Pain Physician 2013; 16:SE229-SE260 • ISSN 2150-1149

Systematic Review

Percutaneous Lumbar Laser Disc Decompression: An Update of Current Evidence

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: Dr. Calodney is a consultant for Stryker, Inc., Medtronic, Inc., and Nimbus Concepts.
Dr. Falco is a consultant for St. Jude Medical Inc. and Joimax Inc.
Dr. Caraway is a consultant for Medtronic, Inc., Spinal Modulation, Inc., and Vertos, Inc..

Manuscript received: 08-12-2012
Revised manuscript received: 02-10-2013
Accepted for publication: 04-01-02013

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Background: Since the descriptions by Mixter and Barr of surgical treatment for rupture of the intervertebral disc in 1934, open surgical procedures have become a common practice. Disc herniations are often classified as being contained or non-contained. The results of open surgical discectomy for contained disc herniation have been poor. Consequently, several less invasive techniques have been developed including percutaneous lumbar laser disc decompression.

Study Design: A systematic review of the literature of percutaneous lumbar laser disc decompression.

Objective: The objective of this systematic review is to evaluate and update the clinical effectiveness of percutaneous lumbar laser discectomy in managing radicular pain secondary to contained disc herniation.

Methods: The available literature on lumbar laser disc decompression in managing chronic low back and lower extremity pain was reviewed. Quality assessment and clinical relevance of randomized trials were graded according to the Cochrane Musculoskeletal Review Group criteria for interventional techniques, and observational studies according to the Newcastle-Ottawa Scale criteria.

The level of evidence was classified as good, fair, and limited or poor based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF).
Data sources included relevant literature identified through searches of PubMed and EMBASE from 1966 to September 2012, and manual searches of the bibliographies of known primary and review articles.

Outcome Measures: Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, opioid intake, and return-to-work.

Short-term effectiveness was defined as effectiveness lasting one year or less, whereas, long-term effectiveness was defined as benefit persisting for greater than one year.

Results: Based on USPSTF criteria, the indicated level of evidence for percutaneous lumbar laser disc decompression is limited for short- and long-term relief.

Limitations: Although laser discectomy has been utilized for many years, there is a paucity of randomized clinical trials.

Conclusion: This systematic review shows limited evidence for percutaneous lumbar laser disc decompression.

Key words: Intervertebral disc disease, chronic low back pain, disc herniation, disc protrusion, radiculitis, contained disc herniation, mechanical disc decompression, percutaneous lumbar laser discectomy, laser assisted spinal endoscopy

Pain Physician 2013; 16:-SE229-SE260

Mixter and Barr (1) described the open surgical treatment for rupture of the intervertebral disc in 1934. Since their report, numerous surgeries have been performed (2-11). Disc pathology may occur in many different forms with disc prolapse, protrusion, or herniation involving nerve root irritation, accounting for less than 10% of all chronic low back pain (5). Disc herniation may be classified as contained (i.e. herniation of the nucleus pulposus through the inner, but not outer annulus) or non-contained (i.e. a non-competent annulus). The main objective of surgical treatment of a disc prolapse, protrusion, or extrusion is the relief of nerve root compression by removing the herniated nuclear material. The Spine Patient Outcomes Research Trial (SPORT) trial demonstrated that back pain improved in intervertebral disc herniation patients treated both surgically and non-surgically, though the degree of improvement was significantly greater in patients who underwent surgery, the difference between patients who underwent surgery and those who did not remained statistically significant at 2 years (6,9-11). In the surgically treated group, the degree of leg pain was greater than the decrease in low back pain (6). Carragee et al (12) studied clinical outcomes after lumbar discectomy for sciatica and found a number of noteworthy results. They demonstrated that patients with no fragment-contained lumbar disc herniations experienced poorer treatment outcomes compared to those with other types of herniations, with 38% having recurrent or persistent sciatica. In these individuals, there was a 10% rate of re-herniation and 5% re-operation rate at a minimum of 2 ½ years after surgery. Patients in the fragment-fissure group, who had disc fragments and small annular defects, had the best overall outcomes and the lowest rates of reherniation (1%) and reoperation (1%). Similar to Carragee et al, Dewing et al (13) showed that patients with sequestered or extruded lumbar disc herniations had significantly better outcomes than those with contained herniations.

Lumbar discectomy has been criticized for producing inconsistent results (5,12,14-24). In a brief literature review, Carragee et al (12) reported that between 20% and 40% of patients who underwent open discectomy for herniated lumbar disc experienced persistent or recurrent sciatica, chronic back pain, or recurrent disc herniation. Donceel and Du Bois (14) reported that success rates for disc surgery varied from 70% to 90%, whereas a literature synthesis by Hoffman et al (17) noted an average discectomy success rate of 67%. Workers' compensation patients may be at an increased risk for poor outcomes after spinal surgery (25-27). One study (15) also found that 43% of injured workers had a poor outcome after lumbar discectomy. In another study evaluating pre-surgery correlates of lumbar discectomy outcomes in workers' compensation patients (19) approximately 25% of individuals experienced poor outcomes, suggesting that secondary gain is associated with a negative treatment outcome. These factors have resulted in a trend toward minimization in operative treatment (28-48). The push for less invasive treatment alternatives has led to a paradoxical surge in the number of modalities available to treat low back pain, and increased utilization of resources (3,5,12,48-87).

The major advantages of using minimally invasive technique for the treatment of degenerative pathology are that the architecture of the spine is better preserved, there is less tissue destruction, and the risks are lower. Percutaneous interventions used to treat lumbar disc herniation can be separated into three major categories: those that utilize dissolution mechanisms (chymopapain), ablative techniques (nucleotomy or discectomy), and vaporization (laser of the nucleus pulposus).

In percutaneous lumbar laser disc decompression, laser energy is delivered to the nucleus pulposus by means of a fiber (44). The fiber is inserted through a thin needle via a posterolateral percutaneous approach under local anesthesia. The absorption of the applied laser energy leads to vaporization of the water content of the nucleus pulposus and a change in its protein structure. The subsequent volume reduction causes a disproportionate decrease in intradiscal pressure, which in turn should theoretically decompress an entrapped nerve root. The first clinical percutaneous lumbar laser disc decompression was performed in Europe by Choy and colleagues in 1986 (45). The US Food and Drug Administration (FDA) approved percutaneous laser disc decompression for use in the United States in 1991 (46).

