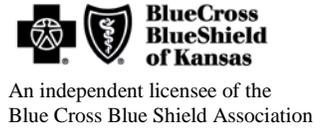


Medical Policy



Title: Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Professional

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Populations	Interventions	Comparators	Outcomes
Individuals with: <ul style="list-style-type: none"> • Discogenic back pain 	Interventions of interest are: <ul style="list-style-type: none"> • Intradiscal electrothermal annuloplasty 	Comparators of interest are: <ul style="list-style-type: none"> • Conservative management • Surgical spinal decompression 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes • Quality of Life • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • Discogenic back pain	Interventions of interest are: • Intradiscal radiofrequency annuloplasty	Comparators of interest are: • Conservative management • Surgical spinal decompression	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • Discogenic back pain	Interventions of interest are: • Intradiscal biacuplasty	Comparators of interest are: • Conservative management • Surgical spinal decompression	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening of annular tissue.

Objective

The objective of this evidence review is to evaluate the efficacy of intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, and intradiscal biacuplasty in the treatment of discogenic back pain.

Background

Discogenic Low Back Pain

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

Some of the electrothermal intradiscal procedures are briefly described.

With the intradiscal electrothermal annuloplasty (IDEA) procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect RF energy, electrothermal heat is generated within the thermal

resistive coil at a temperature of 90°C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with (IDEA) include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) uses direct application of RF energy. With PIRFT, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70°C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty uses 2 cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that by cooling the probes a larger area may be treated than could occur with a regular needle probe.

Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Regulatory Status

A variety of radiofrequency (RF) coagulation devices are cleared for marketing by the U.S. Food and Drug Administration (FDA), some of which are designed for disc nucleotomy. In 2002, the Oratec Nucleotomy Catheter (ORATEC Interventions, Menlo Park, CA, acquired by Smith & Nephew in 2002) was cleared for marketing by FDA through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. The Radionics (a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance by FDA through the 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was cleared for marketing by FDA through the process. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue." FDA product code: GXI.

Note: This evidence review does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar RF device is used to provide lower energy treatment to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. Disc nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated in an effort to provide decompression of a bulging disc.

POLICY

Percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **experimental / investigational**.

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through November 21, 2017. This review is based in part on TEC Assessments from 2002 and 2003.^{1,2}

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

As with any therapy for pain, a placebo effect is anticipated, and thus randomized placebo-controlled trials are necessary to investigate the extent of the placebo effect and to determine whether any improvement with annuloplasty exceeds that associated with a placebo. Therefore, evidence reviewed for this review focuses on RCTs.

Intradiscal electrothermal Procedures

Intradiscal Electrothermal Annuloplasty

Pauza et al (2004)³ published the results of an RCT evaluating intradiscal electrothermal annuloplasty (IDEA; referred to as intradiscal electrothermal therapy in Pauza) in patients with discogenic low back pain, which was the focus of discussion in the 2003 TEC Assessment. The trial included 64 patients with low back pain of more than 6 months in duration who were randomized to IDEA or a sham procedure. Visual analog scale (VAS) scores for pain were reduced by an average of 2.4 cm in the IDEA group compared with 1.1 cm in the sham group, a statistically significant difference between groups ($p=0.045$). The mean change in the Oswestry Disability Index (ODI) score was also significantly greater for the IDEA group than for the sham group. Improvements in the 36-Item Short-Form Health Survey (SF-36) bodily pain subscale

score were slightly higher for the IDEA group. The trial also reported the percent change in VAS scores more than 2.0 cm, which is greater than the minimal clinically significant improvement of 1.8 to 1.9. When the VAS score was dichotomized in this way, a relative risk of 1.5 was observed with a 95% confidence interval of 0.82 to 2.74. While this single-center trial was well-designed with respect to randomization, clear description of the intervention, and use of valid and reliable outcomes measures, it does not permit conclusions about the relative effects of IDEA and placebo, and it is unclear whether IDEA achieves clinically and statistically significant improvements in measures of pain, disability, or quality of life.

