Quantitative Sensory Testing

Description

Quantitative sensory testing (QST) systems are used for the noninvasive assessment and quantification of sensory nerve function in patients with symptoms of, or the potential for neurologic damage or disease. Types of sensory testing include current perception threshold testing, pressure-specified sensory testing (PSST), vibration perception testing, and thermal sensory testing. Information on sensory deficits identified using QST has been used in research settings to understand neuropathic pain better. It could be used to diagnose conditions linked to nerve damage and disease, and to improve patient outcomes by impacting management strategies.

QST systems measure and quantify the amount of physical stimuli required for sensory perception to occur. As sensory deficits increase, the perception threshold of QST will increase, which may be informative in documenting the progression of neurologic damage or disease. QST has not been established for use as a sole tool for diagnosis and management but has been used with standard evaluative and management procedures (eg, physical and neurologic examination, monofilament testing, pinprick, grip and pinch strength, Tinel sign, and Phalen and Roos test) to enhance the diagnosis and treatment-planning process, and to confirm physical findings with quantifiable data. Stimuli used in QST includes touch, pressure, pain, thermal (warm and cold), or vibratory stimuli.

The criterion standard for evaluation of myelinated, large fibers is the electromyography nerve conduction study. However, the function of smaller myelinated and unmyelinated sensory nerves, which may show pathologic changes before the involvement of the motor nerves, cannot be detected by nerve conduction studies. Small fiber neuropathy has traditionally been a diagnosis of exclusion in patients who have symptoms of distal neuropathy and a negative nerve conduction study.
Depending on the type of stimuli used, QST can assess both small and large fiber dysfunction. Touch and vibration measure the function of large myelinated A alpha and A beta sensory fibers. Thermal stimulation devices are used to evaluate pathology of small myelinated and unmyelinated nerve fibers; they can be used to assess heat and cold sensation, as well as thermal pain thresholds. Pressure-specified sensory devices assess large myelinated sensory nerve function by quantifying the thresholds of pressure detected with light, static, and moving touch. Finally, current perception threshold testing involves the quantification of the sensory threshold to transcutaneous electrical stimulation. In current perception threshold testing, typically 3 frequencies are tested: 5 Hz, designed to assess C fibers; 250 Hz, designed to assess A delta fibers; and 2000 Hz, designed to assess A beta fibers. Results are compared with those of a reference population.

Because QST combines the objective physical, sensory stimuli with the subject patient response, it is psychophysical and requires patients who are alert, able to follow directions, and cooperative. Also, to get reliable results, examinations need to include standardized instructions to the patients, and stimuli must be applied consistently by trained staff. Psychophysical tests have greater inherent variability, making their results more difficult to reproduce.

QST has primarily been applied in patients with conditions associated with nerve damage and neuropathic pain. There have also been preliminary investigations to identify sensory deficits associated with conditions such as autism spectrum disorder, Tourette syndrome, restless legs syndrome, musculoskeletal pain, and response to opioid treatment.

**OBJECTIVE**

The objective of this evidence review is to determine whether quantitative sensory testing improves the net health outcome in patients with conditions linked to nerve damage or disease.

**POLICY STATEMENT**

Quantitative sensory testing, including but not limited to current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing, and thermal threshold testing, is considered investigational.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

A number of QST devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Examples are listed in Table 1.

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k)</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA product code: LLN</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Neurometer</td>
<td>Neurotron</td>
<td>Jun 1986</td>
<td>K853608</td>
<td>Current perception threshold testing</td>
</tr>
<tr>
<td>NK Pressure-Specified Sensory Device, Model PSSD</td>
<td>NK Biotechnical Engineering</td>
<td>Aug 1994</td>
<td>K934368</td>
<td>Pressure-specified sensory testing</td>
</tr>
<tr>
<td>AP-4000, Air Pulse Sensory Stimulator</td>
<td>Pentax Precision Instrument</td>
<td>Sep 1997</td>
<td>K964815</td>
<td>Pressure-specified sensory testing</td>
</tr>
</tbody>
</table>

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RATIONALE

Summary of Evidence

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive current perception threshold testing, the evidence includes several studies on technical performance and diagnostic accuracy. The relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The existing evidence does not support the accuracy of current perception threshold testing for diagnosing any condition linked to nerve damage or disease. Studies comparing current perception threshold testing with other testing methods have not reported on sensitivity or specificity. Also, there is a lack of direct evidence on the clinical utility of current perception testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive PSST, the evidence includes several studies on diagnostic accuracy. The relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Current evidence does not support the diagnostic accuracy of PSST for diagnosing any condition linked to nerve damage or disease. A systematic review found that PSST had low accuracy for diagnosing spinal conditions. Also, there is a lack of direct evidence on the clinical utility of current perception testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive vibration perception testing (VPT), the evidence includes several studies on diagnostic accuracy. The relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A few studies have assessed the diagnostic performance of vibration testing using devices not cleared by the FDA. Also, there is a lack of direct evidence on the clinical utility of VPT and, in the absence of sufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive thermal sensory testing, the evidence includes diagnostic accuracy. The relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Two studies identified evaluated the diagnostic accuracy of thermal QST using the same FDA-cleared device. Neither found a high diagnostic accuracy for thermal QST but both studies found the test had potential when used with other tests. The optimal combination of tests is currently unclear. Also, there is a lack of direct evidence on the clinical utility of thermal sensory testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Neurology

The American Academy of Neurology (2003; reaffirmed 2016) concluded that quantitative sensory testing (QST) is probably (level B recommendation) an effective tool for documenting of sensory abnormalities and changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy.\textsuperscript{13,14} Evidence was weak or insufficient to support the use of QST in patients with other conditions (small fiber sensory neuropathy, pain syndromes, toxic neuropathies, uremic neuropathy, acquired and inherited demyelinating neuropathies, or malingering).

American Association of Neuromuscular & Electrodiagnostic Medicine

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM; 2004) published a technology literature review on QST (light touch, vibration, thermal, pain).\textsuperscript{15} The review concluded that QST is a reliable psychophysical test of large- and small-fiber sensory modalities but is highly dependent on the full patient cooperation. Abnormalities do not localize dysfunction to the central or peripheral nervous system, and no algorithm can reliably distinguish between psychogenic and organic abnormalities. The AANEM review also indicated that QST had been shown to be reasonably reproducible over a period of days or weeks in normal subjects, but, for individual patients, more studies are needed to determine the maximum allowable difference between two quantitative sensory tests that can be attributed to experimental error.

The AANEM with American Academy of Neurology and American Academy of Physical Medicine & Rehabilitation (2005) developed a formal case definition of distal symmetrical polyneuropathy based on a systematic analysis of peer-reviewed literature supplemented by consensus from an expert panel.\textsuperscript{18} QST was not included as part of the final case definition, given that the reproducibility of QST ranged from poor to excellent, and the sensitivities and specificities of QST varied widely among studies.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare (2002) announced a national noncoverage policy on sensory nerve conduction threshold testing. Medicare reconsidered its policy, but affirmed it, concluding that any use of sensory nerve conduction threshold testing to diagnose sensory neuropathies or radiculopathies is not reasonable and necessary. This decision was reaffirmed in 2004.\textsuperscript{16} Medicare has not addressed coverage for other types of QST.

REFERENCES


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