Percutaneous lumbar laser disc decompression is an attractive treatment because of its minimally invasive nature and the corresponding decreased risk of structural damage to the muscles, bone, ligaments, and nerves, which in turn may result in a lower prevalence rate of failed back surgery syndrome. In addition, the patients are expected to have less back pain, shorter hospitalization stays, and shorter recovery periods than following conventional surgery. The actual resolution of sciatica may be longer than after conventional surgery, though immediate resolution of symptoms does occur (46). However, considerable skepticism persists regarding technol-

ogy. Despite several published cohort studies and FDA approval, no randomized trial has been performed to date comparing percutaneous lumbar laser disc decompression with conventional surgical procedures. The cohort studies demonstrate safety and suggest potential benefits that may be afforded by percutaneous lumbar laser disc decompression. Brouwer et al (46) have designed a prospective randomized controlled trial (RCT) to assess the effectiveness of percutaneous lumbar laser disc decompression versus conventional open discectomy in the treatment of lumbar disc herniation. The results of this assessment are not available yet. The lack of high grade evidence is reflected in reviews on the subject. Schenk et al (44) concluded that despite the fact that percutaneous lumbar laser disc decompression has been around for almost 20 years, scientific evidence of its efficacy still remains relatively poor, though the potential medical and economic benefits of percutaneous lumbar laser disc decompression are too high to justify discarding it on the sole basis of insufficient scientific proof.

In a Cochrane Collaboration review, Gibson and Waddell (5) presented the results from 40 RCTs and 2 quasi-randomized controlled trials (QRCTs) evaluating surgical interventions for lumbar disc prolapse. This review concluded that the indications for non-traditional forms of discectomy remain unresolved. Trials of 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. Gibson and Waddell (5) concluded that while conventional discectomy provides faster relief from the acute attack of sciatica than other treatments, the unintended consequences on the long-term natural history of the underlying disease are unclear.

In a technology assessment report (47), no randomized published studies of percutaneous lumbar laser disc decompression were identified. However, the majority of the observational studies evaluating percutaneous lumbar laser discectomy showed positive evidence. In a systematic review of percutaneous lumbar laser disc decompression that evaluated 33 publications, none of which were controlled, Singh et al (40) concluded that based on USPSTF criteria, the indicated level of evidence for percutaneous lumbar laser disc decompression was II-2 for short- and long-term relief. In 2009, a non-inferiority study design (46) was published to assess the effectiveness of percutaneous lumbar laser disc decompression versus conventional open discectomy in the treatment of lumbar disc herniation. The protocol asserted that because there was a broad consensus that conventional surgery is the gold standard for surgical intervention for sciatica, percutaneous lumbar laser disc decompression had to be compared to conventional surgery in order to assess its cost-effectiveness.

The underlying treatment principle of percutaneous lumbar laser disc decompression is based on the concept that the intervertebral disc is contained in a closed hydraulic system, so that only contained herniations would be expected to retract in response to a reduction in intradiscal pressure (44). Consequently, the presence of a frank disc extrusion or sequestered herniation is considered to be an exclusion criterion for percutaneous lumbar laser disc decompression. For practical and clinical reasons, patients with critically (< 50%) diminished disc height, significant spinal stenosis, serious neurologic symptoms such as cauda equina syndrome, or other conditions that require acute surgical intervention, are not generally considered candidates for percutaneous lumbar laser disc decompression.

This systematic review was undertaken to evaluate and update the current evidence of percutaneous mechanical disc decompression with lumbar laser discectomy from a previous systematic review (40). For evolving technology, systematic reviews tend to expire within 3 years, leading to recommendations to update them frequently (88,89).

1.0 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 (53,90-97), Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct of randomized trials (98-101), Standards for Reporting Observational Studies (STROBE) (102), Cochrane Collaboration reporting guidelines (53,95), Chou and Huffman's guidelines (55,103), and quality of reporting of analysis (92).

1.1 Criteria for Considering Studies for This Review

1.1.1 Types of Studies

Randomized controlled trials
Non-randomized observational studies
Case reports and reviews for adverse effects

1.1.2 Types of Participants

Participants of interest were adults aged at least 18 years with chronic low back and lower extremity

pain of at least 3 months duration.

Participants must have failed previous pharmacotherapy, exercise therapy, etc., prior to starting interventional pain management techniques.

1.1.3 Types of Interventions

The intervention was lumbar laser disc decompression.

1.1.4 Types of Outcome Measures

- The primary outcome parameter was pain relief.
- The secondary outcome measures were functional improvement; change in psychological status; return-to-work; reduction or elimination of opioid use, other drugs, or other interventions; and complications.
- At least 2 of the review authors independently, in an unblinded standardized manner, assessed the outcomes measures. Any disagreements between reviewers were resolved by a third author and consensus.

1.2 Literature Search

Searches were performed from the following sources without language restrictions:

1. PubMed from 1966
   www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. EMBASE from 1980
   www.embase.com/
3. Cochrane Library
   www.thecochranelibrary.com/view/0/index.html
4. U.S. National Guideline Clearinghouse (NGC)
   www.guideline.gov/
5. Previous systematic reviews and cross references
6. Clinical Trials
   clinicaltrials.gov/

The search period was from 1966 through September 2012.

1.3 Search Strategy

The search strategy emphasized chronic low back and lower extremity pain secondary to disc herniation that was treated with percutaneous lumbar laser disc decompression. The search terms were as follows: "lumbar disc herniation," "contained disc herniation," "percutaneous disc decompression," "percutaneous lumbar laser disc decompression," "lumbar radiculopathy," "sciatica".

At least 2 of the review authors independently, in an unblinded standardized manner, performed each search. Accuracy was confirmed by a statistician. All searches were combined to obtain a unified search strategy. Any disagreements between reviewers were resolved by a third author and consensus.

1.4 Data Collection and Analysis

The review focused on randomized trials, observational studies, and reports of complications. The population of interest was patients suffering with chronic low back and lower extremity pain for at least 3 months. Only percutaneous lumbar laser disc decompression studies were evaluated. All studies documenting appropriate management and reporting outcome evaluations at 12 months or longer were reviewed. Reports without documentation of appropriate diagnosis, non-systematic reviews, book chapters, and case reports were excluded.

1.4.1 Selection of Studies

- In an unblinded standardized manner, 2 review authors screened the abstracts of all identified studies against the inclusion criteria.
- All articles with possible relevance were then retrieved in full text for comprehensive assessment of internal validity, quality, and adherence to inclusion criteria.

1.4.2 Inclusion and Exclusion Criteria

The following are the inclusion and exclusion criteria:

1. Are the patients described in sufficient detail to allow one to decide whether they are comparable to those who are treated in interventional pain management clinical practices?
   A. Setting – office, hospital, outpatient, inpatient
   B. Physician – interventional pain physician, general physician, anesthesiologist, physiatrist, neurologist, rheumatologist, orthopedic surgeon, neurosurgeon, etc.
   C. Patient characteristics - duration of pain
   D. Non-interventional techniques or surgical intervention in the past
2. Is the intervention described in sufficient detail to enable one to apply its use to patients in interventional pain management settings?
   A. Nature of intervention
   B. Frequency of intervention
   C. Duration of intervention
3. Were clinically relevant outcomes measured?
   A. Proportion of pain relief
   B. Disorder/specific disability
   C. Functional improvement

D. Allocation of eligible and non-eligible patients to return to work
E. Ability to work

1.4.3 Clinical Relevance

The clinical relevance of the included studies was evaluated according to 5 questions recommended by the Cochrane Back Review Group (Table 1) (94,104). Each question was scored as positive (+) if the clinical relevance item was met, negative (–) if the item was not met, and unclear (?) if data were not available to answer the question.

