Pain Physician 2017; 20:447-470 • ISSN 1533-3159

Systematic Review

Effectiveness of Thermal Annular Procedures in Treating Discogenic Low Back Pain

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 02-02-2016
Revised manuscript received: 04-28-2016
Accepted for publication: 06-29-2016

Free full manuscript: www.painphysicianjournal.com

Background: Discogenic low back is a distinct clinic entity characterized by pain arising from a damaged disc. The diagnosis is clouded by the controversy surrounding discography. The treatment options are limited, with unsatisfactory results from both conservative treatment and surgery. Multiple interventional therapies have been developed to treat discogenic pain, but most have not yet been validated by high quality studies.

The best studied treatment for discogenic pain is the use of heat, which has been labeled as thermal intradiscal procedures (TIPs) by the Centers for Medicare and Medicaid Services (CMS). As the pathology is located in the annulus, we use the term thermal annular procedures (TAPs).

Objectives: The aim of this study is to evaluate and update the efficacy of TAPs to treat chronic refractory discogenic pain.

Study Design: The design of this study is a systematic review.

Methods: The available literature on TAPs in treating chronic refractory discogenic pain was reviewed. The quality of each article used in this analysis was assessed.

The level of evidence was classified on a 5-point scale from strong, based upon multiple randomized controlled trials (RCTs) to weak, based upon consensus, as developed by the US Preventive Services Task Force (USPSTF) and modified by the American Society of Interventional Pain Physicians (ASIPP).

Data sources included relevant literature identified through searches of PubMed and EMBASE from 1966 to September 2015 and manual searches of the bibliographies of known primary and review articles.

The primary outcome measures were pain relief and functional improvement of at least 40%.

Short-term efficacy was defined as improvement for less than 6 months; long-term efficacy was defined as improvement for 6 months or more.

Results: For this systematic review, 49 studies were identified. Of these, there were 4 RCTs and no observational studies which met the inclusion criteria.

Based upon 2 RCTs showing efficacy, with no negative trials, there is Level I, or strong, evidence of the efficacy of biacuplasty in the treatment of chronic, refractory discogenic pain.

Based upon one high-quality RCT showing efficacy and one moderate-quality RCT interpreted as showing no benefit, there is Level III, or moderate, evidence supporting the use of intradiscal electrothermal therapy (IDET) in treating chronic, refractory discogenic pain.

The evidence supporting the use of discTRODE is level V, or limited.

Conclusion: The evidence is Level I, or strong, that percutaneous biacuplasty is efficacious in the treatment of chronic, refractory discogenic pain. Biacuplasty may be considered as a first-line treatment for chronic, refractory discogenic pain.

The evidence is Level III, or moderate, that IDET is efficacious in the treatment of chronic, refractory discogenic pain.

The evidence is Level V, or limited, that discTRODE is efficacious in the treatment of chronic, refractory discogenic pain.

Key words: Spinal pain, chronic low back pain, intradiscal disorder, IDET, biacuplasty, discTRODE, thermal intradiscal disorders, thermal annular disorders

Pain Physician 2017; 20:447-470

Persistent low back pain which does not arise from the facet or the sacroiliac joints is a frustrating clinical problem (1-5). The intervertebral disc is the most common source of low back pain, estimated to account for about 26 – 42% of cases of persistent low back pain (6-9).

Many different treatments have been used in the effort to cure or relieve the pain of intradiscal disorder. Conservative therapy helps in only about 13% of patients (10), while lumbar epidural injections provide a significant benefit in pain and function in discogenic pain (11). Fusion of the adjacent vertebral bodies has been commonly used, but with a minimal benefit for this diagnosis (12,13). A Cochrane Review concluded that there were open questions about the scientific evidence for fusion to treat low back pain (14). Mirza and Deyo (12) performed a systematic review which concluded that fusion was no better than structured cognitive behavioral therapy for chronic low back pain. Deyo and Weinstein (15) suggested that low back pain should be considered akin to asthma, a chronic disease that requires management rather than an acute disease that can be cured. The natural history of discography-proven intradiscal disorder is persistent pain in about 66% of cases and worsening of pain in 12% (10). Various injection therapies, including ozone, methylene blue, and various biologic preparations, have been tried and show early promise (16-25). Rohof (26) recently evaluated pulsed radiofrequency in the nucleus. Both studies done by Simon et al (27) and Benzel and Perry (28) reviewed discogenic back pain with no highlighting of thermal annular procedures (TAPs).

Intradiscal procedures to treat low back pain have been the focus of several systematic reviews. Malik et al (29), in a 2013 review, found that discogenic pain currently lacks clear diagnostic criteria and uniform treatment or terminology. Balagué et al (30) urged avoiding surgery and overtreatment.

Helm et al (31) found in a 2012 review, of which this review is an update, that the evidence for intradiscal electrothermal therapy (IDET) was fair, while the evidence for discTrode and biacuplasty was poor.

This systematic review focuses on heat to treat internal disc disruption, with the hypothesis being that the thermal ablation of inflamed nerves will resolve pain. This approach has been described by the Centers for Medicare and Medicaid Services (CMS) as thermal intradiscal procedures (TIPs) (32). Given that the source of pain and the pathology to be treated is in the posterior annulus, we describe these therapies as thermal annular procedures (TAPs). CMS has issued a non-coverage determination for TAPs, a decision which has been generally adopted by other payers.

This review is an update of a previous systematic review of the efficacy of TAPs in treating pain arising from intradiscal disorders (31).

Methods

The methodology utilized in this systematic review followed the review process derived from evidence-based, systematic reviews and meta-analyses of randomized trials and observational studies (33-46).

Criteria for Considering Studies for This Review

Types of Studies

The types of studies that were included for consideration were randomized controlled trials (RCTs), non-randomized observational studies, and case reports and reviews for adverse effects.

Types of Participants

In order to be a considered study for this review, the patients in the studies had to have been diagnosed with discogenic pain for at least 3 months.

Types of Interventions

The only type of intervention that was included for this review was TAPs. Other intradiscal treatments, including injection therapies into the disc and the application of heat to the annulus by a laser, are not included in this review.

Types of Outcome Measures

The primary outcome parameter was pain relief; the secondary outcome measure was functional status improvement.

Literature Search

Searches were performed from the following sources and limited to articles published in English:

1. PubMed from 1966
   www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. Cochrane Library
   www.thecochranelibrary.com/view/0/index.html
3. National Guideline Clearinghouse (NGC)
   www.guideline.gov
4. Google Scholar
   https://scholar.google.com
5. Previous systematic reviews
6. Clinical trials
   https://clinicaltrials.gov
7. Communication with investigators active in the field
8. Bibliographies of reviewed papers.

The search period was from 1966 through September 2015.

Search Strategy

The search terms used were "thermal annular", "thermal intradiscal", "degenerative disc disease" and treatment and heat or thermal, "intervertebral disc degeneration" and treatment and heat or thermal, "intra-annular radiofrequency thermal disc therapy", "intradiscal electrothermal therapy", "discTrode", and "biacuplasty."

