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SPECIAL REPORT

VAX - D OUTCOME STUDY RESULTS

In August 1995, MTG reported on a new technological advance for the non-invasive treatment of low back pain and referred leg pain VAX-D therapy. This article was followed by a discussion of reimbursement guidelines in our September 1995 issue. We now report on data derived from twenty-two medical centers involving approximately 900 patients and the clinical effectiveness of the VAX-D therapy.

For most patients, the cause or causes of persistent low back pain remains poorly understood. Although CT and MRI procedures are able to accurately define structural pathology, clinical correlation of these findings to back pain physiology and subjective complaints is often imprecise. The common usage of surgical decompression, epidural blocks, spinal instrumentation, etc., is thought to help patients suffering from back pain, but it stems from the assumption that demonstrated pathologies are the primary source of that pain. However, often the biomechanical function of the disc and the back pain dysfunction remains physiologically unaddressed. As a result, we have repeat surgeries, long-term pain therapies, and disability because patients are unrelieved of their suffering.

The causes of mechanical low back pain will likely include degenerative disc disease; degenerative spondylosis with limitation of range of motion; facet arthropathy; relative lateral recess stenosis; micro-environment pressure changes affecting the thecal and epidural space from disc bulging; subligamentous and/or extruded herniation; and segmental instability. Mechanical low back pain is generally aggravated with activity that increases axial loading on the spine. Examples of this are exacerbation with sitting, standing, and lifting. Patients often describe slight relief with walking or lying down; as such, the spine is unloaded and intradiscal pressure is reduced.

In theory, lumbar traction should be successful in alleviating many of the conditions which cause low back pain and associated radiculopathy. However, a review of the literature, and there are many published articles on this subject, show that studies of clinical efficacy have yielded equivocal results. Lumbar traction cannot achieve decompression due to the design of the mechanical device and overall patient tolerance (Mathews J.A.: "Dynamic Discography: A Study of Lumbar Traction", Annals of Physical Medicine Vol IV, No. 7, 275-279). Technological advances have led to the development of equipment that can achieve, in vivo, decompression of lumbar discs without stimulating reactive reflexes of the lumbar musculature that can overcome efforts to effectively distract (stretch) vertebral bodies.

Judovich (Judovich B.D.: Lumbar Traction Therapy-Elimination of Physical Factors that Prevent Lumbar Stretch", JAMA October 8, 1955; 159(6) 549-550) found that a force of 26 percent of body weight is needed to be applied in order to overcome the resistance between the patient and the table. Patients had difficulty tolerating the needed forces to relieve pain if delivered continuously. Also, the thoracic corsets worn by patients to prevent movement on the table were uncomfortable, restricted respiration, and compromised venous return to the heart.

The VAX-D split table design eliminates frictional resistance between the patient and the table and allows controllable tensions to be applied to the lumbar vertebral column. The patented system is engineered to apply distractive forces in a gradual, progressive fashion and are designed to achieve optimum distraction of the resistance. The therapy is administered via an automated logic control mechanism which systematically applies tensions and rest periods in cyclic fashion.

The patient's upper body is fixed by means of the patient grasping adjustable hand grips, designed to eliminate the use of the thoracic corset and thereby eliminating the risk of circulatory or respiratory compromise. The pelvis is secured with a specially designed harness that adjusts snugly and allows forces to be applied primarily to the lateral pelvic alae thus minimizing anterior-posterior pressures and reactive muscle spasm during the distractive period of each cycle. Thus, VAX-D treatment effectively decompresses the nucleus pulposus to pressures below minus 100 mm Hg., is well tolerated by patients, and provides effective lumbar traction (Ramos G., Martin W.: "Effects of Vertebral Axial Decompression on Intradiscal Pressure", Journal of Neurosurgery Vol 81, September 1994).

VAX-D OUTCOME STUDY

Following two separate FDA approvals (one for the device and one for the safety and efficacy of the treatment/decompression), 22 medical centers were asked to collect data on all patients who received VAX-D therapy for low back pain. The purpose of the study was to assess the efficacy of Vertebral Axial Decompression Therapy in the treatment of low back pain resulting from documented lumbar disc disease.

The patients ranged in age from 25 to 60 years at the treatment onset and they were followed from one to two years. All patients had failed prior attempts at treatment which included physical therapy, acupuncture, chiropractic care, epidural injections, and in some cases, surgical intervention. All patients had documented chronic back pain and pathology was found on MRI or radiographic images. Use of a "double blind" type of study was not practical as patients very early in the study would guess whether they were part of the "sham" group receiving only regular traction or part of the VAX-D therapy group. An earlier study in Canada designed to be "double blind" soon found that patients refused regular traction as they discerned or discovered that they "were not getting the better treatment".

If treatment success is defined as a reduction in pain to 0 or 1 on a 0 to 5 scale, the treatment was successful in 75% of the patients. The success rate varied from 67 % for the patients with extruded

The study was divided into five diagnostic groups which were comprised of patients with extruded herniated discs; multiple herniated discs without extrusion, with or without degenerative disc disease; single herniated disc, regardless of degenerative disease; degenerative disc disease, without herniation; and facet syndrome.