1.4.4 Methodological Quality or Validity Assessment

The methodological quality assessment was performed by 2 review authors who independently evaluated, in an unblinded standardized manner, the internal validity of all studies. Any discrepancies that arose were mediated by a third reviewer and settled by consensus.

The quality of each individual article used in this analysis was assessed by Cochrane review criteria (Table 2) (95) for randomized trials and the Newcastle-Ottawa Scale for observational studies (Tables 3 and 4) (105). For nonrandomized observational studies, outcomes on at least 50 patients should have been reported, or 25 in each group if it was a comparison study. Complications were derived from case reports, clinical studies and review articles, and are reported descriptively. Each study was evaluated by at least 2 authors for adherence to the selection criteria and any disagreements were mediated by a third reviewer. Authors with a perceived conflict of interest were recused from reviewing the relevant manuscript(s).

Only randomized trials and observational meeting at least 50% of their respective inclusion criteria were utilized for analysis. Studies scoring lower are presented descriptively.

1.4.5 Data Extraction and Management

Two review authors independently, in an unblinded standardized manner, extracted the data from the included studies. Disagreements were resolved by discussion between the 2 reviewers; if no consensus could be reached, a third author was called in to break the impasse.

1.4.6 Measurement of Treatment Effect in Data Synthesis (Meta-Analysis)

Data were summarized using meta-analysis when at least 5 studies were available that met the inclusion criteria.

Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. Random-effects meta-analysis to pool data was also used (106).

1.4.7 Outcomes Assessment

In clinical trials, a 2-point decrease in pain on a 0-10 scale has been shown to be "clinically meaningful" for studies evaluating pharmacotherapy for chronic pain in general, (107), chronic musculoskeletal pain (108), and chronic low back pain (90,91,94,109,110). However, when procedural interventions that carry greater costs and risks are evaluated, > 50% pain relief is the most utilized cutoff threshold for designating a treatment outcome as successful (111-136). For this analysis, we defined a positive outcome as either a 3-point decrease in pain on an 11-point rating scale or > 50% reduction from baseline, and clinically relevant functional improvement as a change of 40% or greater using a validated instrument.

1.5 Summary Measures

Summary measures included 50% or greater reduction of pain in at least 40% of the patients, at least a 3-point decrease in pain scores, and a relative risk ratio of adverse events.

Table 1. *Clinical relevance questions.*

	P (+)	N (-)	U (unclear)
A) Are the patients described in detail so that one can decide whether they are comparable to those who are treated in practice?			
B) Are the interventions and treatment settings described in sufficient detail to apply its use in clinical practice?			
C) Were clinically relevant outcomes measured and reported?			
D) Is the size of the effect clinically meaningful?			
E) Do the likely treatment benefits outweigh the potential harms?			

Scoring adapted and modified from Staal JB, et al. Injection therapy for subacute and chronic low-back pain. Cochrane Database Syst Rev 2008; 3:CD001824 (104).

Table 2. *Randomized controlled trials quality rating system.*

A	1. Was the method of randomization adequate?	A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a die (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are: alternation, birth date, social insurance/ security number, date in which they are invited to participate in the study, and hospital registration number.	Yes/No/ Unsure
B	2. Was the treatment allocation concealed?	Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.	Yes/No/ Unsure
C	Was knowledge of the allocated interventions adequately prevented during the study?		
	3. Was the patient blinded to the intervention?	This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.	Yes/No/ Unsure
	4. Was the care provider blinded to the intervention?	This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.	Yes/No/ Unsure
	5. Was the outcome assessor blinded to the intervention?	Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or: –for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes" –for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination –for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome –for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" (caregivers) is scored "yes" –for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data.	Yes/No/ Unsure
D	Were incomplete outcome data adequately addressed?		
	6. Was the drop-out rate described and acceptable?	The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored. (N.B. these percentages are arbitrary, not supported by literature).	Yes/No/ Unsure
	7. Were all randomized participants analyzed in the group to which they were allocated?	All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.	Yes/No/ Unsure
E	8. Are reports of the study free of suggestion of selective outcome reporting?	In order to receive a "yes," the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.	Yes/No/ Unsure
F	Other sources of potential bias:		
	9. Were the groups similar at baseline regarding the most important prognostic indicators?	In order to receive a "yes," groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).	Yes/No/ Unsure
	10. Were co-interventions avoided or similar?	This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.	Yes/No/ Unsure
	11. Was the compliance acceptable in all groups?	The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.	Yes/No/ Unsure
	12. Was the timing of the outcome assessment similar in all groups?	Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.	Yes/No/ Unsure

Adapted and modified from Furlan AD, et al. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine (Phila Pa 1976) 2009; 34:1929-1941 (95).

Table 3. *Newcastle-Ottawa quality assessment scale: Case control studies.*

Selection
1) Is the case definition adequate?
a) yes, with independent validation *
b) yes, e.g. record linkage or based on self reports
c) no description
2) Representativeness of the cases
a) consecutive or obviously representative series of cases *
b) potential for selection biases or not stated
3) Selection of Controls
a) community controls *
b) hospital controls
c) no description
4) Definition of Controls
a) no history of disease (endpoint) *
b) no description of source
Comparability
1) Comparability of cases and controls on the basis of the design or analysis
a) study controls for disc hernation or radiculitis *
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)
Exposure
1) Ascertainment of exposure
a) secure record (eg surgical records) *
b) structured interview where blind to case/control status *
c) interview not blinded to case/control status
d) written self report or medical record only
e) no description
2) Same method of ascertainment for cases and controls
a) yes *
b) no
3) Non-Response rate
a) same rate for both groups *
b) non respondents described
c) rate different and no designation

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.
Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

1.6 Analysis of Evidence

The analysis of the evidence was performed based on United States Preventive Services Task Force (USPSTF) criteria as illustrated in Table 5 (36,130-144). This analysis was conducted using 3 levels of evidence ranging from good, fair, and limited or poor.

At least 2 of the review authors independently, in an unblinded standardized manner, analyzed the evidence. Any disagreements between reviewers were resolved by a third author and consensus. If there were any conflicts of interest (e.g., authorship), those reviewers were recused from assessment and analysis.