Data Collection and Analysis

Two review authors independently, in an unblended and standardized manner, developed the search criteria, searched for relevant literature, and selected the manuscripts.

Selection of Studies

Two review authors screened the abstracts of all of the identified studies against the inclusion criteria. All of the articles with possible relevance were then retrieved in full text for comprehensive assessment of internal validity, quality, and adherence to the inclusion criteria.

Inclusion and Exclusion Criteria

Randomized trials with at least 6 months of follow-up, with statistical analysis, and with at least 25 patients in each group or with appropriate sample size determination were included.

If there were more than 5 randomized trials, then nonrandomized or observational studies were not utilized.

For nonrandomized studies, only the studies with at least 6 months of follow-up and at least 50 patients in each group or with appropriate sample size determination were included.

Methodological Quality or Validity Assessment

The quality of each individual article used in this analysis was assessed by Cochrane Review criteria (Table 1) (47), the American Society of Interventional Pain Physicians (ASIPP) interventional pain management techniques -- Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB) for randomized trials (Table 2) (48), and ASIPP interventional pain management techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR) for nonrandomized and observational studies (Table 3) (49).

Utilizing Cochrane Review criteria, studies meeting the inclusion criteria with at least 8 of 12 criteria were considered high quality and those meeting 5-7 inclusion criteria were considered moderate quality. Any studies meeting criteria of less than 5 were considered as low quality and were excluded.

Based on ASIPP criteria for randomized trials and nonrandomized studies, the studies meeting the inclusion criteria scoring of 32 to 48 were considered high quality trials; studies with scores between 25 and 31 were considered moderate quality; studies scoring less than 25 were considered low quality and were excluded.

For adverse effects, confounding factors, etc., it was not possible to use quality assessment criteria. Thus, these were considered based on interpretation of the reports published and critical analysis of the literature.

Table 1. *Sources of risk of bias and Cochrane Review rating system.*

A	1. Was the method of randomization adequate?	Yes/No/Unsure
B	2. Was the treatment allocation concealed?	Yes/No/Unsure
C	Was knowledge of the allocated interventions adequately prevented during the study?	
	3. Was the patient blinded to the intervention?	Yes/No/Unsure
	4. Was the care provider blinded to the intervention?	Yes/No/Unsure
	5. Was the outcome assessor blinded to the intervention?	Yes/No/Unsure
D	Were incomplete outcome data adequately addressed?	
	6. Was the drop-out rate described and acceptable?	Yes/No/Unsure
	7. Were all randomized participants analyzed in the group to which they were allocated?	Yes/No/Unsure
E	8. Are reports of the study free of suggestion of selective outcome reporting?	Yes/No/Unsure
F	Other sources of potential bias:	
	9. Were the groups similar at baseline regarding the most important prognostic indicators?	Yes/No/Unsure
	10. Were co-interventions avoided or similar?	Yes/No/Unsure
	11. Was the compliance acceptable in all groups?	Yes/No/Unsure
	12. Was the timing of the outcome assessment similar in all groups?	Yes/No/Unsure

Table 2. *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

		Scoring
I.	CONSORT OR SPIRIT	
1.	Trial Design Guidance and Reporting	
	Trial designed and reported without any guidance	0
	Trial designed and reported utilizing minimum criteria other than CONSORT or SPIRIT criteria or trial was conducted prior to 2005	1
	Trial implies it was based on CONSORT or SPIRIT without clear description with moderately significant criteria for randomized trials or the trial was conducted before 2005	2
	Explicit use of CONSORT or SPIRIT with identification of criteria or trial conducted with high level reporting and criteria or conducted before 2005	3
II.	DESIGN FACTORS	
2.	Type and Design of Trial	
	Poorly designed control group (quasi selection, convenient sampling)	0
	Proper active-control or sham procedure with injection of active agent	2
	Proper placebo-control (no active solutions into active structures)	3
3.	Setting/Physician	
	General setting with no specialty affiliation and general physician	0
	Specialty of anesthesia/PMR/neurology/radiology/orthology, etc.	1
	Interventional pain management with interventional pain management physician	2
4.	Imaging	
	Blind procedures	0
	Ultrasound	1
	CT	2
	Fluoroscopy	3
5.	Sample Size	
	Less than 50 participants in the study without appropriate sample size determination	0
	Sample size calculation with less than 25 pts in each group	1
	Appropriate sample size calculation with at least 25 pts in each group	2

Table 2 cont. *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

		Scoring
	Appropriate sample size calculation with 50 pts in each group	3
6.	Statistical Methodology	
	None or inappropriate	0
	Appropriate	1
III.	PATIENT FACTORS	
7.	Inclusiveness of Population	
7a.	For epidural procedures:	
	Poorly identified mixed population	0
	Clearly identified mixed population	1
	Disorders specific trials (i.e., well-defined spinal stenosis and disc herniation, disorder specific, disc herniation or spinal stenosis, or post-surgery syndrome)	2
7b.	For facet or sacroiliac joint interventions:	
	No diagnostic blocks	0
	Selection with single diagnostic blocks	1
	Selection with placebo or dual diagnostic blocks	2
8.	Duration of Pain	
	Less than 3 mos	0
	3–6 mos	1
	> 6 mos	2
9.	Previous Treatments	
	Conservative management including drug therapy, exercise therapy, physical therapy, etc.	
	Were not utilized	0
	Were utilized sporadically in some pats	1
	Were utilized in all pts	2
10.	Duration of Follow-up with Appropriate Interventions	
	Less than 3 mos or 12 wks for epidural or facet joint procedures, etc., and 6 mos for intradiscal procedures and implantables	0
	3–6 mos for epidural or facet joint procedures, etc., or one yr for intradiscal procedures or implantables	1
	6–17 mos for epidurals or facet joint procedures, etc., and 2 yrs or longer for discal procedures and implantables	2
	18 mos or longer for epidurals and facet joint procedures, etc., or 5 yrs or longer for discal procedures and implantables	3
IV.	OUTCOMES	
11.	Outcomes Assessment Criteria for Significant Improvement	
	No descriptions of outcomes OR < 20% change in pain rating or functional status	0
	Pain rating with a decrease of 2 or more points or more than 20% reduction OR functional status improvement of more than 20%	1
	Pain rating with decrease of ≥ 2 points AND ≥ 20% change or functional status improvement of ≥ 20%	2
	Pain rating with a decrease of 3 or more points or more than 50% reduction OR functional status improvement with a 50% or 40% reduction in disability score	2
	Significant improvement with pain and function ≥ 50% or 3 points and 40% reduction in disability scores	4
12.	Analysis of All Randomized Participants in the Groups	
	Not performed	0
	Performed without intent-to-treat analysis without inclusion of all randomized participants	1
	All participants included with or without intent-to-treat analysis	2
13.	Description of Drop Out Rate	
	No description of dropouts, despite reporting of incomplete data or ≥ 20% withdrawal	0
	Less than 20% withdrawal in one yr in any group	1

