Paraspinal Surface Electromyography to Evaluate and Monitor Back Pain

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POLICY

Paraspinal surface electromyography is considered investigational as a technique to diagnose or monitor back pain.

POLICY GUIDELINES

None.

BENEFIT APPLICATION

BlueCard/National Account Issues

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration-approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

Some plans have reported that this technology has been billed using CPT code 95860-95872, which is an incorrect code range that addresses the use of the needle, not surface electromyography.

Some plans may perform spot audits of claims for needle electromyography to determine whether they represent surface electromyography.

Some plans may have notified their providers that use of surface electromyography would be considered part of the evaluation and management of the patient and thus not coded separately.
BACKGROUND

Back Pain

Back pain is a common condition that affects most individuals at some point in their lives. Identifying the pathogenesis of back pain is challenging, in part due to the complex anatomy of the back, which includes vertebrae, intervertebral discs, facet joints, spinal nerve roots, and numerous muscles. Back pain may be related to osteoarthritis, disc disease, subluxation, or muscular pathologies, such as muscle strain or spasm. Moreover, due to referred pain patterns, the location of the pain may not be anatomically related to the pathogenesis of the pain. For example, buttock or leg pain may be related to pathology in the spine. In addition to the diagnostic challenges of back pain is the natural history of acute back pain.

Diagnosis

Aside from physical examination, diagnostic testing includes imaging technologies, such as magnetic resonance imaging, designed to identify pathology (eg, bulging discs), or tests such as discography to localize the abnormality by reproducing the pain syndrome. However, these tests lack specificity and must be carefully interpreted in the context of the clinical picture. For example, magnetic resonance imaging identifies 5% of asymptomatic patients as having bulging discs. However, the presence of a bulging disc may only be clinically significant if correlated with other symptoms. Assessment of the musculature may focus on a range of motion or strength exercises.

In contrast to anatomic imaging, surface electromyography (SEMG), which records the summation of muscle activity from groups of muscles, has been investigated as a technique to evaluate the physiologic functioning of the back. A noninvasive procedure, SEMG differs from needle electromyography, an invasive procedure in which the electrical activity of individual muscles is recorded. Paraspinal SEMG has been explored to evaluate abnormal patterns of electrical activity in the paraspinal muscles in patients with back pain symptoms such as spasm, tenderness, limited range of motion, or postural disorders. The technique is performed using a single or an array of electrodes placed on the skin surface, with recordings made at rest, in various positions, or after a series of exercises. Recordings can also be made by using a handheld device, which is applied to the skin at different sites. Electrical activity is assessed by computer analysis of the frequency spectrum (ie, spectral analysis), amplitude, or root mean square of the electrical action potentials. In particular, a spectral analysis that focuses on the median frequency has been used to assess paraspinal muscle fatigue during isometric endurance exercises. Paraspinal SEMG has been researched as a technique to establish the etiology of back pain and has been used to monitor the response to therapy and establish physical activity limits, such as assessing capacity to lift heavy objects or ability to return to work.

Paraspinal SEMG is an office-based procedure that may be most commonly used by physiatrists or chiropractors. The following clinical applications of the paraspinal SEMG have been proposed:

- clarification of diagnosis (ie, muscle, joint, or disc disease)
- selection of a course of medical therapy
- selection of a type of physical therapy
- preoperative evaluation
- postoperative rehabilitation
- follow-up of acute low back pain
- evaluation of exacerbation of chronic low back pain
- evaluation of pain management treatment techniques.

Treatment
Most cases of acute low back pain resolve with conservative therapy (eg, physical therapy) while continuing normal activities within limits permitted by the pain. Therefore, initial imaging or other diagnostic testing is generally not recommended unless "red flag" warning signs are present or the pain persists for more than four to six weeks. Red flag findings include significant trauma, history of cancer, unrelenting night pain, fevers or chills, and progressive motor or sensory deficits.