1.7 Outcome of the Studies

In the randomized trials, a study was judged to be positive if the effects of percutaneous lumbar laser disc

Table 4. *Newcastle-Ottawa quality assessment scale for cohort studies.*

Selection
1) Representativeness of the exposed cohort
a) truly representative of the average _____ (describe) in the community *
b) somewhat representative of the average _____ in the community *
c) selected group of users e.g. nurses, volunteers
d) no description of the derivation of the cohort
2) Selection of the non exposed cohort
a) drawn from the same community as the exposed cohort *
b) drawn from a different source
c) no description of the derivation of the non exposed cohort
3) Ascertainment of exposure
a) secure record (eg surgical records) *
b) structured interview *
c) written self report
d) no description
4) Demonstration that outcome of interest was not present at start of study
a) yes *
b) no
Comparability
1) Comparability of cohorts on the basis of the design or analysis
a) study controls for disc hernation or radiculitis *
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)
Outcome
1) Assessment of outcome
a) independent blind assessment *
b) record linkage *
c) self report
d) no description
2) Was follow-up long enough for outcomes to occur
a) yes (select an adequate follow up period for outcome of interest) *
b) no
3) Adequacy of follow up of cohorts
a) complete follow up - all subjects accounted for *
b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) *
c) follow up rate < ____% (select an adequate %) and no description of those lost
d) no statement

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.
Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

decompression were statistically and clinically more effective compared to either a placebo control or active control. For observational studies, a study was judged to be positive if the percutaneous lumbar laser disc decompression therapy was statistically and/ or clinically effective compared to baseline parameters. Outcomes were judged at the reference point with positive or negative results reported at 6 months, one year, and

Table 5. *Method for grading the overall strength of the evidence for an intervention.*

Grade	Definition
Good	Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy).
Fair	Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).
Limited or Poor	Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

Adapted and modified from methods developed by U.S. Preventive Services Task Force (137).

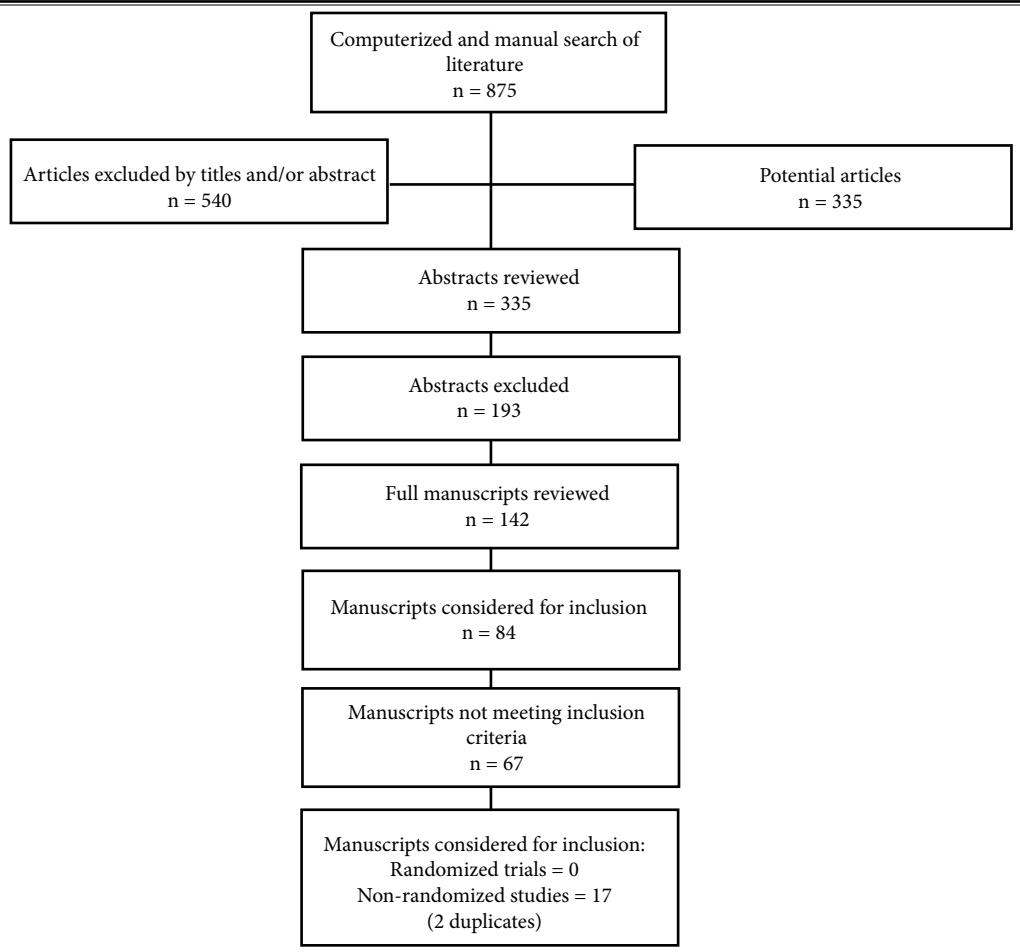

Fig. 1. *The flow diagram illustrating published literature evaluating mechanical lumbar disc decompression with nucleoplasty.*

after one year. Short-term effectiveness was defined as benefit lasting for one year or less. Long-term effectiveness was defined as significant benefit persisting for greater than one year.

2.0 Results

Figure 1 shows a flow diagram of study selection as recommended by Preferred Reporting Items for

Systematic Reviews and Meta-Analyses (PRISMA) (93). There were 84 studies identified (35,46,145-226). Authors were contacted and additional information was obtained for one study (46).

Among the 84 studies identified, 67 were excluded. Table 6 shows the reasons for exclusion of selected articles (35,46,145,146,149,151-155,157-159,161-163,165,167,169,171,172,174-176,179-187,189-193,195,196,202-206,208,210,212,216,219,222,226).

Table 7 illustrates the characteristics of the studies considered for inclusion. There were no randomized trials, 17 observational studies (148,150,160,164,168,170,173,177,178,188,194,197-200,207,211,217), and 2 studies with duplicate (164,170) or triplicate publications (173,188,217). Follow-up periods of less than 12 months were considered short-term, and > 12 months were designated as long-term.

2.1 Clinical Relevance

In the 15 studies assessed for clinical relevance, all met criteria with scores of > 3 out of 5 (148,150,160,164,168,170,173,177,178,188,194,197-200,207,211,217). There was one duplicate (164,170) and one triplicate publication (173,188,217). Table 8 illustrates the assessment of clinical relevance.

