literature for various treatment modalities in order to better evaluate the medical necessity of these types of claims. We particularly chose to study the effects of Vertebral Axial Decompression on intradiscal pressure since reports from various providers have been so positive on the use of VAX-D therapy as an effective means of decompression for the management of patients suffering from herniated and/or degenerative lumbar discs.

Additionally, we found that many patients were being rushed to surgery when they were not candidates for surgery. For these patients, a non-surgical alternative is necessary - one that offers an effective means of returning the patient to a functional level of activity. A search of the literature in the National Library of Medicine revealed several important studies into the effect of Vertebral Axial Decompression on intradiscal pressure. One of the best studies was conducted by the Department of Neurosurgery and Radiology, Rio Grande Regional Hospital, McAllen, and Division of Neurosurgery, Health Sciences Center, University of Texas. In this study, intradiscal pressure measurement was performed by connecting a cannula inserted into the patient's L4-5 disc space to a pressure transducer. The patient was placed in a prone position on a VAX-D therapeutic table and the tensionometer on the table was attached via a pelvic harness.

Changes in pressure were recorded at resting state and while controlled tension was applied by the equipment in the pelvic harness. Intradiscal pressure demonstrated an inverse relationship to the tension applied and tension in the upper range was observed to decompress the nucleus pulposus significantly, to below -100 mm Hg. The results of this study indicated that it was possible to lower pressure in the nucleus pulposus of herniated lumbar discs to levels significantly below the 0 mm Hg when distraction tension was applied according to the protocol described for Vertebral Axial Decompression therapy. In another study, "The efficacy of traction for lumbar back pain: design of a randomized clinical trial" by Beurskens, et al, motorized, continuous traction was compared to sham or low-dose traction. Primary measures were the patient's global impression of the effect and severity of three main complaints.

Secondary effect measures were functional status, pain, range of motion, work absence and recurrences. The effect measures were rated before the patients were randomly divided into treatment groups, at four weeks, 12 weeks, and six months later.

Other studies have been conducted worldwide with similar results: vertebral axial decompression was found to significantly reduce symptoms and return the patient to work at an earlier date than other modalities, recurrence, for compliant patients, was also significantly reduced. An interesting finding of all studies was that patient identification/selection was most important in those most likely to benefit from this modality.

VAX-D THERAPEUTIC DEVICE

The VAX-D (Vertebral Axial Decompression) therapeutic table was designed by Allan Dyer, M.D., Ph.D., Phm.B., former Deputy Minister of Health in Canada and pioneer of the heart defibrillator. As is often the case, Dr. Dyer himself suffered a herniated disc. After conventional therapy failed, Dr. Dyer formulated the theories that led to a six-year collaboration in the design of the VAX-D Table. The initial clinical trial was done at University Hospital in London with subjective indices of pain and disability recorded daily along with analgesic use. Neurological dysfunction was assessed on a weekly basis. The research protocol, under the supervision of the Neurosurgical Department, assessed the degree of remission attained after ten daily therapy sessions. Seventy percent of the patients achieved a significant remission of their symptoms as measured using the Oswestry Pain and Disability Index. This parallels the success rate reported for patients with subligamentous lumbar herniations, treated surgically with percutaneous discectomy. Although percutaneous discectomy is not recommended for cases with extruded hernias, 11% of the patients treated successfully with VAX-D showed extruded segments on their MRI. A follow-up study of patients a year later did not uncover any unexpected level of relapse. These findings were reinforced by comparisons of pre and post MRI films taken on successfully treated patients which provided radiological evidence of a reduction in the size and extent of some of the subligamentous herniations after therapy.

Of the patients diagnosed with degenerative disc disease, decompression of the intervertebral disc created a beneficial diffusion gradient in excess of 150mm Hg., between the disc and the adjacent

vertebral bodies, which facilitates rehydration of the disc.

VAX-D utilizes a patented hand-grip method of restraining the upper body while the pelvic belt is attached to the movable tensionometer housing. The divided table provides for progressive distraction between the pelvic girdle and the fixed shoulder girdle under controlled parameters determined by the logic control system. The degree of intervertebral distraction and subsequent decompression level achieved is maximum at the lower levels and decreases gradually toward the upper levels of the lumbar column. Intradiscal pressure measurements on patients undergoing this therapy have shown that the extent of decompression measured in mm Hg. follows an inverse relationship to the tension applied to the pelvic belt during therapy. This relationship and the precise control provided by the VAX-D table enables a therapist to focus decompression to the level of the anatomical defect.