Table 2 cont. *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

		Scoring
	Less than 30% withdrawal at 2 yrs in any group	2
14.	Similarity of Groups at Baseline for Important Prognostic Indicators	
	Groups dissimilar with significant influence on outcomes with or without appropriate randomization and allocation	0
	Groups dissimilar without influence on outcomes despite appropriate randomization and allocation	1
	Groups similar with appropriate randomization and allocation	2
15.	Role of Co-Interventions	
	Co-interventions were provided but were not similar in the majority of participants	0
	No co-interventions or similar co-interventions were provided in the majority of the participants	1
V.	RANDOMIZATION	
16.	Method of Randomization	
	Quasi randomized or poorly randomized or not described	0
	Adequate randomization (coin toss, drawing of balls of different colors, drawing of ballots)	1
	High quality randomization (computer-generated random sequence, pre-ordered sealed envelopes, sequentially ordered vials, telephone call, pre-ordered list of treatment assignments, etc.)	2
VI.	ALLOCATION CONCEALMENT	
17.	Concealed Treatment Allocation	
	Poor concealment of allocation (open enrollment) or inadequate description of concealment	0
	Concealment of allocation with borderline or good description of the process with probability of failure of concealment	1
	High quality concealment with strict controls (independent assignment without influence on the assignment sequence)	2
VII.	BLINDING	
18.	Patient Blinding	
	Patients not blinded	0
	Patients blinded adequately	1
19.	Care Provider Blinding	
	Care provider not blinded	0
	Care provider blinded adequately	1
20.	Outcome Assessor Blinding	
	Outcome assessor not blinded or was able to identify the groups	0
	Performed by a blinded independent assessor with inability to identify the assignment-based provider intervention (i.e., subcutaneous injection, intramuscular distant injection, difference in preparation or equipment use, numbness and weakness, etc.)	1
VIII.	CONFLICTS OF INTEREST	
21.	Funding and Sponsorship	
	Trial included industry employees	-3
	Industry employees involved; high levels of funding with remunerations by industry or an organization funded with conflicts	-3
	Industry or organizational funding with reimbursement of expenses with some involvement	0
	Industry or organization funding of expenses without involvement	1
	Funding by internal resources only with supporting entity unrelated to industry	2
	Governmental funding without conflict such as NIH, NHS, AHRQ	3
22.	Conflicts of Interest	
	None disclosed with potential implied conflict	0
	Marginally disclosed with potential conflict	1
	Well-disclosed with minor conflicts	2
	Well-disclosed with no conflicts	3

Table 2 cont. *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

		Scoring
	Hidden conflicts with poor disclosure	–1
	Misleading disclosure with conflicts	–2
	Major impact related to conflicts	–3
TOTAL MAXIMUM		48

Table 3. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.*

I.	STROBE OR TREND Guidance	Scoring
1.	Study Design Guidance and Reporting	
	Case report/case series	0
	Study designed without any guidance	1
	Study designed with minimal criteria and reporting with or without guidance	2
	Study designed with moderately significant criteria or implies it was based on STROBE or TREND without clear description or the study was conducted before 2011 or similar criteria utilized with study conducted before 2011	3
	Designed with high-level criteria or explicitly uses STROBE or TREND with identification of criteria or conducted prior to 2011	4
II.	DESIGN FACTORS	
2.	Study Design and Type	
	Case report or series (uncontrolled – longitudinal)	0
	Retrospective cohort or cross-sectional study	1
	Prospective cohort case-control study	2
	Prospective case-control study	3
	Prospective, controlled, nonrandomized	4
3.	Setting/Physician	
	General setting with no specialty affiliation and general physician	0
	Specialty of anesthesia/PMR/neurology, etc.	1
	Interventional pain management with interventional pain management physician	2
4.	Imaging	
	Blind procedures	0
	Ultrasound	1
	CT	2
	Fluoroscopy	3
5.	Sample Size	
	Less than 100 participants without appropriate sample size determination	0
	At least 100 participants in the study without appropriate sample size determination	1
	Sample size calculation with less than 50 pts in each group	2
	Appropriate sample size calculation with at least 50 pts in each group	3
	Appropriate sample size calculation with 100 pts in each group	4
6.	Statistical Methodology	
	None	0
	Some statistics	1
	Appropriate	2
III.	PATIENT FACTORS	
7.	Inclusiveness of Population	
7a.	For epidural procedures:	

Table 3 cont. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.*

I.	STROBE OR TREND Guidance	Scoring
	Poorly identified mixed population	1
	Poorly identified mixed population with large sample (≥ 200)	2
	Clearly identified mixed population	3
	Disorders specific trials (i.e., well-defined spinal stenosis and disc herniation, disorder specific, disc herniation or spinal stenosis, or post-surgery syndrome)	4
7b.	For facet or sacroiliac joint interventions:	
	No specific selection criteria	1
	No diagnostic blocks based on clinical symptomatology	2
	Selection with single diagnostic blocks	3
	Selection with placebo or dual diagnostic blocks	4
8.	Duration of Pain	
	Less than 3 mos	0
	3–6 mos	1
	> 6 mos	2
9.	Previous Treatments	
	Conservative management including drug therapy, exercise therapy, physical therapy, etc.	
	Were not utilized	0
	Were utilized sporadically in some pts	1
	Were utilized in all pts	2
10.	Duration of Follow-up with Appropriate Interventions	
	3 mos or less for epidural or facet joint procedures, etc., and 6 mos for intradiscal procedures and implantables	1
	3–6 mos for epidural or facet joint procedures, etc., or 1 year for intradiscal procedures or implantables	2
	6–12 mos for epidurals or facet joint procedures, etc., and 2 yrs or longer for discal procedures and implantables	3
	18 mos or longer for epidurals and facet joint procedures, etc., or 5 yrs or longer for discal procedures and implantables	4
IV.	OUTCOMES	
11.	Outcomes Assessment Criteria for Significant Improvement	
	No descriptions of outcomes OR < 20% change in pain rating or functional status	0
	Pain rating with a decrease of 2 or more points or more than 20% reduction OR functional status improvement of more than 20%	1
	Pain rating with decrease of ≥ 2 points AND ≥ 20% change or functional status improvement of ≥ 20%	2
	Pain rating with a decrease of 3 or more points or more than 50% reduction OR functional status improvement with a 50% or 40% reduction in disability score	2
	Significant improvement with pain and function ≥ 50% or 3 points and 40% reduction in disability scores	4
12.	Description of Drop Out Rate	
	No description despite reporting of incomplete data or more than 30% withdrawal	0
	Less than 30% withdrawal in one yr in any group	1
	Less than 40% withdrawal at 2 yrs in any group	2
13.	Similarity of Groups at Baseline for Important Prognostic Indicators	
	No groups or groups dissimilar with significant influence on outcomes despite proper allocation	0
	Groups dissimilar without significant influence on outcomes despite proper allocation	1
	Groups similar with appropriate allocation	2
14.	Role of Co-Interventions	
	Dissimilar co-interventions or similar co-interventions in some of the participants	1
	No co-interventions or similar co-interventions in majority of the participants	2
V.	ASSIGNMENT	