Table 6. *Reasons for exclusion of selected studies of lumbar laser discectomy studies.*

STUDY	REASON FOR EXCLUSION
Ohnmeiss et al, 1994 (35)	The study included less than 50 patients (41 patients).
Brouwer et al, 2009 (46)	This was a study protocol for a prospective randomized controlled trial to assess the effectiveness of percutaneous lumbar laser disc decompression versus conventional open discectomy in the treatment of lumbar disc herniation.
Zhao et al, 2012 (145)	This recent study included only 25 patients. They hypothesized that insertion of the needle into the extruded part of the nucleus pulposus will decrease its volume and provide superior clinical effects compared to therapies that decreased the volume of the intradiscal nucleus pulposus.
Varanius et al, 2012 (146)	The authors described characterization of intervertebral disc material by autofluorescence induced by laser light.
Sato et al, 2011 (149)	The study described the effect of Ho:Yag laser irradiation on intervertebral disc cells.
Qin et al, 2010 (151)	This study evaluated the long-term effectiveness of percutaneous lumbar laser disc decompression in the treatment of cervical spondylosis.
Haufe et al, 2010 (152)	This study evaluated the role of laser disc decompression for thoracic disc disease in 10 patients.
Lee & Kang, 2010 (153)	The authors evaluated 30 patients with radicular pain due to contained disc herniation with a 9.7 month follow-up.
Ren et al, 2010 (154)	This study assessed the imaging data of 22 patients suffering from cervical spondylosis or lumbar spondylosis who were treated with percutaneous lumbar laser disc decompression.
Kim et al, 2009 (155)	The authors described a removal of a discal cyst using a percutaneous endoscopic interlaminar approach in a case report with a laser.
Arts et al, 2008 (157)	This was a survey in the Netherlands of management of sciatica due to lumbar disc herniation. The survey results showed that unilateral transflaval discectomy was the most frequently performed procedure and was expected to be most effective, whereas percutaneous lumbar laser disc decompression was expected to be the least effective. Recurrent disc herniation was expected to be lowest after bilateral discectomy and highest after percutaneous lumbar laser disc decompression. Complications were expected to be highest after bilateral discectomy and lowest after unilateral transflaval discectomy.
Morelet et al, 2007 (158)	The authors examined 149 patients; however, 1-year follow-up was only reported in 59 patients.
Kobayashi et al, 2007 (159)	This was a case report of a nerve root heat injury induced by percutaneous lumbar laser disc decompression.
Goupille et al, 2007 (161)	This is a review article of percutaneous lumbar laser disc decompression for the treatment of lumbar disc herniation.
Ishiwata et al, 2007 (162)	This study describes magnetic resonance-guided percutaneous lumbar laser disc decompression for lumbar disc herniation in 32 patients.
Li et al, 2007 (163)	The authors described percutaneous lumbar laser disc decompression in 47 patients with cervical disc herniation.
Gupta et al, 2006 (165)	This study was conducted to assess percutaneous lumbar laser disc decompression in 40 patients with contained lumbar disc herniation who did not respond to 6 weeks of conservative treatment. The authors reported good immediate relief and follow-up for 1 to 7 years. However, the sample size was small.

Table 6. (cont) *Reasons for exclusion of selected studies of lumbar laser discectomy studies.*

STUDY	REASON FOR EXCLUSION
Lee et al, 2006 (167)	Endoscopic discectomy in < 50 patients
Iwatsuki et al, 2005 (169)	This was an experimental study evaluated the effect of laser irradiation for leaking nucleus pulposus in rabbits.
McMillan et al, 2004 (171)	This is a preliminary report on 32 consecutive patients with 3-month follow-up in a general pain clinic population.
Taşdemiroğlu et al, 2004 (172)	Spondylodiscitis – review of complications
Maksymowicz et al, 2004 (174)	The authors compiled data on percutaneous lumbar laser disc decompression regarding mechanisms of action, indications, and contraindications.
Sobieraj et al, 2004 (175)	The authors evaluated early results of percutaneous lumbar laser disc decompression as a treatment for discogenic lumbar pain.
Agarwal, 2003 (176)	The study included less than 50 patients (36 patients).
Schick & Döhnert, 2002 (179)	The authors described a technique of microendoscopy using a laser in medial lumbar disc herniation.
Hellinger et al, 2001 (180)	The authors provided a biophysical explanation for Nd:YAG percutaneous lumbar laser disc decompression success in 21 patients.
Sato et al, 2001 (181)	The authors described the use of a new ICG-dye-enhanced diode laser for percutaneous lumbar laser disc decompression in 12 dogs.
Boult et al, 2000 (182)	This was a systematic review of the literature on percutaneous endoscopic laser discectomy with respect to safety and efficacy.
Gevargez et al, 2000 (183)	The authors described CT-guided percutaneous lumbar laser disc decompression in 26 patients with a 4-week follow-up.
Tonami et al, 1999 (184)	Complication – osteogenesis of vertebral body
Choy, 1999 (185)	This was a case report describing early relief of erectile dysfunction after laser decompression of a herniated lumbar disc.
Hellinger, 1999 (186)	The author described technical aspects of percutaneous cervical and lumbar laser-disc-decompression and nucleotomy.
Steiner et al, 1998 (187)	The authors described MR guidance of laser disc decompression in 7 patients.
Senel et al, 1998 (189)	The manuscript was not available.
Savitz et al, 1998 (190)	Described endoscopic surgery with laser assistance
Dangaria, 1998 (191)	The author described the results of laser-assisted disc ablation after unsuccessful percutaneous disc decompression in 15 patients.
Gangi et al, 1998 (192)	Described laser applications in interventional musculoskeletal radiology
Choy & Ngeow, 1998 (193)	The authors described percutaneous lumbar laser disc decompression in spinal stenosis in 35 patients.
Tonami et al, 1997 (195)	Short-term follow-up
Plancarte & Calvillo, 1997 (196)	Complication – complex regional pain syndrome (CRPS) Type II
Schatz & Talalla, 1995 (202)	Preliminary experience with percutaneous lumbar laser disc decompression in the treatment of sciatica was described in 14 patients.
Liebler, 1995 (203)	The authors assessed 117 patients; however, only 46 patients were available at 1-year follow-up.
Casper et al, 1995 (204)	The authors described the evolution of percutaneous lumbar laser disc decompression method using Holmium: YAG laser.
Chambers et al, 1995 (205)	The authors described a percutaneous lumbar laser disc decompression registry.
Choy, 1995 (206)	This was a description of percutaneous lumbar laser disc decompression techniques using Nd:YAG laser.
Botsford, 1995 (208)	This manuscript described the role of radiology in percutaneous lumbar laser disc decompression.
Simons et al, 1994 (210)	Short-term follow-up with < 50 patients
Quigley et al, 1994 (212)	Basic science in-vitro study
Davis, 1992 (216)	The study included less than 50 patients (40 patients).
Ascher, 1991 (219)	The author reported 4-year results on 292 patients; however, only 197 were available for follow-up. Consequently, this report was excluded from evidence assessment. These patients may have been included in previous publications.
Yonezawa et al, 1990 (222)	Basic science study
Farrar et al, 1998 (226)	A case report of possible salmonella osteomyelitis of the spine following laser disc decompression.

