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Medical Policy Manual

Topic: Automated Percutaneous and Endoscopic Discectomy

Date of Origin: October 2005

Section: Surgery

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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

Back pain or radiculopathy related to herniated discs is an extremely common condition and a frequent cause of chronic disability. Surgical decompression is often considered when the pain is unimproved with conservative therapy and is clearly neuropathic in origin, resulting from irritation of the nerve roots.

This policy addresses percutaneous and endoscopic removal of disc material as minimally invasive alternatives to open surgical excision for disc decompression. The percutaneous approach involves placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Endoscopic decompression is performed under visual control and may be intradiscal or may involve the extraction of non-contained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Endoscopic discectomy may also be referred to as arthroscopic discectomy.

Regulatory Status

The Stryker DeKompressor® Percutaneous Discectomy Probe (Stryker) and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process. Both have the same labeled intended use,

i.e., “for use in aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.”

A variety of endoscopes and associated surgical instruments have received marketing clearance through the FDA’s 510(k) process.

Note: This policy does *not* address intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), or laser discectomy and radiofrequency disc decompression which are considered in separate medical policies (see Cross References below).

MEDICAL POLICY CRITERIA

Percutaneous and endoscopic discectomy are considered **investigational** as techniques for intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.

SCIENTIFIC EVIDENCE

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both of these outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, large, blinded, randomized controlled trials (RCTs) with long-term follow-up are necessary in order to establish the safety and efficacy of percutaneous and endoscopic discectomy compared with open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. These comparisons are necessary to determine whether any beneficial treatment effects of percutaneous and endoscopic discectomy outweigh any risks and provide a significant advantage over conventional open discectomy techniques.

Literature Appraisal

The focus of the following literature review is on systematic reviews, randomized controlled trials, and clinical practice guidelines.

Automated Percutaneous Discectomy (APD)

All of the studies on APD focused on lumbar disc herniation. There were no clinical trials of APD for cervical or thoracic disc herniation.

Systematic Reviews

In 2007, Gibson and Waddel published an updated Cochrane review of surgical interventions for lumbar disc prolapse.[1] Four trials on APD met inclusion criteria, two comparing APD to chymopapain chemonucleolysis[2,3] and two comparing APD to microdiscectomy[4,5]. These trials suggested that APD produced inferior results to either of the established procedures, though the patient selection criteria may have been inappropriate in the Revel et al trial[2]. The authors concluded that, while there is considerable

evidence of efficacy for conventional surgical discectomy, there is insufficient evidence on percutaneous discectomy techniques including APD to draw firm conclusions. "Trials of automated percutaneous discectomy and laser discectomy suggest that clinical outcomes following treatment are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged."

Numerous subsequent systematic reviews have found no new randomized trials and reached the same conclusion as Gibson and Waddel.[6-11]

Randomized Controlled Trials

No new reports of randomized trials were found since those summarized in the systematic reviews above.

The 4 RCTs reviewed in the systematic reviews had a number of methodological limitations including small size, high loss to follow-up, inadequate randomization procedure, between-group heterogeneity, and other significant design flaws. For example, the LAPDOG study was initially designed to recruit 330 patients, but only was able to recruit 36 patients for reasons that were not readily apparent to the authors.[5] Of the evaluable 27 patients, 41% of the percutaneous discectomy patients and 40% of the conventional discectomy patients were assessed as having successful outcomes at 6 months. The authors concluded that this trial was unable to enroll sufficient numbers of patients to reach a definitive conclusion. The authors stated, "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation."

<u>Microendoscopic Discectomy (MED)</u>

Systematic Reviews

- The 2007 Gibson and Waddel Cochrane review found one small RCT[12] that reported comparable outcomes between percutaneous endoscopic discectomy (n=20) and microdiscectomy (n=20).[1] However, the authors considered the interpretation of the outcomes of this trial to be limited due to the small size of the study groups.

- In 2010, Nellensteijn and colleagues published a systematic review of the literature limited to the transforaminal approach for endoscopic surgery for symptomatic lumbar disc herniations that included English, German, and Dutch language articles published through May 2008.[13] One RCT, 7 non-randomized or inadequately randomized controlled trials, and 31 observational studies were identified. Only the RCT[14] (n=60) was determined to have a low risk of bias. Analysis of the 8 controlled trials found no significant differences between the endoscopic and open microdiscectomy groups for leg pain reduction (89% vs. 87%), overall improvement (84% vs. 78%), re-operation rate (6.8% vs. 4.7%) or complication rate (1.5% vs. 1%, all respectively). The methodologic quality of these studies was described as poor, providing insufficient evidence to support or refute this procedure. The limitations of this systematic review included heterogeneity of the included studies with regard to patient selection criteria, indications for surgery, surgical techniques, outcomes and outcome measurement tools, and duration of follow-up.