**Regulatory Status**

SEMG devices approved by the U.S. Food and Drug Administration include those that use a single electrode or a fixed array of multiple surface electrodes. Examples include the CMAP Pro (Medical Technologies) and Model 9200 EMG System (Myotronics-Noromed).

Several U.S. Food and Drug Administration-approved devices combine SEMG along the spine with other types of monitors. For example, in 2007, the Insight Discovery (Fasstech) was cleared for marketing through the 510(k) process. The device contains six sensor types, one of which is for SEMG. The indications include measuring bilateral differences in SEMG along the spine and measuring SEMG along the spine during functional tasks. (Earlier Insight models had fewer sensors.) U.S. Food and Drug Administration product code: IKN.

**RATIONALE**

This evidence review was created in August 2000 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through April 1, 2019.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

**Surface Electromyography**

SEMГ has been used as a research tool to evaluate the performance of paraspinal muscles in patients with back pain and to further understand the etiology of low back pain. Preliminary research has also been performed to determine which SEMГ parameters best differentiate patients with and without back pain.

**Clinical Context and Test Purpose**

The purpose of paraspinal SEMГ in patients who have back pain is to identify the pathogenesis of the pain (ie, muscle, joint, or disc disease) to inform a decision on a treatment plan.

The question addressed in this evidence review is: Does paraspinal SEMГ improve the net health outcome in individuals with back pain?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are individuals with back pain.
Interventions
Paraspinal SEMG is a noninvasive technique that aggregates data on muscle activity from groups of muscles. One or more electrodes are placed on the skin surface, and recordings are taken at rest, in various positions, or during a series of exercises.

Comparators
Other noninvasive techniques to assess back pain include a clinical examination and imaging technologies.

Outcomes
The general outcomes of interest are a reduction in back pain and improvement in activities of daily living.

Both false-positive test results and false-negative results can lead to an incorrect recommendation for the type of treatment or no treatment at all. Some treatments are long-term programs, and if individuals are incorrectly referred to the program, more appropriate therapy will be delayed.

Timing
Testing would occur before determining a treatment plan.

Setting
Paraspinal SEMG can be performed in an office setting by physiatrists, chiropractors, or physical therapists.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

No articles that directly compare the results of SEMG (which tests groups of muscles) with needle electromyography (which tests individual muscles) for diagnosing any specific muscle pathology were identified in literature searches. However, the pathology of individual muscles (ie, radiculopathy, neuropathy) may represent a different process than the pathology of muscle groups (ie, muscle strain, spasm), and thus SEMG may be considered by its advocates as a unique test for which there is currently no criterion standard. Nevertheless, even if one accepts this premise, there are inadequate data to evaluate the diagnostic performance of SEMG. In some instances, the asymmetrical electrical activity may have been used to define abnormality; results may be compared with normative data. However, no published literature was identified defining what degree of asymmetry would constitute abnormality.

A study by du Rose and Breen (2016) looked into the relationship between lumbar intervertebral range of motion and paraspinal muscle activity in healthy adults, as measured by SEMG and quantitative fluoroscopy, to establish "normal" measurements.7 Fluoroscopic images and SEMG measurements were taken for 20 men with no history of low back pain (LBP). What would be considered normal intervertebral ranges of motion were related to a diverse set of muscle activation patterns as measured
by SEMG. The authors concluded that larger sample sizes and measurements from patients with LB P would be needed to establish standard criterion.

Absent a criterion standard diagnostic test, correlation with the clinical symptoms and physical exam is critical. De Luca (1993) published a series of studies investigating a type of SEMG called the Back Analysis System, consisting of surface electrodes and other components to measure the electrical activity of muscles during isometric exercises designed to produce muscle fatigue. Using physical exam and clinical history as a criterion standard, De Luca (1993) found that the Back Analysis System accurately identified control and back pain patients 84% and 91% of the time, respectively, with the values increasing to 100% in some populations. (Accuracy was defined as the sum of true-positive and true-negative results.) However, these studies were not designed as a clinical diagnostic tool per se but were intended to investigate the etiology of back pain and to investigate muscular fatigue patterns in patients with and without back pain.