Table 7. Study characteristics of published reports of percutaneous lumbar laser disc decompression.

Study/Methods	Study Characteristics	Participants	Intervention(s)	Outcome Measure(s)	Result(s)	Conclusion(s) Short term relief ≤ 12 mos. Long-term relief > 12 mos.
Duarte & Costa, 2012 (148)	Prospective observational study	205 patients with lumbar radicular pain and a contained disc herniation on imaging.	Percutaneous lumbar laser discectomy under CT guidance and local anesthesia	Pain, function, medication usage	67% of the patients reported good results and 9% acceptable results	Positive short and long-term results
Menchetti et al, 2011 (150)	Multicenter retrospective study with a mean follow-up of 6 years	900 patients with radicular symptoms secondary to disc herniation.	Percutaneous lumbar laser disc decompression	Pain, function, medication usage	The success rate at mean follow-up of 5 years (2 to 6 years) was 70% with a very low complication rate.	Positive short-term and long-term results
Iwatsuki et al, 2007 (160)	Observational report	65 consecutive patients with lumbar disc herniation and radicular pain. Subjects stratified based on Lasègue's sign.	Percutaneous lumbar laser disc decompression	Pain, function, medication usage	Percutaneous lumbar laser disc decompression was effective for 80% of patients with Lasègue's sign but ineffective for those without.	Positive results in patients with positive Lasègue's sign
Tassi, 2006, 2004 (164,170)	Comparative study	500 patients who underwent percutaneous lumbar laser disc decompression for radicular pain were compared to 500 patients treated with microdiscectomy.	Percutaneous lumbar laser disc decompression versus microdiscectomy	Pain, function, medication usage	84% of patients had a good or excellent outcome in percutaneous lumbar laser disc decompression group vs. 85.6% in microdiscectomy group. Complications occurred in 2.2% of microdiscectomy patients and no laser decompression patients.	Positive short-term and long-term results
Zhao et al, 2005 (168)	Case-controlled study	173 patients meeting the inclusion criteria with disc herniation were studied. 139 patients had a good indication and 34 had a relative contraindication (e.g. spinal stenosis).	Percutaneous lumbar laser disc decompression	Pain relief, function, adverse effects	Excellent (45%) or good (37%) result obtained in higher proportion of patients with a good indication than in those with a contraindicative (32% and 24%, respectively).	Positive short-term and long-term results
Choy, 2004, 1998, 1992 (173,188*,217)	Prospective study that included both animal and human parts.	350 patients who underwent lumbar percutaneous laser decompression procedures	Percutaneous lumbar laser disc decompression	Pain, function, medication usage	75% overall success rate. Complication rate was 1%.	Positive long-term experience
Grönemeyer et al, 2003 (177)	Observational study	200 patients with non-sequestered, contained lumbar disc herniation.	Percutaneous lumbar laser disc decompression under CT/fluoroscopic guidance	Reduction in sensory and motor impairment.	In 85% of patients, pain was eliminated or reduced. 43% were pain-free. Relief lasted an average of 3 ± 2 years.	Positive short-term and long-term results

Table 7 (cont). Study characteristics of published reports of percutaneous lumbar laser disc decompression.

Study/Methods	Study Characteristics	Participants	Intervention(s)	Outcome Measure(s)	Result(s)	Conclusion(s) Short term relief ≤ 12 mos. Long-term relief > 12 mos.
Knight & Goswami, 2002 (178)	Observational study	576 patients with lumbar disc protrusion and positive discography	Percutaneous lumbar laser disc decompression	Patient target achievement scores, patient satisfaction	At 1-year, 60% of patients demonstrated good to excellent results; 20% had satisfactory outcome. At 3-years, 51% had good results. 4 patients developed aseptic discitis. 17% required further surgical intervention.	Positive short-term and long-term results
Nerubay et al, 1997 (194)	Prospective study	50 patients with low back and radicular pain caused by an L4-5 protruded disc.	Percutaneous lumbar laser discectomy	Pain, function, medication usage	74% of the patients had excellent or good results.	Positive short-term and long-term relief in a small study
Gangi et al, 1996 (197)	Retrospective study	119 with lumbar disc herniation	Percutaneous lumbar laser disc decompression under CT guidance	Pain relief, function, medication usage	77% of patients had good or fair outcome. In 64% of these patients, a decrease in size of disc herniation was observed after 6 months.	Authors did not identify the number of patients with good response.
Bosacco et al, 1996 (198)	Prospective evaluation with retrospective comparison to open discectomy patients	63 patients with L4-5 lumbar disc herniation and radicular pain were compared with 70 patients undergoing open discectomy.	Percutaneous lumbar laser discectomy under fluoroscopy without discography	Pain relief, function, duration of postoperative stay, return-to-work	Overall good or excellent results in 65% of patients compared to discectomy 85%. Lower costs ($7,720) compared to discectomy ($14,600).	Positive results in a small study compared with open discectomy.
Siebert et al, 1996 (199)	Retrospective study	180 patients with contained disc herniation.	Percutaneous lumbar laser disc decompression	Pain relief	73% success rate.	Positive short-term and long-term results
Casper et al, 1996 (200)	Prospective study	100 patients with non-sequestered herniated disc.	Percutaneous lumbar laser disc decompression	Pain relief, mobility, function, return-to-work	87% of patients had successful outcome with independent evaluation.	Positive short-term and long-term results
Casper et al, 1995 (207)	Prospective study	223 patients with lumbar disc herniation.	Percutaneous lumbar laser disc decompression	Pain relief, function, medication usage	84% success rate	Positive short-term and long-term results
Botsford, 1994 (211)	Retrospective study	90 patients with lumbar disc herniation & positive discography.	Percutaneous lumbar laser disc decompression under fluoroscopy with discography	Pain relief, function, medication usage	Good or fair response in 73% of patients	Positive short-term and long-term results

numbers reported from Choy et al, 1998 (188)

Table 8. *Clinical relevance of included studies.*

Manuscript Author(s)	A) Patient description	B) Description of interventions and treatment settings	C) Clinically relevant outcomes	D) Clinical importance	E) Benefits versus potential harms	Total Criteria Met
Duarte & Costa, 2012 (148)	+	+	+	+	+	5/5
Menchetti et al, 2011 (150)	+	+	+	+	+	5/5
Iwatsuki et al, 2007 (160)	+	+	+	+	+	5/5
Tassi, 2006, 2004 (164,170)	+	+	+	+	+	5/5
Zhao et al, 2005 (168)	+	+	+	+	+	5/5
Choy et al, 2004, 1998, 1992 (176,188,217)	+	+	+	+	+	5/5
Grönemeyer et al, 2003 (177)	+	+	+	+	+	5/5
Knight & Goswami, 2002 (178)	+	+	+	+	+	5/5
Nerubay et al, 1997 (194)	+	+	+	+	+	5/5
Gangi et al, 1996 (197)	+	+	+	+	+	5/5
Bosacco et al, 1996 (198)	+	+	+	+	+	5/5
Siebert et al, 1996 (199)	+	+	+	+	+	5/5
Casper et al, 1996 (200)	+	+	+	+	+	5/5
Casper et al, 1995 (207)	+	+	+	+	+	5/5
Botsford, 1994 (211)	+	+	+	+	+	5/5

+ = positive; - = negative; U = unclear

Scoring adapted from Staal JB, et al. Injection therapy for subacute and chronic low-back pain. Cochrane Database Syst Rev 2008; 3:CD001824 (104).