PATIENT SELECTION/TREATMENT PARAMETERS

Any disc problem except a rupture, unstable spondylolisthesis, and/or other related fractures of the pelvis can be treated with the VAX-D modality. Diagnosis should be confirmed by CAT scan or MRI and treatment referrals made by specialists in orthopedics, internal medicine, neurology, neurosurgery, physiatry, and physicians at pain or rehab clinics.

Each treatment session averages 30-45 minutes in duration. Research has established that optimum clinical results are achieved with sessions consisting of 10 to 20 decompression-relaxation cycles administered once or twice daily. Most patients with low back pain syndrome achieve relief of pain while undergoing therapy and require, on average, one session each day for 10 to 20 sessions to attain remission of debilitating symptoms. The number of sessions depends on the severity of the underlying condition. Herniated discs generally respond within 10 - 20 sessions while patients with degenerated discs may need ongoing therapy at regular intervals to remain pain free. Patients with posterior facet syndromes, however, usually achieve complete remission with fewer than 20 sessions.

Although research has demonstrated remission in the majority of patients using the VAX-D Table, individuals whose lifestyle or work environment tends to expose them to higher risk factors have

found that occasional follow-up sessions offer protection against disabling exacerbations. Patients in this category, according to outcome studies, often develop a sensitivity to the need for return sessions.

The use of VAX-D in conjunction with Percutaneous Discectomy, is not contraindicated and has been tested in patients that continue to complain of post surgical low back pain. The impression gained during clinical trials was that the dual approach offers more than one level of herniation in which only the major segment was excised percutaneously. Patients with a history of previous laminectomy may be undertaken when the extent of surgical excision has not compromised the vertebral articulations and ligament structures.

As part of the overall therapeutic protocol in the management of patients suffering from low back pain, certain pharmacological and physical modalities have been found to be of value as adjuncts to vertebral axial decompression therapy. The routine use of anti-inflammatory medications adds to a patient's comfort level and assists them to maintain a regular treatment regimen and facilitates recovery. The relief of associated localized soft tissue inflammations and irritation during treatment is a rationale for prescribing NSAIDS. Since intradiscal pressures are reduced substantially to negative levels during VAX-D therapy, creating diffusion gradients in excess of 200 mm Hg. across vertebral end plates, clinical researchers proposed that this diffusion gradient facilitates migration of serum levels of anti-inflammatory compounds into intervertebral spaces and to the site of the intervertebral lesions.

Calcium supplements (an essential element in the progress of skeletal muscle relaxation) is especially important for the paravertebral muscles ("strut") that have a tendency to react with spasms to painful lumbar stimuli. Calcium supplements reduce the incidence of spasms when their daily intake exceeds 800 mg.

Pelvic support belts are necessary for patients who must travel any distance or may be subject to acceleration and deceleration forces in transit. They should also be worn when any postural strain is felt or anticipated as well as whenever the patient engages in activities that may evoke lumbar flexion or rotational movements during the period of time they are on a course of VAX-D therapy.

Lastly, physical therapy modalities of hot or cold packs, interferential electrical stimulation, ultrasound and massage are designed to provide muscle relaxation to those patients experiencing muscle spasms during the sessions. Home exercise programs taught to patients to strengthen the abdominal and paravertebral muscles must be limited to positions that do not cause flexion of the lumbar spine. In the post treatment period, patients treated for posterior facet syndromes are usually able to resume full activities immediately. For the more serious lumbar dysfunctions that involve intervertebral discs such as herniation and/or degenerative disc disease, one or two months should pass before engaging in body contact sports or strenuous work and recreational activities.

DETERMINATION

Researchers in the clinical trials on the fully automated and computerized VAX-D device revealed that their patient population was referred to a neurosurgical department because they had failed to respond to other non-interventional therapies. Coupled with modern imaging technology that recorded modifications in the extent of herniated discs with VAX-D therapy, no other non-interventional means of treating low back pain, mechanical or otherwise, has shown such promise.

MTG recommends the FDA approved VAX-D therapy for those patients who meet patient selection criteria. MTG is researching cost comparisons of outpatient VAX-D therapy to hospital and surgical decompression and other procedures and will publish that data in our September issue. We will also discuss coding and reasonable charge for this therapy.