In 2005, Freeman et al reported on an industry-sponsored, double-blinded, sham-controlled randomized trial evaluating IDEA (referred to as intradiscal electrothermal therapy in this report) in patients with chronic discogenic low back pain, marked functional disability, magnetic resonance imaging evidence of degenerative disc disease, and failure of conservative management.⁴ Both the active IDEA and sham groups had an intradiscal catheter that was navigated to cover at least 75% of the posterior annulus. Planned enrollment based on power analysis was for 75 patients; however, the trial was stopped early due to slower than expected recruitment after 57 patients (38 IDEA, 19 placebo) had been enrolled. Follow-up was for 6 months, and the outcome measure was successful treatment response, as defined by all of the following: (1) no neurologic deficit; (2) an increase on the Low Back Outcome Score of at least 7 points; and (3) improvements in the SF-36 physical functioning and bodily pain subscales scores of at least 1 standard deviation. No subject in either group achieved a successful treatment response. Outcomes were similar between the intradiscal electrothermal therapy and sham groups on the Low Back Outcome Score (38.31 vs 37.45), ODI score (39.77 vs 41.58), SF-36 subscale scores (35.10 vs 30.40), the Zung Depression Index score (41.39 vs 40.82), and the Modified Somatic Perception Questionnaire score (8.67 vs 8.6), respectively. None of the subgroup analyses showed statistically or clinically significant differences in study outcomes. No serious adverse events were reported in either group.

Section Summary: Intradiscal Electrothermal Annuloplasty

Two RCTs on IDEA have reported conflicting results, with one finding a benefit for IDEA and the other no benefit. The most recent RCT identified was from 2005. No recent literature on IDEA has been identified.

Percutaneous Intradiscal Radiofrequency Annuloplasty

There is relatively little published data on percutaneous intradiscal radiofrequency thermocoagulation (PIRFT). In 2001, Barendse et al reported on a double-blind trial that randomized 28 patients with chronic low back pain to PIRFT or a sham-control group.⁵ The primary outcome was the percentage of success at 8 weeks, as measured by changes in pain level, impairment, ODI scores, and analgesics taken. At the end of 8 weeks, there were 2 treatment successes in the sham group and one in the treatment group. Trialists concluded that PIRFT was no better than placebo in reducing pain and disability.

In 2009, Kvarstein et al published 12-month follow-up from an RCT of intra-annular radiofrequency thermal disc therapy using the discTRODE probe.⁶ Recruitment was discontinued when blinded interim analysis of the first 20 patients showed no trend toward overall effect or difference in pain intensity between active and sham treatment at 6 months. At 12 months, there was a reduction from baseline pain but no significant difference between the groups. Two patients from each group reported an increase in pain.

Section Summary: Percutaneous Intradiscal Radiofrequency Annuloplasty

Two sham-controlled randomized trials showed no evidence of a benefit with PIRFT. One study found that only 1 of 14 patients was considered a treatment success. The other was terminated after blinded interim analysis showed no trend to benefit compared with sham.

Intradiscal Radiofrequency Biacuplasty

Kapural, Desai, and colleagues have published several studies on the use of transdiscal radiofrequency annuloplasty using 2 transdiscal probes (biacuplasty) in patients with discogenic lower back pain, including a 2013 industry-sponsored, phase 1, double-blind RCT and a 2016 RCT.⁷⁻¹⁰

In the phase 1 RCT by Kapural et al (2013), of 1894 patients screened, 1771 (94%) did not meet inclusion criteria.⁷ Sixty-four subjects consented and were enrolled. Outcome measures were the SF-36 physical functioning subscale (0-100), a numeric rating scale (NRS) for pain (0-10), and the ODI (0-100). There were no significant differences between the groups at 1 month or 3 months. At 6 months, the biacuplasty group showed a significantly greater change from baseline for the SF-36 (15.0 vs 2.63), NRS (-2.19 vs -0.64), and ODI (-7.43 vs 0.53) scores. Mean SF-36 and NRS scores were considered to be clinically significant, but mean ODI scores did not achieve the minimally important difference of 10 points. With clinical success defined post hoc as a 15-point increase in physical function together with a greater than 2-point decrease in pain, 30% of biacuplasty patients and 3% of sham-treated patients were considered successful. There was no significant difference in opioid use between groups.

In 2015, Kapural et al reported on the unblinded 12-month follow-up from this phase 1 trial.⁸ Improvements continued through 12 months, with a change from baseline to posttreatment of 47.0 to 68.9 (of 100) on the SF-36 physical functioning subscale ($p < 0.01$) and 7.1 to 4.4 (of 10) on the NRS ($p < 0.01$). Although the change in NRS score was statistically significant, the magnitude of the decrease was modest, and a final NRS score (4.4) remained high. The change in ODI score (from 40.37 at baseline to 32.44 at 12 months) was also modest ($p = 0.05$). Opioid usage did not decrease significantly (53.47 mg at baseline to 34.07 mg at follow-up, $p = 0.23$).

