Surface Electromyography (SEMG) Including Paraspinal SEMG

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Next Review: April 2018
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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

Surface electromyography (SEMG) is a non-invasive, computer-based procedure, most commonly used in an office setting to assess muscle function by recording muscle activity from above the muscle on the skin surface.

MEDICAL POLICY CRITERIA

Note:
This policy addresses only the use of surface electromyography alone or in combination with other services. See the Cross References below for additional gait analysis criteria not specifically addressed in this policy.

Dynamic surface electromyography (SEMG), including paraspinal SEMG, is considered investigational for all indications, including but not limited to any of the following:

A. Diagnosing and monitoring of back pain
B. Evaluation of myoclonus
C. Component of gait analysis
SEMГ includes a scanner with surface electrodes that record electrical impulses of nerves at rest (i.e. static) and during activity (i.e. dynamic) in order to characterize the electrical potential of a specific muscle or group of muscles. Electrical activity can be assessed by computer analysis of the frequency spectrum (i.e., spectral analysis), amplitude, or root mean square of the electrical action potentials.

Unlike needle electromyography (NEMГ), SEMГ utilizes electrodes that record from a wide muscle area, have a relatively low frequency band, low signal resolution, and are highly susceptible to movement.[1] SEMГ has been proposed as a diagnostic tool in patients with various degenerative, neuromuscular or motor control disorders such as: back pain, intervertebral disc disease, soft tissue injury, temporomandibular joint dysfunction (TMJ), bruxism (teeth grinding), nerve root irritation, and scoliosis.

PARASPINAL SEMГ

Like SEMГ, paraspinal SEMГ is performed using a single or multiple 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. Spectral analysis focusing on the median frequency has been used to assess paraspinal muscle fatigue during isometric endurance exercises.

Paraspinal SEMГ is typically performed by physiatrists or chiropractors as a technique to evaluate the physiological functioning of the back, specifically the function of the paraspinal muscles. This technique has been intended for use in patients with back pain symptoms such as spasm, tenderness, limited range of motion, or postural disorders, particularly as it relates to assessing the patient’s capacity to lift heavy objects, or the ability to return to work.

The following clinical applications of paraspinal SEMГ have been proposed:

- Clarification of a diagnosis (i.e., muscle, joint, or disc disease)
- Selection of a medical therapy course
- Selection of a physical therapy plan
- Pre-operative evaluation
- Post-operative rehabilitation
- Follow-up evaluation of acute low back pain
- Evaluation of exacerbation of chronic low back pain
- Evaluation of pain management treatment techniques

REGULATORY STATUS

SEMГ devices approved by the U.S. Food and Drug Administration (FDA) include those that use a single electrode or a fixed array of multiple surface electrodes. Several FDA-approved devices combine SEMГ with other types of monitors.
Surface and paraspinal surface electromyography (SEMG) have been proposed as a research tool to evaluate the performance of nerves and muscles in patients with neuromuscular disorders, as a component of gait analysis, and to further understand the etiology of the resulting symptomatology, such as pain. However, validation of its use as a clinical diagnostic technique involves a sequential three-step procedure as follows:

1. **Analytical Validity** - of a device is typically assessed by studies that compare test measurements with a gold standard, and those that compare results taken with the same device on different occasions (“test-retest”).

2. **Clinical Validity** - is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with the gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true positive), while specificity indicates the ability to detect patients who are suspected of disease but who do not have the condition (true negative). Therefore, evaluation of diagnostic performance requires independent assessment by the two methods in a population of patients who are suspected of disease but who do not all have the disease.

3. **Clinical Utility** - is established when the evidence demonstrates that the diagnostic information obtained from a test can be used to benefit patient management and improve health outcomes. Typically, randomized trials are needed to demonstrate the impact of the test on net health outcomes.

The following discussion focuses on these three steps as they apply to surface EMG, including paraspinal SEMG.

**ANALYTICAL VALIDITY**

Several studies using different SEMG devices have suggested that paraspinal SEMG, in general, is a reliable technique, based on coefficients of variation or test-retest studies,[2-7] or ability to differentiate healthy test subjects from those with back pain.[8-10] These studies use a range of different methodologies and SEMG parameters, and do not address the accuracy or validity of the test. No studies were identified that compared the performance of SEMG to a gold standard reference test.