Table 3 cont. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.*

I.	STROBE OR TREND Guidance	Scoring
15.	Method of Assignment of Participants	
	Case report/case series or selective assignment based on outcomes or retrospective evaluation based on clinical criteria	1
	Prospective study with inclusion without specific criteria	2
	Retrospective method with inclusion of all participants or random selection of retrospective data	3
	Prospective, well-defined assignment of methodology and inclusion criteria (quasi randomization, matching, stratification, etc.)	4
VI.	CONFLICTS OF INTEREST	
16.	Funding and Sponsorship	
	Trial included industry employees with or without proper disclosure	-3
	Industry employees involved; high levels of funding with remunerations by industry or an organization funded with conflicts	-3
	Industry or organizational funding with reimbursement of expenses with some involvement or no information available	0
	Industry or organization funding of expenses without involvement	1
	Funding by internal resources only	2
	Governmental funding without conflict such as NIH, NHS, AHRQ	3
TOTAL MAXIMUM		48

Data Extraction and Management

Methodologic quality assessment was performed by the authors with groups of 2 authors reviewing multiple manuscripts. The assessment was carried out independently in an unblended and standardized manner to assess the methodologic quality and internal validity of all of the studies considered for inclusion. Any discrepancies in the methodologic quality assessment were evaluated by a third reviewer and settled by consensus.

If there was a conflict of interest with a reviewed manuscript, the involved author(s) did not review the manuscript for methodologic quality assessment.

Meta-Analysis

If the literature search provided at least 3 randomized trials meeting the inclusion criteria and they were clinically homogenous for each modality and region evaluated, a meta-analysis was performed.

Data were summarized using a meta-analysis when at least 3 studies per type of modality were available that met the inclusion criteria of discogenic pain.

Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. A random-effects meta-analysis to pool data was also used. For placebo-controlled trials, the net effect between 2 treatments was utilized. However, for active-controlled trials, the differences between baseline and at the follow-up period were utilized.

Definition of Successful Outcomes

Previously, the consensus was that at least a 2-point change on a 0 to 10-point pain scale, such as the visual analog scale (VAS) or numerical rating scale (NRS), was necessary to document a clinically meaningful change (37,38,41,47,50-56). The current review will use the more rigorous standard of 40% pain relief (57-70).

This study will define clinically meaningful pain relief and functional status improvement as a 40% reduction from baseline.

Short-term efficacy was defined as improvement for less than 6 months; long-term efficacy was defined as improvement for 6 months or longer.

Grading of Evidence

The grading of the evidence was performed using ASIPP's modification of the United States Preventive Services Task Force's (USPSTF) 5-point scale and other criteria (71-78).

Table 4 shows the evidence rating, ranging from Level I, consensus, at the bottom, to Level IV, multiple RCTs, as the strongest level of evidence.

Results

Fig. 1 shows a flow diagram of study selection as recommended by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (42).

There were 49 studies considered for inclusion. Of these, 33 manuscripts were excluded from further

Table 4. *ASIPP grading of evidence*

Level I	Evidence obtained from multiple relevant high quality RCTs
Level II	Evidence obtained from at least one relevant high quality RCT or multiple relevant moderate or low quality RCTs
Level III	Evidence obtained from at least one relevant moderate or low quality RCT with multiple relevant observational studies OR Evidence obtained from at least one relevant high quality nonrandomized trial or observational study with multiple moderate or low quality observational studies
Level IV	Evidence obtained from multiple moderate or low quality relevant observational studies
Level V	Opinion or consensus of large group of clinicians and/or scientists

At least 60% of studies in the direction of the objective being assessed.

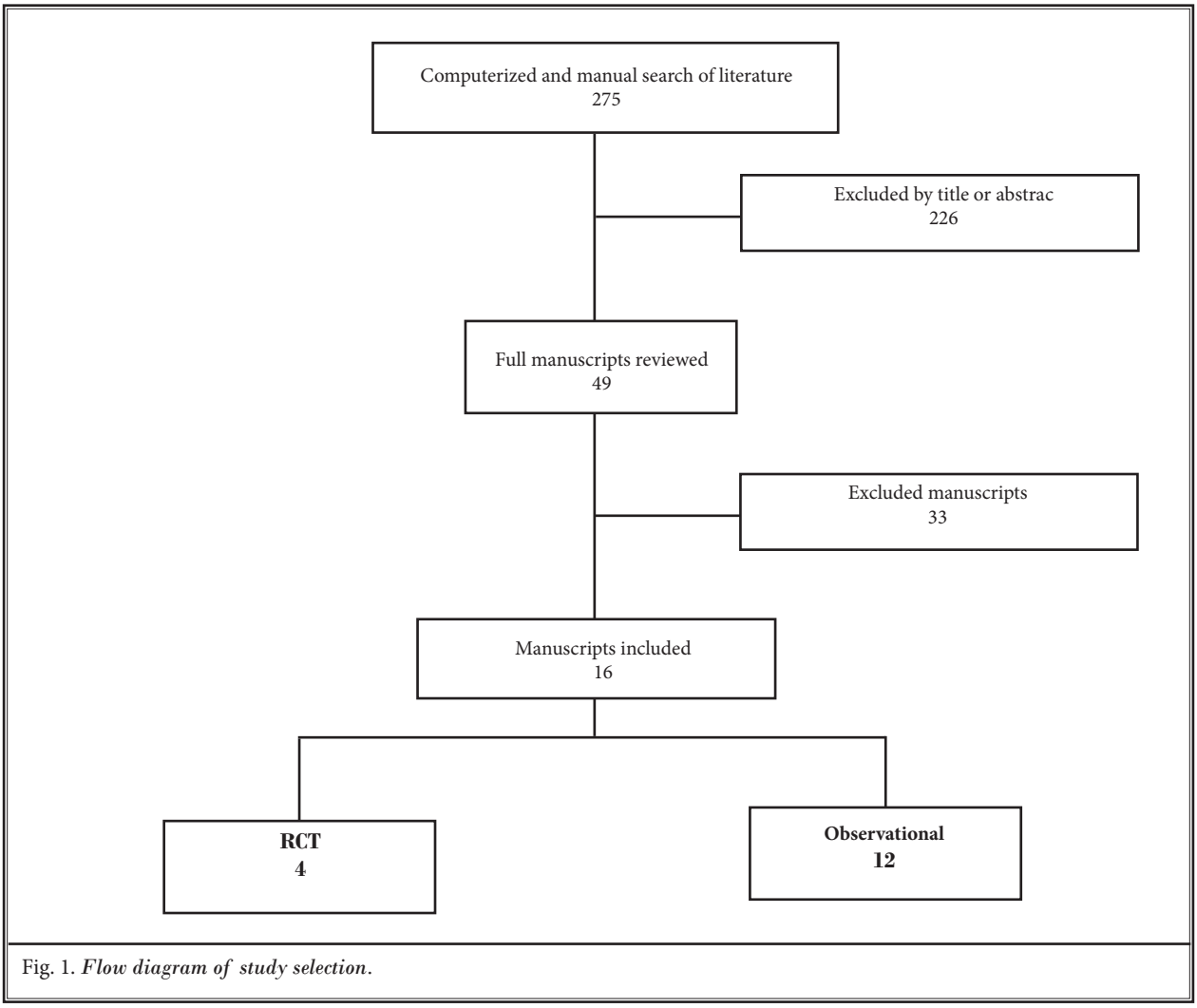

Fig. 1. *Flow diagram of study selection.*

evaluation. Table 5 shows the reasons for exclusion.