2.2 Methodological Quality Assessment

A methodological quality assessment of the observational studies meeting inclusion criteria was carried out utilizing the Newcastle-Ottawa Scale as illustrated in Tables 9 and 10. Studies scoring 67% or higher were considered high quality, studies scoring 50% or higher were considered moderate quality, and studies scoring less than 50% were considered to be low quality, and hence were excluded.

2.3 Meta-Analysis

There were no randomized trials available. Consequently no meta-analysis was feasible.

2.4 Analysis of Evidence

Based on the USPSTF criteria, the evidence is considered at 3 levels – good, fair, and limited or poor. Table 11 illustrates the results of 15 observational studies (with 2 duplicates) evaluating the effectiveness of percutaneous lumbar laser disc decompression in managing disc herniation.

Based on all available observational studies, the evidence is limited for percutaneous lumbar laser disc decompression in managing disc herniation. However, the results of an ongoing randomized, double-blind controlled trial have not been published yet.

3.0 Complications

Complications of percutaneous lumbar laser disc decompression are classified into intraoperative and postoperative complications (44,159,176,187,188,192,194, 198,202,209,213,218,219,226-248). The most frequently described complication (spondylo)discitis (187,188,192,202,219,231), which can be either aseptic and septic. The reported frequency of discitis varies from 0% (176,194,198,209) to 1.2% (192). Aseptic discitis results from heat damage to either the disc or adjacent vertebral endplates (229). The goal of percutaneous lumbar laser disc decompression is to leave the annulus fibrosis and surrounding tissues unaffected, while selectively reducing the volume of nucleus pulposus tissue. Consequently, the extent of heat penetration should be kept as low as possible (44), which may reduce the likelihood of heat injury. This complication can also be avoided with careful monitoring of patient complaints during the procedure, and appropriate ad-

Table 9. *Methodological quality assessment of case control studies utilizing Newcastle-Ottawa quality assessment scale.*

	Iwatsuki et al (160)	Tassi (164,170)	Zhao et al (168)
Selection			
1) Is the case definition adequate?			
a) yes, with independent validation *			
b) yes, e.g. record linkage or based on self reports	X	X	X
c) no description			
2) Representativeness of the cases			
a) consecutive or obviously representative series of cases *	X	X	X
b) potential for selection biases or not stated			
3) Selection of Controls			
a) community controls *	X	X	X
b) hospital controls			
c) no description			
4) Definition of Controls			
a) no history of disease (endpoint) *			
b) no description of source			
Comparability			
1) Comparability of cases and controls on the basis of the design or analysis			
a) study controls for disc herniation or radiculitis*	X	X	X
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)			
Exposure			
1) Ascertainment of exposure			
a) secure record (eg surgical records) *	X	X	X
b) structured interview where blind to case/control status *			
c) interview not blinded to case/control status			
d) written self report or medical record only			
e) no description			
2) Same method of ascertainment for cases and controls			
a) yes *	X	X	X
b) no			
3) Non-Response rate			
a) same rate for both groups *	X	X	X
b) non respondents described			
c) rate different and no designation			
SCORE	7/12	7/12	7/12

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.
Adapted and modified from: Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

justments of the laser power, pulse rate, and/ or pulse interval when heat sensations occur. Septic discitis typically occurs as a result of infection during needle placement (232-236). The use of antibiotic prophylaxis may further reduce the risk of septic discitis, though several systematic reviews have questioned the utility of this approach (249-251). In addition, the use of laser may have an inhibitory effect on bacterial growth (252).

Table 10. *Methodological quality assessment of cohort studies utilizing Newcastle-Ottawa quality assessment scale.*

	Duarte & Costa (148)	Menchetti et al (150)	Choy (173, 188,217)	Grönemeyer et al (177)	Knight & Goswami (178)
Selection					
1) Representativeness of the exposed cohort					
a) truly representative of the average ___ (describe) in the community*	X	X	X	X	X
b) somewhat representative of the average pain patients in the community *					
c) selected group of users e.g. nurses, volunteers					
d) no description of the derivation of the cohort					
2) Selection of the non exposed cohort					
a) drawn from the same community as the exposed cohort *	X	X	X	X	X
b) drawn from a different source					
c) no description of the derivation of the non exposed cohort					
3) Ascertainment of exposure					
a) secure record (eg surgical records) *	X	X	X	X	X
b) structured interview *					
c) written self report					
d) no description					
4) Demonstration that outcome of interest was not present at start of study					
a) yes *	X	X	X	X	X
b) no					
Comparability					
1) Comparability of cohorts on the basis of the design or analysis					
a) study controls for disc herniation or radiculitis *	X	X	X	X	X
b) study controls for any additional factor* (This criteria could be modified to indicate specific control for a second important factor.)					
Outcome (Exposure)					
1) Assessment of outcome					
a) independent blind assessment *					
b) record linkage*	X	X	X	X	X
c) self report					
d) no description					
2) Was follow-up long enough for outcomes to occur					
a) yes (select an adequate follow up period for outcome of interest) *	X	X	X	X	X
b) no					
3) Adequacy of follow up of cohorts					
a) complete follow up - all subjects accounted for *					
b) subjects lost to follow up unlikely to introduce bias - small number lost - > _____ % (select an adequate %) follow up, or description provided of those lost) *	X	X	X	X	X
c) follow up rate < _____% (select an adequate %) and no description of those lost					
d) no statement					
SCORE	8/12	8/12	8/12	8/12	8/12

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Adapted and modified from: Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. 67www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

Table 10 (cont). *Methodological quality assessment of cohort studies utilizing Newcastle-Ottawa quality assessment scale.*

