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Medical Policy Manual

Topic: Vertebral Axial Decompression

Date of Origin: April 1998

Section: Medicine

Last Reviewed Date: March 2014

Policy No: 45

Effective Date: June 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Vertebral axial decompression is a type of spinal traction that has been investigated as a technique to reduce intradiscal pressure and relieve pain associated with herniated intervertebral discs or degenerative disc disease. The therapy may also be called axial spinal distraction or motorized spinal traction, and the devices used for the therapy may also be referred to as power or motorized traction equipment.

A pelvic harness is worn by the patient. The specially equipped table on which the patient lies is slowly extended, and a distraction force is applied via the pelvic harness until the desired tension is reached. This is followed by a gradual decrease of the tension, and the cycle is repeated. The cyclic nature of the treatment allows the patient to withstand stronger distraction forces compared to static lumbar traction techniques. The level of tension is individually calibrated and recorded. An individual session typically includes 15 cycles of tension, lasting approximately 30 minutes; 10 to 15 daily treatments may be administered.

Regulatory Status

Several devices used for vertebral axial decompression have received 510(k) marketing clearance from the US Food and Drug Administration (FDA). According to the FDA-labeled indications, vertebral axial decompression may be used as a treatment modality for patients with incapacitating low back pain, and for decompression of the intervertebral discs and facet joints. Numerous devices have received FDA

510k approval as powered traction equipment, including but not limited to the following:

- Accu-Spina System™ (North American Medical Corp.)
- Antalgic-Trak (Spinetronics)
- Decompression Reduction Stabilization (DRS) System (Integra Lifesciences)
- DRX2000, DRX3000, and DRX9000 (Axiom)
- Dynatron 900 (Dynatronics)
- Ever-Trac ET-800 (Everyway Medical)
- IDD Therapy® (Intervertebral Differential Dynamics Therapy)
- Integrity Spinal Care System (Integra Lifesciences)
- Lordex ® Spinal Decompression Unit (Lordex)
- Rich-Mar Spina-Mobilizor (Naimco Medical)
- SpineMED® Decompression System (SpineMED)
- Triton ® DTS ™ / Tru-Trac ® / TX ® Traction System (Chattanooga Group)
- VAX-D ® Therapeutic Table (Vat-Tech, Inc.)

MEDICAL POLICY CRITERIA

Vertebral axial decompression is considered **investigational**.

SCIENTIFIC EVIDENCE[1]

The primary beneficial outcomes of interest for treatments for spinal pain are relief of pain and improvement in the ability to function. These are subjective outcomes that can be influenced by nonspecific effects, placebo response, and the natural history of the disease. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) with sufficient long-term follow-up are required to control for the nonspecific effects and to determine whether any treatment effect from vertebral axial decompression (VAD) provides a significant advantage over placebo/sham treatment or other non-surgical treatment options.

The following discussion is focused on technology assessments and RCTs.

Literature Appraisal

Technology Assessments

A 2007 technology assessment conducted by the Agency for Health Care Research and Quality (AHRQ) conclude that "Currently available evidence is too limited in quality and quantity to allow for the formulation of evidence-based conclusions regarding the efficacy of decompression therapy as a therapy for chronic back pain when compared with other non-surgical treatment options. Of the studies examined for assessment of efficacy, neither included patients over 65 years of age. Adverse event reporting for decompression therapy is infrequent. There was one case report of an enlargement of an existing disc protrusion, and other studies reported worsening of pain in some patients."[2]

Randomized Clinical Trials

Sham-controlled Randomized Trial

Results from a randomized sham-controlled trial of intervertebral axial decompression were published in 2009.[3] Sixty subjects with chronic symptomatic lumbar disc degeneration or bulging disc with no radicular pain and no prior surgical treatment (dynamic stabilization, fusion, or disc replacement) were randomly assigned to a graded activity program with an AccuSPINA device (20 traction sessions during 6 weeks, reaching >50% body weight), or to a graded activity program with a non-therapeutic level of traction (<10% body weight). In addition to traction, the device provided massage, heat, blue relaxing light, and music during the treatment sessions. Neither patients nor evaluators were informed about the intervention received until after the 14-week follow-up assessment, and intention-to-treat analysis was performed (93% of subjects completed follow-up).

Both groups showed improvements in validated outcome measures (visual analog scores for back and leg pain, Oswestry Disability Index, and Short-Form 36), with no differences between the treatment groups. For example, visual analog scores for low back pain decreased from 61 to 32 in the active group and from 53 to 36 in the sham group. Evidence from this recent randomized controlled trial does not support an improvement in health outcomes with vertebral axial decompression.

Other Randomized Trials

Two small randomized studies (n=27 and 64) reported little to no difference between patients treated with or without mechanical traction.[4,5]

Sherry and colleagues conducted a randomized trial comparing vertebral axial decompression (using theVAX-D device) with transcutaneous electrical nerve stimulation (TENS).[6] While a 68% success rate was associated with VAX-D compared to a 0% success rate associated with TENS therapy, without a true placebo control, the results are difficult to interpret scientifically.

Clinical Practice Guidelines

American College of Physicians and the American Pain Society[7]

A joint ACP/APS evidence-based practice guideline for low back pain gave intermittent or continuous traction by any method (i.e., free weights and pulley, motorized equipment, inversion techniques, or overhead harness) a Grade D recommendation, defined as, “[t]he panel recommends against offering the intervention. The panel found at least fair evidence that the intervention is ineffective or that harms outweigh benefits.”

North American Spine Society (NASS)

The evidence-based guidelines from the considered the evidence to be insufficient to recommend the use of any type of traction in the treatment of lumbar disc herniation with radiculopathy[8] and lumbar spinal stenosis.[9]

Summary

Current evidence does not permit conclusions concerning the efficacy of vertebral axial decompression (VAD) on health outcomes. The only randomized trial published to date did not show a benefit of VAD

compared with the sham/placebo control group. In addition, clinical practice guidelines have concluded that there is insufficient evidence on the efficacy of spinal traction by any method including VAD. Therefore, vertebral axial decompression is considered investigational.

REFERENCES

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	None	

CODES	NUMBER	DESCRIPTION
HCPCS	S9090	Vertebral axial decompression, per session