In the 2016 RCT by Desai et al, 63 patients with lumbar discogenic pain diagnosed by provocation discography were randomized to intradiscal biacuplasty plus conservative medical management ($n = 29$) or medical management alone ($n = 34$).⁹ Another 234 patients were scheduled for diagnostic discography but did not meet inclusion criteria. The primary outcome (the mean reduction in VAS score for pain at 6 months) was significantly greater in the biacuplasty group (-2.4) than in the medical management group (-0.56; $p = 0.02$). The secondary outcomes were not statistically significant, which included the proportion of responders, defined as a 2-point or 30% decrease in VAS scores, which was achieved in 50% of the biacuplasty group compared to 18% of controls ($p = 0.073$). Investigators did not report whether the trial was adequately powered. Other limitations of this industry-sponsored trial were the lack of a sham-control and patient blinding, which could contribute to a placebo effect in the subjective pain outcomes.

Of the 29 patients originally randomized to intradiscal biacuplasty, 22 (76%) were available for 12-month follow-up.¹⁰ Mean 12-month change in VAS score was -2.2 (from 6.7 at baseline to 4.4 at 12 months, $p = 0.001$). After 6 months, patients randomized to medical management were

allowed to receive intradiscal biacuplasty and were followed for another 6 months; 25 of 34 patients crossed over. VAS score improved from 7.0 to 4.7 ($p < 0.001$) in the crossover group, and 55% were considered to be responders.

Section Summary: Intradiscal Radiofrequency Biacuplasty

Two industry-sponsored RCTs have assessed use of biacuplasty to treat chronic low back pain. In one, only 6% of subjects screened met the strict inclusion and exclusion criteria for the study. Significant differences in outcomes were observed at 6 months, but not at 1 month or 3 months, and the definition of successful treatment appears to have been post hoc. In the second multicenter RCT, 63 patients met inclusion criteria, which included a positive result on provocation discography. There was a significant treatment effect for the primary outcome measure, but not the secondary outcome measures. This trial was not sham-controlled, and it was not reported whether it was adequately powered. Additional sham-controlled trials in a broader population of patients are needed to determine the effect of this treatment with greater certainty.

Summary of Evidence

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, radiofrequency annuloplasty, or biacuplasty, the evidence includes a small number of randomized controlled trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty have reported conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. There is a lack of evidence to support a role for radiofrequency annuloplasty with either a single or a double (biacuplasty) probe. One sham-controlled randomized controlled trials assessing biacuplasty has suggested that this procedure may provide modest benefit to highly select patients; confirmation of these results in a broader population is needed. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

A 2013 review of the evidence informing American Society of Interventional Pain Physicians guidelines found limited-to-fair evidence for intradiscal electrothermal therapy (IDET; another term for intradiscal electrothermal annuloplasty) and biacuplasty and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation (PIRFT).¹¹ These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET.¹² Complications included catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for PIRFT was limited, with complications similar to IDET.¹²

National Institute for Health and Care Excellence

A National Institute for Health and Care Excellence (NICE) guidance, updated in 2016, indicated that the evidence on safety and efficacy of PIRFT for low back pain was “limited” and should only be used by “special arrangement”.¹³

The NICE guidance on electrothermal annuloplasty was also updated in 2016.¹⁴ NICE considered evidence on the efficacy of PIRFT for low back pain to be inconsistent and of poor quality,

although no major safety concerns were identified. NICE recommended PIRFT only with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in December 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral, including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)
62290	Injection procedure for discography, each level: lumbar
62291	Injection procedure for discography, each level: cervical or thoracic
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation

- There are 2 CPT category I codes specific to this procedure: 22526 and 22527.
- Discography may be performed at several levels to determine the location of the pathogenic disc. It has been reported that the following CPT codes have been used to describe the initial discography procedure: 62290, 62291, 72285, 72295

DIAGNOSIS

Experimental / Investigational for all diagnoses related to this policy.

REVISIONS

02-08-2010	The Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
12-01-2011	Description section updated
	Rationale section updated
	References updated
01-01-2012	In Coding section:

	<ul style="list-style-type: none"> ▪ Revised CPT code nomenclature: 62310, 62311
11-06-2012	Rational section updated
	In Coding section: Revised CPT code nomenclature: 62292
	References updated
10-13-2015	Description section updated
	Rationale section updated
	In Coding section: <ul style="list-style-type: none"> ▪ Removed CPT Codes: 62292, 62310, 62311, 64640, 64999
	References updated
02-15-2017	Title revised to "Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty" from "Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty, and Percutaneous Intradiscal Radiofrequency Annuloplasty"
	Description section updated
	In Policy section: <ul style="list-style-type: none"> ▪ Removed "percutaneous" and "thermocoagulation" and added "annuloplasty" to read "Percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered experimental / investigational."
	Rationale section updated
	References updated
03-01-2018	Description section updated
	Rationale section updated
	References updated

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