Hu et al (2010, 2014) in Hong Kong, published 2 articles on dynamic topography, an approach to analyzing SEMG findings. Both studies included patients with LBP and healthy controls; all participants underwent SEMG at study enrollment and then back pain patients participated in a rehabilitation program. The first study found different dynamic topography at baseline between the healthy people and back pain samples (a more symmetric pattern in healthy controls). After physical therapy, the dynamic topography images of back pain patients were more similar to the healthy controls on some of the parameters assessed. In the second study, following rehabilitation, back pain patients were classified as responders or nonresponders based on changes in back pain severity. Some associations were found between baseline SEMG parameters and response to rehabilitation. SEMG was not repeated after the rehabilitation program, and thus it is unclear whether there are any significant associations between continued symptoms and SEMG abnormalities. Moreover, it is unclear how SEMG analysis would affect treatment decisions for patients with LBP.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

A number of studies have described SEMG as an aid in classifying LBP. Most of this research has focused on the use of SEMG to assess muscle fatigability rather than on how information from test findings could enhance patient management. While SEMG may be used to document muscle spasm or other muscular abnormalities objectively, it is unclear how such objective documentation would supplant or enhance clinical evaluation, or how this information would be used to alter the treatment plan. In part, the difficulty in clinical interpretation is understanding the extent to which the SEMG abnormalities are primary or secondary. Additionally, as noted in the Background section, no specific workup is recommended for acute LBP without warning signs.

The following studies have proposed using SEMG results to inform treatment decisions; however, none provided data to validate whether treatment based on SEMG results in improved outcomes.
In a study of patients with chronic LBP (n=216) by Kienbacher et al (2016), SEMG showed potential to discriminate between impaired and unimpaired neuromuscular regulation of back extensors, which would provide useful information for designing individualized exercise programs.14

In a study of patients with LBP (n=27) and pain-free controls (n=23) by Schabrun et al (2017), SEMG detected a loss of discrete motor cortical organization of the paraspinal muscles among those with LBP.15, The invasive technique of needle electromyography is usually performed to detect this pathology. Patients with cortical reorganization may benefit from motor skill training.

In 2 older studies (1988, 1992), SEMG was shown to differentiate muscle spasm from muscle contracture.16,17 Muscle spasm would be treated with relaxation therapy, and contracture would be treated with stretching exercises.

**Chain of Evidence**

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Current evidence on clinical validity does not permit construction of a chain of evidence to support the use of SEMG as a diagnostic tool for evaluating and monitoring back pain.

**Summary of Evidence**

For individuals who have back pain who receive paraspinal SEMG for evaluation and monitoring, the evidence includes several nonrandomized studies on using findings to classify back pain. The relevant outcomes are test accuracy and validity, symptoms, functional outcomes, quality of life, and resource utilization. There have been no studies directly comparing SEMG with other noninvasive techniques for evaluating back pain, and standard criteria for normal and abnormal SEMG measurements have not been determined. SEMG has been proposed as a noninvasive technique providing objective measurements that would inform treatment decisions in patients with back pain. While studies have shown that SEMG results have detected different pathologies in patients with back pain, none of the studies reported health outcomes. There is also no data on the impact of SEMG for managing patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

American College of Occupational and Environmental Medicine

Guidelines from the American College of Occupational and Environmental Medicine (2011) did not recommend surface electromyography as a technique for diagnosing low back disorders, based on insufficient evidence of efficacy.19

American Pain Society

The American Pain Society (2009) issued guidelines on the evaluation and management of low back pain.20 When discussing the diagnostic accuracy of nonimaging tests, the guidelines stated that "There is no evidence supporting the use of thermography or surface electromyography for diagnosis of low back pain (level of evidence: fair)."

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**
Paraspinal Surface Electromyography to Evaluate and Monitor Back Pain

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in May 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**ESSENTIAL HEALTH BENEFITS**

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

**REFERENCES**


**CODES**

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