Table 6 illustrates the characteristics of the trials considered for inclusion.

Methodological Quality Assessment

A methodological quality assessment of the RCTs meeting inclusion criteria was carried out utilizing Cochrane Review criteria, presented in Table 7.

A methodological quality assessment of both randomized trials and observational studies was also done utilizing ASIPP criteria, as shown in Table 8 and Table 9.

Table 5. *List of excluded randomized and non-randomized studies.*

Study	Number of Pts	Treated vs. Control	Follow-up Period	Reason for Exclusion
RCTs				
Kapural (131)	55	Biacuplasty v sham	6 mos	Same pt population as Kapural 2015, which presented 12-mo follow-up
Barendse et al (132)	28	13 intranuclear radiofrequency; 15 needle placement without radiofrequency	8 wks	Dealt with intranuclear radiofrequency rather than an annular procedure
Cao et al (133)	120	6 arms of 20 each	6 mos	Dealt in intranuclear injection of steroids rather than an annular procedure
Ercelen et al (134)	37	19 intranuclear radiofrequency-120 sec; 18 intranuclear radiofrequency-360 sec	6 mos	Dealt with intranuclear radiofrequency rather than an annular procedure
Kvarstein (135)	20	DiscTRODE v sham	12 mos	Failure to have >25 pts in each group
Non-Randomized Studies				
Rohof (26)	76	Intranuclear pulsed radiofrequency	12 mos	No annular procedure was performed.
Hashemi et al (136)	37	Intradiscal ozone for disc herniation	6 mos	Did not deal with annular disease
Yin et al (21)	15	Inject fibrin sealant for discogenic pain	2 yrs	Failure to meet criteria of > 50 pts; did not deal with application of heat to annulus
Saal & Saal (137)	25	IDET	Mean 7 mos	Same database as Saal 2002
Finch et al (138)	46	31 treated with discTRODE; 15 controls	12 mos	Failure to meet criterion of at least 25 pts in each group
Kapural et al (139)	3	Biacuplasty		Failure to meet criteria of > 50 pts; dealt with thoracic pain
Kapural et al (140)	1	Biacuplasty	1 yr	Case study
Kapural et al (81)	42	21 IDET; 21 discTrode	12 mos	Failure to meet criterion of 25 pts in each group
Mekhail & Kapural (141)	34	IDET	12 mos	Failure to meet criteria of > 50 pts
Kapural et al (142)	34	17 IDET 1-2 level disc disease; 17 IDET multilevel disc disease	12 mos	Failure to meet criterion of 25 pts in each group
Kapural et al (143,144)	15	Biacuplasty	6 mos; 12 mos	Failure to meet criteria of > 50 pts
Assietti (145)	50	IDET	24	Duplicate of Assietti 2010, as an abstract presentation
Cohen et al (146)	9	IDET	6 mos	Failure to meet criteria of > 50 pts
Derby et al (147)	36	IDET	12 mos	Failure to meet criteria of > 50 pts
Derby et al (148)	35	IDET	16 mos	Failure to meet criteria of > 50 pts; same pt population as Derby 2004
Endres et al (149)	54	IDET	3 mos–2 yrs	Data provided were inadequate for any type of conclusion
Ergün et al (150)	39	IDET	18 mos	Failure to meet criteria of > 50 pts
Freedman et al (151)	41	IDET	6–46 mos	Failure to meet criteria of > 50 pts
Gerstein et al (152)	27	IDET	12 mos	Failure to meet criteria of > 50 pts
Karasek & Bogduk (153,154)	53	36 treated with IDET/17 control	12 mos; 24 mos	Failure to meet criteria of 25 pts in each group; both studies evaluated same data base.
Lee et al (155)	51	32 IDET one level; 19 IDET multilevel	24 mos	Failure to meet criteria of 25 pts in each group
Lutz et al (156)	33	IDET	Mean 15 mos	Failure to meet criteria of > 50 pts

Table 5 cont. *List of excluded randomized and non-randomized studies.*

Study	Number of Pts	Treated vs. Control	Follow-up Period	Reason for Exclusion
Maurer & Squillante (157)	70	IDET	24 mos	Same patient population as Maurer 2008
Saal & Saal (158)	62	IDET	12 mos	Same patient population as Saal 2002
Singh (159)	23	IDET	6 mos	Failure to meet criteria of > 50 patients
Spruit & Jacobs (160)	20	IDET	6 mos	Failure to meet criteria of > 50 pts

Table 6. *Assessment of randomized trials and observational studies for inclusion criteria.*

	Type of Study	Number of patients	Treatment vs. Comparator	Length of Follow up	Outcome Parameters	Comments
RANDOMIZED						
Kapural (82)	RA, PC, P	55	Biacuplasty=27; sham=28	12 mos	SF-36, NRS, ODI	Randomized, double-blinded study; treatment vs sham
Desai (83)	RA, AC, P	63	Biacuplasty +conventional medical management=29; conventional medical management=34	6 mos	VAS, SF-36, ODI, BID	Randomized, double-blinded study; treatment vs active control
Pauza (79)	RA, PC, P	64	IDET=37; sham=27	6 mos	VAS, ODI, SF-36	40% of pts had 50% relief
Freeman (80)	RA, PC, P	57	IDET=38; sham=19	6 mos	VAS, ODI, SF-36. LBOS	No improvement in either group
OBSERVATIONAL						
Derby et al (161)	RE	109	IDET=74; injection=35 IDET vs restorative injections	6–18 mos	VAS	Analysis of patients treated from 1/00 to 10/02; pain relief of 1.27 for IDET and 2.2 for injection; 35% of IDET pts were worse; 0% of injection pts were worse.
Tsou et al (162)	P	93	IDET	3 yrs	Percent improvement – 100%, > 50%, < 50%, no change or increase	The results were positive in short term and long term with 62% at 3 mos, 74% at 6 mos, 63% at one yr, 60% at 2 yrs, and 48% at 3 yrs.
Assietti et al (163)	P	50	IDET	24 mos	VAS, ODI, Prolo Score	68% improvement at 24 mos; predictors of success include discographic pain concordance, disc height (Pfirrmann Grade), HIZ, and percentage of annulus covered.
Bryce et al (164)	P	86	IDET	24 mos	VAS, RMDQ	Significant relief in women and age 18 - 45; relief in men lasted 3 - 6 mos
Cohen et al (85)	RE	79	IDET	6 mos	VAS	48% of pts had > 50% relief at 6 mos; obesity is a risk factor.
Davis et al (89)	RE	60	IDET	12 mos	Surgical treatment for back pain after IDET	48 of 60 pts completed the interview process; 6 ps had surgery at one yr and 4 more at 2 yrs. 37% of pts were satisfied with the procedure at one yr.