- In 2013, Smith et al. published a systematic review of microendoscopic discectomy for lumbar disc herniation.[15] A search for controlled trials published after the 2007 Gibson and Waddel Cochrane

review through September 2012 identified 4 RCTs. None of the studies found a significant difference in ODI scores compared with open discectomy or microdiscectomy. In the largest study which included 240 patients, Teli et al. reported an increase in the number of severe complications in the microendoscopic discectomy group.[16] In another large study with 112 patients Garg et al. found a shorter hospital stay with no significant changes in ODI or complication rates but recommended that microendoscopic discectomy should not be attempted without appropriate training.[17] The 2 other trials included in the review were small with 22[18] and 40[19] patients.

Randomized Controlled Trials

The following is a summary of randomized or quasi-randomized trials that were not included in the above systematic reviews.

- Cervical disc decompression

  In a 2009 article Ruetten et al. compared anterior endoscopic discectomy with ACDF in 120 patients with mediolateral cervical disc herniations.[20] The duration of pain ranged from 4 to 128 days. The mean operating time was 32 minutes for the endoscopic discectomy compared to 62 minutes for ACDF. In the endoscopic discectomy group, bone resection was required to reach the epidural space or the foramen in 55% of cases. At 24 months, 103 patients (86%) were available for follow-up examinations. The revision rate was 6.1% for ACDF and 7.4% for endoscopic discectomy; these were not significantly different. Excluding 4 patients who were revised by ACDF, 85 patients (85.9%) had no arm pain; there were no significant differences in clinical outcomes between the 2 groups. Advantages and disadvantages of the anterior endoscopic approach were discussed, including a difficult learning curve.

- Lumbar disc decompression

  In 2014 Hussein et al. reported the outcomes of 200 patients randomized to either microendoscopic lumbar discectomy (n=95) or to a control group in which patients underwent open lumbar discectomy (n=90).[21] The patients and investigators were not blinded to the treatment assignments. By 8 years follow-up, data was available for 185 patients; 15 patients were lost to follow-up, 10 due to subsequent same-level fusion, 3 due to death unrelated to surgery, and 2 who did not response to telephone calls. Relief of leg pain was statistically significant for both groups, with no significant between-group difference. Back pain was significantly improved in the endoscopic group throughout the entire follow-up period. However, in the control group the significant improvement in back pain following surgery deteriorated over time; by 8 years follow-up, back pain scores in this group had worsened significantly from preoperative scores. There were no serious complications in either group. This was a well-designed, long-term RCT that require validation in additional well-designed RCTs.

Clinical Practice Guidelines

<u>American Society of Interventional Pain Physicians (ASIPP)</u>[22]

In 2013 a task force of the ASIPP published updated guidelines for interventional techniques in the management of chronic spinal pain. The evidence for APD and for percutaneous lumbar discectomy was rated as limited for short- and long-term relief based on all observational studies. An evidence rating of limited is defined as evidence insufficient to assess effects on health outcomes because of

limited number or inadequate power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or execution, gaps in the chain of evidence, or lack of information on important health outcomes. The ASIPP concluded that this technique may be performed when indicated, but did not provide patient selection criteria. Nor was the recommendation graded; the authors indicated only that this recommendation was based on "individual experience and the large amount of literature." Therefore, this recommendation is not considered evidence-based.

Endoscopic discectomy is not addressed.

American Pain Society (APS)[23]

The 2009 clinical practice guidelines from the APS found insufficient evidence to evaluate alternative surgical methods to standard open discectomy and microdiscectomy such as percutaneous techniques including automated percutaneous discectomy and endoscopic-assisted.

North American Spine Society (NASS)[24]

The 2012 practice guidelines from the NASS on the diagnosis and treatment of lumbar disc herniation with radiculopathy recommended that endoscopic percutaneous discectomy or automated percutaneous discectomy could be considered for the treatment of these patients. Both recommendations were grade C recommendations (from poor quality evidence). However, a separate recommendation stated that evidence is insufficient to recommend for or against use of automated percutaneous discectomy compared with open discectomy.

Summary

The current published evidence is insufficient to determine whether percutaneous or endoscopic discectomy is as safe and effective as open surgical discectomy, the current standard of care for surgical removal of damaged intervertebral disc material. In addition, there are no evidence-based clinical practice guidelines from U.S. professional societies that recommend these techniques. Therefore, percutaneous or endoscopic discectomy are considered investigational.

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CROSS REFERENCES

Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation, Surgery, Policy No. 118

Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Energy (Nucleoplasty), Surgery, Policy No. 131

Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176

CODES	NUMBER	DESCRIPTION
CPT code 62287 specifically describes a percutaneous aspiration or decompression procedure of the lumbar spine. This code does not distinguish between an aspiration procedure (addressed in this policy) and a laser decompression procedure (addressed in separate medical policies). Also note that this code is specifically limited to the lumbar region. Although the majority of percutaneous discectomies are performed on lumbar vertebrae, the FDA labeling of the Stryker DeKompressor Percutaneous Discectomy Probe includes the thoracic and cervical vertebrae.		
CPT	62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
	64999	Unlisted procedure; nervous system
HCPCS	C2614	Probe, percutaneous lumbar discectomy