NUCLEOPLASTY PERCUTANEOUS DISC DECOMPRESSION

ISSUE

Blue Shield has received requests for coverage of nucleoplasty percutaneous disc decompression for herniated discs. The Medical Policy Committee on Quality and Technology is asked to review the published data regarding the efficacy and safety of this new technology in clinical practice.

CURRENT BLUE SHIELD POLICY

Current Blue Shield policy (06/09/99) states that, “Percutaneous intradiscal radiofrequency thermocoagulation for low back pain is investigational and not eligible for coverage.” Furthermore, Blue Shield policy (10/15/01) states that “percutaneous laser disc decompression is investigational and not eligible for coverage.” Conservative measures and other surgical modalities are eligible for coverage.

BACKGROUND

Low back pain is the most common cause of morbidity and chronic pain in the U.S.. Herniation of a lumbar disc is sometimes responsible. The incidence of disc herniation in the U.S. is approximately 1.7% (Choy, 1995b). The disc resembles a filled jelly donut, being composed of a series of firm, fibrous rings (annulus fibrosus) surrounding a soft, jelly-like core (nucleus pulposus). Herniation occurs when the nucleus material escapes through the annulus. Even in the absence of frank disc herniation, however, degeneration and bulging of the disc may itself be the source of the low back pain. There are nerve endings and fibers in the outer half of the annulus fibrosus (Houpt et al, 1996).

The usual treatment for a patient with a symptomatic, nonsequestered herniated nucleus pulposus first involves conservative measures, such as nonsteroidal anti-inflammatory drugs, physical therapy, muscle relaxants, selective nerve blocks, epidural steroids, and in some cases chiropractic care (Casper et al, 1996). Traditionally, further treatment for a disc herniation that has been unresponsive to conservative measures has involved either open laminectomy or discectomy. Patients often benefit from complete surgical removal of the intervertebral disc and vertebral fusion; measurable decrease in preoperative pain has been noted in >80% in various series (Lee et al, 1995).
BACKGROUND, continued

Minimally invasive intradiscal techniques and percutaneous procedures have recently been employed as an alternative to conventional surgical methods. These have included chemonucleolysis, manual percutaneous discectomy, automated percutaneous discectomy, endoscopic posterolateral discectomy, and laparoscopic discectomy and fusion, and percutaneous laser disc decompression (also known as laser discectomy) (Maroon et al, 1996; Fehlings, 1996).

**Nucleoplasty Percutaneous Disc Decompression**

Nucleoplasty percutaneous disc decompression is a new, “minimally invasive” procedure to provide symptomatic relief of pain caused by a herniated intervertebral disc (Sanders, 2001). Nucleoplasty is performed in the outpatient setting under fluoroscopic guidance and local anesthesia. In nucleoplasty, the target tissue is the nucleus pulposus of the intervertebral disc (Sanders, 2001), the main constituent of which is water (Quigley, 1996).

In nucleoplasty, a multifunctional bipolar radiofrequency device is used to generate thermal energy (heat) to ablate (remove) or coagulate tissue. Thermal damage to nearby tissues is minimized since these effects are achieved at temperatures of approximately 40-70°C.

During the procedure, the patient is placed in the lateral position with the affected side up. After localization of the disc level, a thin gauge (18- to 20-gauge) needle with a stylet is introduced and placed percutaneously at the nucleus/annulus junction. A radiofrequency device (the Perc-D SpineWand™) is introduced through an introducer needle and advanced into the nucleus pulposus. Using the ablation mode, the device is advanced (“channeled”) into the nucleus, stopping before reaching the anterior annular wall. Coagulation mode is then used while withdrawing the device. The same procedure is repeated six times within the disc. The needle is then removed and a bandage placed on the skin. The procedure takes between 20 and 30 minutes.

It is theorized that the change in the nucleus pulposus causes a decrease in intradiscal pressure which in turn allows the herniated material to retreat toward the center of the disc.
Nucleoplasty Percutaneous Disc Decompression, continued

Proponents of nucleoplasty cite several potential advantages over open discectomy procedures: possibly reduced morbidity, less potential for perineural scarring, less intraoperative blood loss, fewer complications of epidural fibrosis, transverse myelitis or disc space infection, reduced patient recovery times, and a faster return to normal activity. In addition, the procedure can be repeated, and it does not preclude future surgical treatment.

