Automated Percutaneous and Percutaneous Endoscopic Discectomy

Description

Surgical management of herniated intervertebral discs most commonly involves discectomy or microdiscectomy, performed manually through an open incision. Automated percutaneous discectomy involves placement of a probe within the intervertebral disc under image guidance with aspiration of disc material using a suction cutting device. Endoscopic discectomy involves the percutaneous placement of a working channel under image guidance, followed by visualization of the working space and instruments through an endoscope, and aspiration of disc material.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of automated percutaneous discectomy or endoscopic percutaneous discectomy improves the net health outcome in individuals with herniated intervertebral discs.

POLICY STATEMENT

Automated percutaneous discectomy is considered investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

Percutaneous endoscopic discectomy is considered investigational as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

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BENEFIT APPLICATION

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

Percutaneous discectomy may be performed by surgeons, but anesthesiologists or other physicians whose practices focus on pain management may also perform this procedure.

FDA REGULATORY STATUS

The Dekompressor Percutaneous Discectomy Probe (Stryker), Hemiatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome (Clarus Medical) are examples of percutaneous discectomy devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA indication for these products is for "aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine." FDA product code: HRX.

A variety of endoscopes and associated surgical instruments have also been cleared for marketing by FDA through the 510(k) process.

RATIONALE

Summary of Evidence

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc fragment compressing a lumbar nerve causing radiculopathy in the absence of lumbar stenosis or severe bony foraminal stenosis. However, the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have herniated intervertebral disc(s) who receive percutaneous endoscopic discectomy, the evidence includes a number of RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Many of the RCTs were conducted at a single center in Europe. Some trials have reported outcomes at least as good as traditional approaches with an open incision, while 1 RCT from a different center in Europe reported a trend toward increased complications and reherniations using an endoscopic approach. There are few reports from the United States. Clinical input suggests this intervention may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy according to clinical input expert opinion. However, respondents were mixed in the level of support of this indication, and overall there was not a preponderance of clinical input support in general cases. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE; 2005) published guidance on automated percutaneous mechanical lumbar discectomy, indicating there was limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, and evidence from small RCTs showed conflicting results. The guidance indicated that, in view of uncertainty about the efficacy of the procedure, it should not be done without special arrangements for consent and for audit or research. The guidance was considered for an update in 2009, but failed review criteria; the 2005 guidance is therefore considered current.

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A NICE (2016) guidance on percutaneous transforaminal endoscopic lumbar discectomy for sciatica was published. The guidance stated that current evidence is adequate to support the use of percutaneous transforaminal endoscopic lumbar discectomy for sciatica. Choice of operative procedure (open discectomy, microdiscectomy, or percutaneous endoscopic approaches) may be influenced by symptoms, location, and size of the prolapsed disc.

A NICE (2016) guidance on percutaneous interlaminar endoscopic lumbar discectomy for sciatica was also published. The guidance stated that current evidence is adequate to support the use of percutaneous interlaminar endoscopic lumbar discectomy for sciatica. Choice of operative procedure (open discectomy, microdiscectomy, or percutaneous endoscopic approaches) may be influenced by symptoms, location, and size of the prolapsed disc.

**American Society of Interventional Pain Physicians**

The guidelines from the American Society of Interventional Pain Physicians (2013) indicated that the evidence for percutaneous disc decompression with the Dekompressor was limited. There were no recommended indications for the Dekompressor.

**North American Spine Society**

The North American Spine Society (2014) published clinical guidelines on the diagnosis and treatment of lumbar disc herniation. Table 1 summarizes recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy.

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Grade or LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy.</td>
<td>B</td>
</tr>
<tr>
<td>There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy.</td>
<td>I</td>
</tr>
<tr>
<td>Endoscopic percutaneous discectomy may be considered for treatment.</td>
<td>C</td>
</tr>
<tr>
<td>Automated percutaneous discectomy may be considered for treatment.</td>
<td>C</td>
</tr>
<tr>
<td>Patients undergoing percutaneous endoscopic discectomy experience better outcomes if &lt;40 years and symptom duration &lt;3 months.</td>
<td>II</td>
</tr>
</tbody>
</table>

LOE: level of evidence.

Grade B: fair evidence (level II or III studies with consistent findings; grade C: poor quality evidence (level IV or V studies). Level of evidence II: lesser quality randomized controlled trial (eg, <80% follow-up, no blinding, or improper randomization), prospective comparative study, systematic review of level II studies or level I studies with inconsistent results; level of evidence III: case control, retrospective, systematic review of level III studies; level of evidence IV: case series; level of evidence V: expert opinion.

**American Pain Society**

The clinical practice guidelines from the American Pain Society (2009) found insufficient evidence to evaluate alternative surgical methods to standard open discectomy and microdiscectomy, including laser or endoscopic-assisted techniques, various percutaneous techniques, coblation nucleoplasty, or the Dekompressor.

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U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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.

REFERENCES

15. NA

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2012</td>
<td>New policy</td>
<td>Percutaneous and Endoscopic discectomy are considered investigational.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 1-4, 10, 22-23, 25, and 27-29 added; policy statement clarified to read “back pain and/or radiculopathy”</td>
</tr>
<tr>
<td>June 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review, references 13, 14, 18 added; policy statements unchanged.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review, references 17-18, 27, and 34 added; policy statement changed to investigational from not medically necessary.</td>
</tr>
<tr>
<td>June 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 6, 2017; references 10, 15-16, 18 and 21 added. Policy statements unchanged. Policy title changed to “Automated Percutaneous and Percutaneous Endoscopic Discectomy”.</td>
</tr>
<tr>
<td>March 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 4, 2018; reference 21 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 18, 2019; references added. Policy statements unchanged.</td>
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