**CLINICAL VALIDITY**

No articles were identified comparing the results of SEMG (which tests groups of muscles) with needle electromyography (which tests individual muscles) for diagnosing any specific muscle pathology. It is recognized that the pathology of individual muscles (i.e., radiculopathy, neuropathy, etc.) may represent a different process than the pathology of muscle groups (i.e., muscle strain, spasm, etc.); thus, SEMG may be considered by its advocates as a unique test for which there is currently no gold standard. Even if one accepts this premise, there are inadequate data to evaluate the diagnostic performance of SEMG. No articles were identified in the published peer-reviewed literature that established definitions of normal or abnormal SEMG. In some instances, asymmetrical electrical activity may have been used to define abnormality; results may be compared to a “normative data base.” However, there is a lack of published literature defining what degree of asymmetry would constitute abnormality, or how a normative database was established.[11]
In the absence of a gold standard diagnostic test, correlation with the clinical symptoms and physical examination is critical.

Wang (2016) published a systematic review (SR) including eleven case-control, cohort, and cross-sectional studies that evaluated the benefit of trunk muscle activity for patients with spinal cord injury (SCI), using SEMG. The studies methodology varied; thus, could not be evaluated together. For example, two studies compared trunk muscles in SCI patients versus those in a normal healthy control group and three studies compared truck muscle activity in SCI patients with different levels of trunk muscle impairment. The authors concluded that because trunk muscle activity can increase independence and quality of life, SEMG is a useful objective tool for measuring muscle activity for patients with SCI, but more larger studies are needed with attention to comparison of trunk muscle activity in different SCI populations and to further define SEMG protocols.

Earp (2016) published a study that compared vastus lateralis muscle activity during heavy squat (HS) and unloaded jump squat (JS) activities for 10 patients using SEMG. Testing occurred over two days to determine if a hypothesis that regional hypertrophy occurred during heavy squat and unloaded squat activities. The authors concluded that SEMG showed more hypertrophy in HS versus JS, which was opposite of previous research outcomes. They concluded SEMG is not a good tool for this type of assessment.

Chmielewska (2016) published a six-week biofeedback training for 21 continent women who had never been pregnant beyond 20 weeks, using SEMG as a measurement tool. The goal was to determine if SEMG-biofeedback training could assist in pelvic floor muscle relaxation; thus, decreasing involuntary urine leakage. Training occurred three times a week for six weeks. SEMG evaluation occurred at baseline, three weeks, six weeks and one month following training. The results showed an increase in pelvic floor relation. The authors concluded that additional research is needed.

De Luca published a series of studies investigating a type of SEMG called the Back Analysis System (BAS), consisting of surface electrodes and other components to measure the electrical activity of muscles during isometric exercises designed to produce muscle fatigue. Using physical examination and clinical history as a gold standard, the author found that BAS was able to accurately identify "control" and "back pain" patients 84% and 91% of the time, respectively, with the values increasing to 100% in some populations of patients. (Accuracy is the sum of true positive and true negative results.) However, these studies were not designed as a clinical diagnostic tool, 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 in Hong Kong published two articles on dynamic topography, an approach to analyzing SEMG findings. The studies had similar protocols. Both included low back pain patients 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 healthy people and people with back pain, e.g., 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 that were 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 following the rehabilitation program, and thus it is not
clear whether there are any significant associations between continued symptoms and SEMG abnormalities. Moreover, it is not clear how SEMG analysis would affect treatment decisions for low back pain patients.

**CLINICAL UTILITY**

**SEMG**

Numerous studies were identified which incorporated the use of SEMG as an assessment tool to evaluate muscle strength and movement,[16-23] temporomandibular joint dysfunction and disorders,[24-26] and various causes of muscle pain,[27-30] however, no studies were identified which demonstrated how SEMG may be used to improve treatment decisions or health outcomes related to any disorder.

A 2000 SR by Pullman and colleagues, indicated that SEMG was not found to be better or equivalent to NEMG in diagnosing neuromuscular disease due to electrical cross-talk of muscles, intervening soft tissues, and poor fidelity recordings as a result of limited spatial resolution.[1]

In 2008, Meekins and colleagues conducted a SR of studies published from 1994-2006 which evaluated SEMG in the diagnosis and treatment of nerve and muscle disorders.[31] Authors concluded that:

1. SEMG may be useful in adding information in the study of fatigue in post-poliomyelitis syndrome and electromechanical coupling dysfunction in myotonic dystrophy." However, this recommendation was based upon Class III, Level C data indicating studies were retrospective in nature, focused on SEMG for a specific condition and that data indicated SEMG may be possibly effective, ineffective, or harmful for the given condition in the specific population.