The procedure has only applied to lumbar disc herniations.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1

ArthroCare Corporation, Sunnyvale, CA received FDA 510K clearance on August 17, 2000 as “substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act”. The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

TA Criteria 2 and 3

There are no peer-reviewed published studies concerning nucleoplasty. Specifically, no randomized, concurrently controlled, blinded trials comparing nucleoplasty outcomes with conventional conservative measures or open discectomy or laminectomy have been published.

The only available studies of nucleoplasty are summarized in abstracts, several of which are animal studies (Chen et al, 2001a; Chen et al, 2001b) or human cadaver studies (Chen et al, 2001c; Yetkinler et al, 2001); three abstracts summarize case series of nucleoplasty in humans (Chen et al, 2001d; Sharps, 2001; Singh, 2001).
TA Criteria 2 and 3, continued

Patients included in the abstracts have included those with axial and/or radicular symptoms. Patients were generally excluded from studies if they had MRI evidence of extruded or sequestered disc fragments, neurological deficits, spinal stenosis, severe degenerative disc disease, prior operated disc, prior thermally or chemically treated disc, systemic inflammatory disease, infection, unstable medical condition, or abnormal psychometric test (Chen et al, 2001d).

Outcomes assessed in the various clinical trials summarized below include relief of pain, satisfaction with treatment with NASS Patient Satisfaction form, Short Form (SF-36) Health Status Questionnaire Physical Function Subscale, analgesic use and duration, leg range of motion, and activities of daily living, such as duration of ability to stand, sit and walk (Chen et al, 2001; Singh, 2001). In the abstracts, pain relief has usually been assessed by the Visual Analog Scale, ranging from 0 = no pain, to 10 = worst possible pain (Gevargez et al, 2000).

Level of Evidence: 5

Patient Risks and Complications

No adverse effects have been reported in the abstracts. However, all of the series have small numbers (18-44) of patients. With such small numbers, data regarding safety may be unreliable, especially for infrequent complications.

Pending Trials

There are three trials currently pending publication.

Without control patients, it is impossible to assess the magnitude of a placebo effect from the nucleoplasty procedure, particularly for the subjective outcomes. The lack of matched control groups also precludes comparison of nucleoplasty with traditional conservative therapies or open surgical procedures.
TA Criterion 4

The established alternatives to nucleoplasty for treatment of a disc herniation include conservative measures, such as nonsteroidal anti-inflammatory drugs, physical therapy, selective nerve blocks, epidural steroids, and chiropractic care, and for disc herniation that has been unresponsive to conservative measures, either open laminectomy or discectomy.

A literature review has concluded that standard open discectomy results in better short-term relief of sciatica (65-85%) than conservative treatment (36%) (Hoffman et al, 1993) and a meta-analysis of randomized studies has concluded that surgical discectomy produces better results than placebo treatment (Gibson, 1999).

TA Criterion 5

The number of centers performing nucleoplasty appears to be limited. There are no published data to conclude that the efficacy and safety of the nucleoplasty procedure have been established in the investigational setting, let alone under conditions of usual medical practice. Whether nucleoplasty will be effective in improving health outcomes when used to treat individuals with herniated lumbar discs in the community setting under conditions of usual medical practice remains to be demonstrated.

RECOMMENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA has not yet reviewed this topic.

California Orthopedic Association

The Association does not have a formal position statement regarding this procedure. Representation at the meeting has been requested.

California Association of Neurological Surgeons

A position statement and representation at the meeting has been requested.
CONCLUSION

Published evidence in peer-reviewed journals concerning the safety and efficacy of nucleoplasty is unavailable. Only abstracts from uncontrolled case series are available. No randomized, concurrently controlled, blinded trials comparing nucleoplasty outcomes with conventional conservative measures or open discectomy or laminectomy have been published. Long-term follow-up results are lacking.

In the case series there have been only small numbers (≤ 100) of patients. With such small numbers, data regarding safety may be unreliable, especially for infrequent complications.

Established alternatives to nucleoplasty for treatment for a disc herniation such as open discectomy are available, and comparisons of nucleoplasty outcomes with conventional conservative measures or open discectomy or laminectomy have not been published.

The published data are not sufficient to conclude that the efficacy and safety of the nucleoplasty percutaneous disc decompression procedure have been established in the investigational setting, let alone under conditions of usual medical practice.

Nucleoplasty percutaneous disc decompression requires further evaluation in a controlled trial to assess its efficacy as an alternative treatment procedure for disc herniation.

At this time, TA criteria 2-5 are not met.

RECOMMENDATION

It is recommended that nucleoplasty percutaneous disc decompression does not meet Blue Shield TA criteria.

Committee approval as recommended

February 13, 2002

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