Table 6 cont. *Assessment of randomized trials and observational studies for inclusion criteria.*

	Type of Study	Number of patients	Treatment vs. Comparator	Length of Follow up	Outcome Parameters	Comments
Derby et al (165)	RE	99	IDET	18 mos	VAS	Analysis of 129 pts treated from 1/6/99 to 1/6/00; 30 had fusion and were excluded, 83% had leg pain without sciatica, and 63.9% of patients had mean pain relief of 3.28/10. Relief of low back and leg pain was correlated.
Maurer et al (166)	RE	56	IDET	6 mos	VAS, SF-36	75% had ≥ 2-point improvement in pain severity or ≥ 10-point improvement of SF-36 domains.
Nunley et al (167)	RE	53	IDET	12 mos	VAS, ODI	Mean reduction in VAS was 62%; mean reduction in ODI was 69%.
Saal & Saal (168)	RE	58	IDET	24 mos	VAS, SF-36, Sitting tolerance	50% of pts had a ≥ 4-point improvement in VAS.
Webster et al (169)	RE	142	IDET	Mean 22 mos	Narcotic use, lumbar injections, Surgery	142 cases obtained from workers' compensation files
Wetzel et al (170)	P	78	IDET	24 mos	VAS, ODI	Mean reduction in VAS of 2.8

RA = randomized; PC = placebo-control; AC = active-control; P = prospective; RE = retrospective; VAS = visual analog scale; ODI = Oswestry Disability Index; RMDQ = Roland Morris Disability Questionnaire; P-3 = Pain Patient Profile; FBSS = failed back surgery syndrome; ROM = range of motion; ADLs = activities of daily living; SF36 = Short-Form 36; NRS = numerical rating scale; LBOS = low back outcome score

Table 7. *Methodological quality assessment of randomized trials of TAPs utilizing cochrane review criteria.*

	Kapural 2015 (82)	Desai (83)	Pauza (79)	Freeman (80)
Randomization adequate	Y	Y	Y	U
Concealed treatment allocation	Y	Y	Y	U
Patient blinded	Y	Y	Y	Y
Care provider blinded	N	N	N	U
Outcomes assessor blinded	Y	Y	Y	Y
Drop-out rate described	Y	Y	Y	Y
All randomized participants analyzed in the group	Y	Y	Y	Y
Reports of the study free of suggestion of selective outcome reporting	Y	Y	Y	Y
Groups similar at baseline regarding most important prognostic indicators	Y	Y	Y	N
Co-intervention avoided or similar in all groups	Y	Y	Y	Y
Compliance acceptable in all groups	Y	Y	Y	Y
Time of outcome assessment in all groups similar	Y	Y	Y	Y
Score	11/12	11/12	11/12	8/12

Meta-Analysis

There were not a sufficient number of homogeneous TAP studies to allow a meta-analysis.

Study Characteristics

Table 10 shows the study characteristics of the included studies for randomized trials and observational studies evaluating TAPs.

Analysis of Evidence

Three devices have been evaluated for the treatment of intradiscal pain. IDET uses conductive heat

Table 8. *Methodologic quality assessment of RCTs utilizing IPM – QRB criteria.*

		Kapural (82)	Desai (83)	Pauza (79)	Freeman (80)
I.	Trial design and guidance reporting				
1.	Consort or spirit	2	2	2	1
II.	Design factors				
2.	Type and design of trial	3	2	3	3
3.	Setting/physician	3	3	2	1
4.	Imaging	3	3	3	3
5.	Sample size	2	2	2	1
6.	Statistical methodology	1	1	1	1
III.	Patient factors				
7.	Inclusiveness of population	2	2	2	2
8.	Duration of pain	2	2	2	2
9.	Previous treatments	2	2	2	2
10.	Duration of follow-up with appropriate interventions	1	0	0	0
IV.	Outcomes				
11.	Outcomes assessment criteria for significant improvement	2	1	2	1
12.	Analysis of all randomized participants in the groups	2	2	1	1
13.	Description of dropout rate	1	0	1	1
14.	Similarity of groups at baseline for important prognostic indicators	2	2	2	0
15.	Role of co-interventions	1	1	1	1
V.	Randomization				
16.	Method of randomization	2	2	2	0
VI.	Allocation concealment				
17.	Concealed treatment allocation	2	2	2	1
VII.	Blinding				
18.	Patient blinding	1	0	1	1
19.	Care provider blinding	0	0	0	0
20.	Outcome assessor blinding	1	1	1	1
VIII.	Conflicts of interest				
21.	Funding and sponsorship	1	1	1	1
22.	Conflicts of interest	3	3	1	1
Total		39/48	34/48	34/48	25/48

delivered by placing a catheter across the posterior annulus or nuclear-annular junction. DiscTRODE uses unipolar radiofrequency delivered by a catheter placed across the outmost aspect of the annulus. Biacuplasty uses bipolar and unipolar radiofrequency delivered by probes placed in the annulus, augmented by cooling technology to increase lesion size and allow a bipolar lesion.

Table 11 summarizes the results of therapeutic studies evaluating these technologies.

IDET

There are 2 studies of acceptable methodological quality regarding IDET. The study done by Pauza et al (79) is a high-quality study showing the efficacy of IDET; the study done by Freeman et al (80) is a moderate-quality study which indicates that there was no difference between the IDET and placebo groups. Freeman's study does not highlight that there was no benefit from either the treatment or the placebo, a finding which is concerning given the role of placebo effects.

Table 9. *IPM checklist for assessment of nonrandomized or observational studies of TAPs utilizing IPM-QRBNR.*

		Derby et al (160)	Tsou et al (161)	Assietti et al (162)	Bryce (163)	Cohen et al (85)	Davis et al (89)
I.	Study design and guidance reporting						
1.	Strobe or trend guidance	1	0	0	0	0	0
II.	Design factors						
2.	Study design and type	1	0	0	0	1	0
3.	Setting/physician	2	1	1	2	2	1
4.	Imaging	3	3	3	3	3	3
5.	Sample size	0	0	0	0	0	0
6.	Statistical methodology	2	2	2	2	2	1
III.	Patient factors						
7.	Inclusiveness of population	3	3	3	3	3	3
8.	Duration of pain	2	2	2	2	2	1
9.	Previous treatments	2	2	2	2	2	0
10.	Duration of follow-up with appropriate interventions	1	2	3	2	1	2
IV.	Outcomes						
11.	Outcomes assessment criteria for significant improvement	0	2	1	0	2	0
12.	Dropout rate	0	0	0	0	0	0
13.	Similarity of groups at baseline for important prognostic indicators	0	0	0	0	0	0
14.	Role of co-interventions	2	0	0	0	0	0
V.	Assignment						
15.	Method of assignment of participants	1	1	1	1	1	1
VI.	Conflicts of interest						
16.	Funding and sponsorship	2	2	2	2	3	2
Total		22/48	20/48	20/48	19/48	21/48	14/48

There are also multiple single-arm, observational studies which were not of sufficient quality to include in the current analysis.