2. On the basis of two class III studies, sEMG may be useful to detect the presence of neuromuscular disease (Level C rating).

3. Data were deemed insufficient to determine the ability of SEMG in distinguishing between neuropathic and myopathic disorders, disease severity, to compare the utility of SEMG with NEMG, or as a study of fatigue in myophosphorylase deficiency, muscle fiber and motor unit propagation in myotonia congenita and hypokalemic periodic paralysis, or in evaluation of disease progression in myotonic dystrophy and Charcot–Marie–Tooth disease.

Included studies were small in nature and differed in the utilization of SEMG techniques, diagnostic reference standard and outcome measures. Authors indicated that additional studies were needed that compare SEMG to a carefully selected gold standard, in studies with adequate blinding which address a broad spectrum of subjects. The authors also noted that the lack of standardization of SEMG protocols and lack of methodological documentation prohibited pooled analysis. Well-designed, randomized controlled trials (RCTs) which evaluate SEMG compared to standard assessment measures are required in order to assess the efficacy of SEMG as a diagnostic tool for any condition.

**Paraspinal SEMG to Diagnose Back Pain**
Several articles described the use of SEMG as an aid in classifying low back pain. The articles focused on the use of spectral analysis to assess muscle fatigability. However, it is unclear how this information may be used in the management of the patient. For example, while the innovators of the BAS system indicated that SEMG can suggest potential therapies by distinguishing deconditioning from muscle inhibition secondary to pain-related behavior, no clinical studies described the use of SEMG in suggesting therapy.

In another application of SEMG, Arena and colleagues assessed the amplitude of SEMG recordings as a measure of paraspinal muscle tension in 66 patients and reported that the degree of muscle tension did not correlate with pain levels. These findings raised questions about the role of biofeedback, muscle relaxants, or other therapies designed to reduce muscle tension.

While SEMG may be used to objectively document muscle spasm or other muscular abnormalities, 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. For example, SEMG has been proposed as a technique to differentiate muscle spasm from muscle contracture, with muscle spasm treated with relaxation therapy, and contracture treated with stretching exercises. However, there are no data to validate that such treatment suggested by SEMG resulted in improved outcomes. Part of the difficulty in clinical interpretation is understanding, to what extent, the SEMG abnormalities are primary or secondary. In addition, no specific workup is recommended for acute low back pain without warning signs.

A review of spinal muscle evaluation in low-back pain patients indicated that the validity of SEMG remains controversial. The authors noted that although many studies showed increased fatigability of the paraspinal muscles in patients with low back pain, it is not known whether these changes are causes or consequences of the low back pain. Also, “the considerable inter-individual variability and the absence of normative data complicate the description of normal or abnormal profiles, thereby limiting the diagnostic usefulness of SEMG.”

**Gait Analysis**

The ideal study design to demonstrate the clinical utility of gait analysis would be a RCT comparing treatment decisions and health outcomes in patients managed with and without SEMG as a component of gait analysis. Although numerous studies were identified in which SEMG was used as a component of gait analysis to evaluate a specific treatment, no RCT were identified which evaluated the contribution of SEMG as a component of gait analysis to diagnose or treat any condition.

**Myoclonus**

The evidence regarding the use of SEMG to diagnose or treat myoclonus associated with any condition is limited to small case series and case reports.

**PRACTICE GUIDELINE SUMMARY**

No clinical practice guidelines from U.S. professional societies were found that address the use of SEMG to diagnose conditions associated with myoclonus or as a component of gait analysis.
SUMMARY

There is not enough research to show that surface electromyography (SEMG), including paraspinal SEMG improves health outcomes for any indication, including but not limited to the diagnosis and monitoring of back pain, evaluation of myoclonus or as a component of gait analysis. No clinical guidelines based on research recommend SEMG for any indication. Therefore, the use of the use of SEMG, including paraspinal SEMG, is considered investigational for all indications.

REFERENCES


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