Each patient chose a subjective pain index ranging from 0 to 5 (5 being severe pain) and a disability index of 0 to 3 (3 being bedfast). Each was also assessed for objective signs of decreased mobility on a 0 to 3 scale (3 being completely immobile). They were assigned by diagnosis into one of the above five groups.

All patients received VAX-D Therapy of at least 10 sessions plus additional treatments if the patient continued to improve. Patient history, schedule, including frequency and intensity of therapy, was recorded along with patient symptoms and satisfaction with treatment. Measurements were made at the beginning, mid-point, and end of treatment.

Success rates for herniated discs was 74%, 77% for patients with degenerative disc disease or single herniated discs. It was 71% for people with multiple herniated discs and 70% for facet syndrome.

On a pain scale of 0 (none) to 5 (severe), the people with extruded herniated discs had an average pain of 4.19 at the beginning of treatment and an average of 1.33 after treatment, a reduction of 68%. The cases of multiple herniated discs went from 4.15 to 1.17, a reduction of 72%. The patients with a single herniation had a reduction from 4.14 to 1.08, or 74%. The degenerative disc cases went from 3.94 to 1.03, a 74% reduction. Those with facet syndrome went from 4.10 to 0.97, a 76% reduction in pain.

In summary, the data on mobility and ADL appear to correspond to pain results and it appears that approximately 20 treatments with VAX-D Therapy has been proven to be effective in about three-fourths of all patients who have any combination of these types of disc disease.

MTG would like to thank the authors (Dr. Earl Gose, Professor of Bioengineering, University of Illinois at Chicago, and neurologists William Naguszewski, M.D. and Robert Naguszewski, M.D. of the Coosa Medical Group, Rome, Georgia), for allowing us to report some of their preliminary study results. Their complete findings will be included in the final paper to be published in the Journal of Neurological Research.

REIMBURSEMENT ISSUES

VAX-D Therapy has not yet been included in CPT, but it is our understanding that efforts are underway in the request for a new code. Until such time physicians performing this modality are using an unlisted code (Physical Medicine, Code 97799 -Unlisted physical medicine/rehabilitation service or procedure). Code 97039 (Unlisted modality that requires direct one on one patient contact by the provider - specify type and time if constant attendance) may also be appropriately used.

MTG does not consider VAX-D Therapy to be investigational; it has two separate FDA approvals and has been used to successfully treat patients by various providers around the country and in Canada during the past three or more years.

In adjudicating a claim for VAX-D Therapy, it is MTG's recommendation that claims personnel should review the claim (s) for the following documentation:

All listed diagnoses should be confirmed by MRI/x-ray. Relevant ICD-9 Codes are: 715.9, 722.1, 722.10, 722.52. 723.0, 723.1, 724.02, 724.06, 724.3, 724.9, 729.2. 739.3, 782.0, and 722.83;

Complete description of treatment regimen, speciality of prescribing physician, diagnosis, length of treatment, etc. should accompany any use of an unlisted code.

Other Physical Medicine modalities such as hot/cold packs (97010) and electrical stimulation (97032) may be useful before or after each VAX-D Therapy session. Some discomfort may be associated with this therapy and physicians have found the above or similar modalities helpful in reducing such discomfort. These codes are appropriately billed on the 1500 in addition to the unlisted code for the VAX -D Therapy.

The use of Code 97012 for the VAX-D Therapy is inappropriate. This code indicates "unattended traction, 15 minutes" and this modality has no similarity to the VAX-D device and subsequent treatment using this device. Traction, as the literature notes, does not effect the same result as the VAX-D table; traction is for 15 minutes, VAX-D approximately 45 minutes. VAX-D is an attended modality and calculations must be made for each patient before his/her therapy session. Ordinary traction does not achieve decompression. The literature reports that significant decompressive force develops as the VAX-D Therapeutic Table develops forces over 40 pounds. Once in therapeutic range of 60 to 100 pounds, VAX-D therapy develops negative intradiscal pressures of negative 150 to 250 mm mercury (Ramos et al).

Calculated Relative Value units for this therapy would be approximately 13.0 per session or a converted national average of $133 plus the indicated geographical locale factor. Chicago, for instance, has a geographical locale factor of 1.21; therefore, $133 x 1.21 = $157.30. For an average 20 sessions per patient treatment plan, as indicated in the Outcome Study results, a total treatment cost of $3146 would be usual and customary for a patient being treated in the Chicago city area. Compared to the overall cost of surgical intervention, or long-term pain/disability reimbursement, this treatment appears to be very cost-beneficial.

An MD in an appropriate speciality should prescribe VAX-D Therapy (ie neurologist, orthopaedist, neurosurgeons, internists, physiatrists, pain clinic specialists, or anesthesiologists);