Based upon one high quality study showing efficacy and one moderate quality study which either shows lack of efficacy or which should be excluded for methodological flaws, the evidence for the use of IDET is Level III, fair.

discTRODE

There are no high quality studies showing the efficacy of IDET. There is one study excluded for failing to meet inclusion criteria showing that IDET was more effective than discTRODE (81).

Based upon the ASIPP criteria, the evidence for the efficacy of discTRODE is Level V, low.

Biacuplasty

There are 2 high quality RCTs of biacuplasty. One utilizes a true placebo to demonstrate efficacy, with 40% improvement in pain and function at 12 months (82). The second study incorporates an active comparator to document the superiority of biacuplasty over conventional medical management, with 50% of the treated group having at least a 2-point increase in VAS, compared to 18% of the medically managed group (83).

Based upon evidence from 2 high quality RCTs, there is level I, strong, evidence, supporting the use of biacuplasty for discogenic low back pain.

Complications

The published literature regarding biacuplasty has not shown any complications.

Table 10. *Study characteristics of RCTs and observational studies which meet quality criteria.*

Study Characteristic; Methodological Quality Scoring	Number of Patients & Selection Criteria	Intervention/ Control	Outcome Measures	Time of Measurement	Results	Weaknesses	Strengths	Conclusions
Kapural 2015 (82) RCT; placebo-control; 39/48	27 Biacuplasty; 30 sham. Low back pain unresponsive to conservative treatment; positive discography; one or 2-level disease; cross-over was allowed at 6 mos	Biacuplasty vs placement outside of the disc with no RF energy applied.	SF-36, NRS, ODI	6 and 12 mos	SF36 improved by 46%; NRS improved by 38%; 36% had both a > 2-point change in NRS and >15 increase SF-36	5 drop-outs in treatment group and 4 in cross-over group; average pain reduction was 40%	High-quality randomized study with a true placebo showing efficacy of the procedure.	Biacuplasty is a safe and effective treatment that offers an alternative to fusion.
Desai (83) RCT; active-control; 34/48	63 Lumbar discogenic; pain diagnosed with discography	Biacuplasty +conventional medical management (CMM)=29; CMM=34	VAS, SF-36, ODT	6 mos	Mean VAS reduction with biacuplasty was 2.4, vs .56 in CMM, 50% of treated had ≥2-point reduction or ≥30% reduction in VAS vs 18% in CMM.	Pain relief measured as 2 points or 30% on VAS instead of 50%	High-quality study showing efficacy.	Biacuplasty is more effective than CMM in treating low back pain.
Pauza (79) RCT; placebo–control; 34/48	37=IDET, 27=sham; 6-mo history of low back pain unresponsive to conservative treatment; positive discography	IDET vs placement of introducer needle outside of the disc. Both groups were exposed to same visual and auditory stimulation.	VAS, SF-36, ODI	6 mos	24% of IDET had >75% relief vs 4% of sham. 40% of IDET had ≥50% relief, compared to 33% of sham. Pts with pain <7 before treatment did better than those ≥7. Pts with ODI <40 had minimal relief.	Highly selective study, selecting 64 of 1360 candidates. Study not fully powered. 50% did not get relief.	High-quality study showing efficacy of IDET with persistent relief. Strong placebo effect, which did not persist. Clarification that high VAS and low disability lead to less benefit.	High-quality study showing efficacy of procedure.
Freeman (80) RCT;placebo–control; 25/48	38 IDET; 19 sham 3-mo history of low back pain unresponsive to conservative treatment; positive discography	Both groups had IDET catheter placed. Treatment group's cable was attached to the generator; the sham's cable was not. Unclear if both groups were exposed to same visual and auditory stimulation.	LBOS, SF-36 subscales of bodily pain and physical functioning. VAS, ODI	6 mos	No improvement in any parameter for either the treatment or the placebo group.	No placebo response; not fully powered.	Prospective, randomized, placebo-controlled study	Moderate-quality study

VAS= visual analog scale; NRS= numeric rating scale; ODI= Oswestry Disability Index; LBOS= Low Back Outcome Score

Table 11. *Efficacy of TAPs*

Study Study Characteristic Methodological Quality Scoring	Patients	Interventions	Pain Relief and Function		Result		Comments
			6 mos	12 mos	6 mos	12 mos	
Kapural 2015 (82) RA placebo–controlled; 39/48	57	Biacuplasty vs placebo	NRS 38% improvement; SF-36 46% improvement	NRS 40% improvement SF-36 46% improvement	P	P	High-quality study showing efficacy
Desai (83) RA active–control; 34/48	63	Biacuplasty vs conventional medical management (CMM)	50% of treated had ≥2-point reduction or ≥30% reduction in VAS vs. 18% in active-control	NA	P	NA	High-quality study showing superiority of biacuplasty over CMM
Pauza (79) RA placebo-controlled; 34/48	64	IDET vs placebo	VAS 40% had 50% relief	NA	P	NA	High-quality study showing efficacy
Freeman (171) RA placebo-controlled; 25/48	57	IDET vs placebo	No change in treated or placebo	NA	N	NA	Moderate-quality study with methodological flaw of no placebo response.

RA = randomized; DB = double-blind; AC = active control; SI = significant improvement; P = positive; N = negative; NA = not applicable VAS= visual analog scale; NRS= numeric rating scale; ODI=Oswestry Disability Index

There are no new reports of complications regarding IDET since the 2012 systematic review (84). Cohen et al (85) reported up to a 10% complication rate, with either increased or new pain, all of which resolved within weeks.

Disc herniation after IDET has been reported (86,87). Discitis, osteonecrosis, and the development of grade 1 anterolisthesis have been reported, as has catheter shearing (88-90). Cauda equina syndrome has also been reported (91-93). Derby et al (94) reported a review of 1,675 IDET procedures and 35,000 medical device reports from the Food and Drug Administration. There were 6 nerve root injuries, 5 of which were related to the placement of the introducer needle. They resolved spontaneously. Six cases of disc herniation were reported, 2 of which required discectomy. In addition, 19 cases of catheter breakage were reported.

There are no published cases of complications from discTRODE (95). Adverse events may be underreported and may include possible permanent damage to traversing motor roots.

The incidence of complications from a TAP, particularly biacuplasty, is low. The procedures should be considered low risk for adverse events.

Discussion

The concept that the disc could be a source of pain, without nerve root irritation, was first proposed by Crock in 1970 (96). Intradiscal disorder (IDD) is a distinct entity from other sources of low back pain, including disc herniation, spinal stenosis, or degenerative disc disease (DDD), without evidence of injury to the annulus (10,97). The intervertebral disc consists of the nucleus pulposus, the annulus, and the vertebral endplates. The normal nucleus pulposus consists of collagen and elastin fibers in a hydrated gel. The annulus consists of 15–25 concentric collagen fibers and serves to contain the nucleus as the nucleus moves in response to the distribution of load associated with movement of the spine (98). Degeneration of the disc is a normal process and is associated with a loss of water and proteoglycans from the nucleus, with a decreased ability to transfer stresses to the annulus. A degenerated disc need not be painful (99).

There is extensive literature confirming the inner-

vation of the disc (7,100-111). The posterior disc, the posterior longitudinal ligament, and the ventral dura are innervated by the sinuvertebral nerve, which has a somatic contribution from the ventral ramus and a sympathetic contribution from the gray ramus communicantes (7). The sympathetic fibers have both efferent and afferent components, consistent with the ability to convey pain impulses (112-115).

In a normal disc, nerves extend only into the outer one-third of the annulus. With aging, the annulus can tear. The disc attempts to heal a tear in the annulus. This healing process starts with a local inflammatory response, including neovascularization of the tear. Macrophagesand mast cells migrate into the tear, with the production of growth factors. This process leads to the development of fibrosis and inflammatory granulation tissue. Nerves capable of expressing both sympathetic and nociceptive pain extend from their normal location in the outer one-third of the annulus into the deeper layers of the annulus (107,108,116,117). There, factors associated with the inflammatory response, such as various interleukins, prostaglandins, and tissue necrosis factor, can sensitize both the somatic and sympathetic nerves (7). Further, sympathetic efferents may, in response to ischemia or inflammation, initiate a pain impulse leading to peripheral sensitization of the intradiscal pain receptors. This sympathetically initiated peripheral sensitization may explain why some degenerated discs are painful and others are not (99).

Provocation discography is the gold standard for diagnosing pain caused by internal disc disruption (6,98,118). A recent systematic review of provocation lumbar discography by Manchikanti et al (119) found the evidence supporting the use of discography to be fair, on the 3-point, good, fair or poor/limited scale. There are no reliable clinical findings upon which to make the diagnosis, as the sensitivity of these clinical findings is too low (119-122). MRI has also been evaluated as a tool to identify painful IDD. Kang et al (123) found that a high intensity zone on the T2, imaged with a disc protrusion, correlated well with positive discography, although the sensitivity was only 45%. Lei et al (124) developed a 4-point scale incorporating disc height, MRI signal, and annular tears to identify intradiscal disorder. They found a sensitivity of 94% of MRI findings predicting discography findings, although it is not clear that manometry was used for discography.

Once identified, IDD is difficult to treat. Given the limited success of fusion, there is a need for therapies to help patients with IDD who either do not want surgery or who are not candidates for surgery. In addition, cost pressures, the introduction of alternate payments systems, and the increasing importance of comparative effectiveness research create an impetus for cost-effective therapies, such as interventional techniques, to treat the problem of IDD that is unresponsive to conservative therapy (125).

This review focuses on the use of heat to treat IDD, both because heat was the first technology introduced to treat the problem and because heat is the best-studied technology. Studies are underway to evaluate various injection therapies and also to evaluate heat applied by laser from the epidural space. As these studies become available, future reviews can evaluate them.

Heat has been applied to the disc in 3 different ways. IDET uses conductive heating, in which a wire is heated up, transmitting energy to the annulus. For IDET to work, a wire needs to be passed across the posterior annulus, a task which can be frustrating in the presence of a diseased annulus.

DiscTRODE and biacuplasty both use radiofrequency energy, in which high frequency, on the order of 500,000 Hz, is passed into the tissue. This energy does not cause the wire to heat up, but rather creates ionic movement in the tissues, generating heat. Thus, in conductive heating, the wire heats the tissues, whereas in radiofrequency heating, the tissues heat the wire. One effect of radiofrequency heat is that it can cause charring around the wire, decreasing conductance of the energy and limiting the size of the lesion. DiscTRODE functions by utilizing a wire placed across the posterior annulus to generate a unipolar radiofrequency lesion. DiscTRODE does not solve the technical issue of passing a wire across a diseased annulus. Biacuplasty does not require placement of a wire across the annulus as it incorporates water to remove heat from the distal probe, preventing charring and allowing both a larger lesion and a bipolar lesion, so that heat can be applied to the annulus without passing a wire across the annulus. Biacuplasty has been referred to a cooled radiofrequency, causing some to confuse it with pulsed radiofrequency, in which radiofrequency energy is used to generate temperatures below the level needed to create neural damage. What is cooled in biacuplasty is the probe; the temperatures generated are the same as generated in standard heat radiofrequency.

Of the 3 technologies, the level of evidence of discTRODE is limited.

IDET does have a high quality study supporting its use. Pauza et al (79) have been criticized for showing

benefit "only a small proportion of highly selected subjects" (126). That criticism discounts the fact that efficacy studies are, by design, highly selective and that 40% of these patients with refractory pain had 50% relief. IDET, and TAPs in general, as evinced by the CMS non-coverage determination, by the presence of a second RCT showing no difference between IDET and the placebo treatment. .Unfortunately, this description of the findings is not accurate. Freeman et al (80) found that neither the treatment nor the placebo arm had any improvement. The existence of a placebo effect has been confirmed (127,128). While one would not be surprised if both the treatment and placebo arms showed the same benefit, the absence of any placebo effect is not expected and suggests the presence of a nocebo effect (129,130). The absence of placebo effect indicates a serious methodological flaw, so that no determination of efficacy can be made from this paper.

Biacuplasty has 2 high quality studies, both published in 2015, showing benefit over both placebo and alternative treatment, specifically conservative medical management. These studies have been criticized on the basis that the studies do not show robust enough pain or functional improvement. Kapural et al (82) found a roughly 40% mean improvement in both pain and function at 12 months in a population for which we have no other proven treatment options. Essentially all patients in the placebo-controlled study had pain for more than 2 years (131).

In addition to high quality evidence supporting the use of biacuplasty, the ability to generate heat across the annulus using a bipolar lesion resolves the technical problem of passing a wire across the annulus.

Based upon efficacy shown in high quality studies, technical improvements, and the absence of other treatment options which have evidence documenting their efficacy, biacuplasty should be considered as an option for patients with discogenic back pain refractory to other treatments.

Conclusion

Discogenic pain, or IDD, is a distinct clinical entity in which the attempts to heal a damaged annulus lead to sensitized nerves and pain. Treatment of discogenic pain can be frustrating. Heat applied to the annulus has been used to treat discogenic pain. IDET has quality evidence supporting its use, but a countervailing study has been interpreted to show lack of efficacy of the procedure. There is no high quality evidence supporting the use of discTRODE.

Biacuplasty has 2 high quality studies, one with a placebo-control and another with an active comparator, showing efficacy. Given the lack of treatment options with evidence showing efficacy and given the documented superiority of biacuplasty over conventional medical treatment, biacuplasty should be considered as a treatment option in patients with refractory discogenic pain.

Acknowledgments

We would like to thank the staff of Pain Physician for their assistance and the editorial board of Pain Physician for their review and criticism in improving the manuscript.

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