	Nerubay et al (194)	Gangi et al (197)	Bosacco et al (198)	Siebert et al (199)	Casper et al (200)	Casper et al (207)	Botsford (211)
Selection							
1) Representativeness of the exposed cohort							
a) truly representative of the average __ (describe) in the community*	X	X	X	X	X	X	X
b) somewhat representative of the average pain patients in the community*							
c) selected group of users e.g. nurses, volunteers							
d) no description of the derivation of the cohort							
2) Selection of the non exposed cohort							
a) drawn from the same community as the exposed cohort*	X	X	X	X	X	X	X
b) drawn from a different source							
c) no description of the derivation of the non exposed cohort							
3) Ascertainment of exposure							
a) secure record (eg surgical records)*	X	X	X	X	X	X	X
b) structured interview*							
c) written self report							
d) no description							
4) Demonstration that outcome of interest was not present at start of study							
a) yes*	X	X	X	X	X	X	X
b) no							
Comparability							
1) Comparability of cohorts on the basis of the design or analysis							
a) study controls for disc herniation or radiculitis*	X	X	X	X	X	X	X
b) study controls for any additional factor* (This criteria could be modified to indicate specific control for a second important factor.)							
Outcome (Exposure)							
1) Assessment of outcome							
a) independent blind assessment*							
b) record linkage *	X	X	X	X	X	X	X
c) self report							
d) no description							
2) Was follow-up long enough for outcomes to occur							
a) yes (select an adequate follow up period for outcome of interest)*	X	X	X	X	X	X	X
b) no							
3) Adequacy of follow up of cohorts							
a) complete follow up - all subjects accounted for *							
b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) *	X	X	X	X	X	X	X
c) follow up rate < ____% (select an adequate %) and no description of those lost							
d) no statement							
SCORE	8/12	8/12	8/12	8/12	8/12	8/12	8/12

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Adapted and modified from: Wells GA, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. 67www.ohri.ca/programs/clinical_epidemiology/oxford.asp (105).

Table 11. *Results of observational studies of the effectiveness of percutaneous lumbar laser disc decompression.*

Study	Methodological Quality Scoring	Number of Participants	Significant Pain Relief	Results
			> 12 mos.	Long-term > 12 mos.
Duarte & Costa, 2012 (148)	8/12	205	67%	P
Menchetti et al, 2011 (150)	8/12	585	78%	P
Iwatsuki et al, 2007 (160)	8/12	+ Lasègue's Sign = 25	80%	P
Tassi, 2006, 2004 (164,170)	8/12	500	83.8%	P
Zhao et al, 2005 (168)	8/12	173	76.8%	P
Choy et al, 2004, 1998, 1992 (173,188*,217)	8/12	350	75%	P
Grönemeyer et al, 2003 (177)	8/12	200	73%	P
Knight & Goswami, 2002 (178)	8/12	310	60%	P
Nerubay et al, 1997 (194)	8/12	50	74%	P
Gangi et al, 1996 (197)	8/12	119	76.5%	P
Bosacco et al, 1996 (198)	8/12	61	66%	P
Siebert et al, 1996 (199)	8/12	180	72.8%	P
Casper et al, 1996 (200)	8/12	100	80%	P
Casper et al, 1995 (207)	8/12	223	84%	P
Botsford, 1994 (211)	8/12	90	73.3%	P
TOTAL		3,171	75%	

numbers reported from Choy et al, 1998 (188)
P = positive

Bleeding, including the development of an epidural hematoma, may occur after percutaneous lumbar laser disc decompression (237-243). However, reports of the latter are available in the literature. The potential adverse effects of radiation exposure (244-247) and complications relating to general anesthesia or excessive sedation are well-known (248).

One complication that may be common when a CO2 laser is used is thermal nerve root damage, which in one study occurred with an incidence of 8% (44,159,194). However, the high rate of this complication may be in part due to the fact that it must be delivered via a fixed metal canula, so the high rate may not be representative for percutaneous lumbar laser disc decompression in routine clinical practice (44). In a series of 164 laser discectomies, Ohnmeiss et al (35) reported that the tip of the instrument bent in one case, 12 patients complained of postoperative dermatomal dysesthesia which subsequently resolved in 5 cases, and 2 patients experienced signs of reflex sympathetic dystrophy. In a multi-center, retrospective analysis of 658 cases by Mayer et al (227), the authors found a 1.1% intraoperative complication rate and a 1.5% postoperative complication rate. They reported new-onset radicular deficits in 4 patients (0.5%), L5 nerve root injury in 3 cases, vascular injuries in 2 cases, sigmoid artery injury in one patient, an anomalous iliolumbar artery injury in one patient, and a transverse process injury in one patient. In another case report, a patient developed a subacute cauda equina syndrome after percutaneous lumbar laser disc decompression (228).

In a 2012 publication by Cselik et al (147), the impact of infrared laser light-induced ablation at different wavelengths on bovine intervertebral discs ex vivo was evaluated by MRI and histology. They concluded that the 1470-nm laser light had an effect through the entire nucleus pulposus and not only at the site of the quartz fiber, whereas with the 980-nm laser irradiation, significant changes were demonstrated only at the application site.

Sato et al (149) assessed the effect of Ho:YAG laser irradiation on intervertebral disc cells. They concluded that the total energy emitted influenced by irradiation conditions, which when appropriately selected may allow optimization of cryoprotection and promotion of matrix synthesis in clinical practice. Plasma membrane damage was higher and remained high long after irradiation when 54-J was used, whereas residual cell count tended to be higher with 27-J. Proteoglycan synthesis was higher in the 27-G group than in the 54-J group,

with some conditions showing marked activation of proteoglycan synthesis that was maintained for significant time periods after irradiation. They also concluded that 3 dimensional cultural models of intervertebral disc cells are useful for clarifying the relationship between cell reactions and the photoacoustic and photothermal effects following laser irradiation. In a survey on the management of sciatica due to lumbar disc herniation in the Netherlands, Arts et al (157) showed that recurrent disc herniation was expected to be highest after percutaneous lumbar laser disc decompression, whereas it was anticipated to be less after unilateral transflaval discectomy, and lowest after bilateral discectomy.

4.0 Discussion

This systematic review evaluated the role of lumbar disc decompression with percutaneous lumbar laser discectomy. The present evaluation indicates limited evidence for short- and long-term relief based on 15 observational studies.

In percutaneous lumbar laser disc discectomy, laser energy is used to reduce intradiscal pressure by vaporizing a small volume of the nucleus pulposus, which reduces the pressure between the nucleus pulposus and the peridiscal tissue, thereby causing retraction of the herniation away from the nerve root. A major premise for this assumption is that in a closed hydraulic system (i.e. contained disc herniation) with good disc height on the steep portion of the pressure-volume curve, small reductions in volume can result in large enough decreases in pressure to effect significant disc retraction. The systematic review by Gibson and Waddell (5) concluded that clinical outcomes following lumbar laser discectomy are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is important. The evidence for percutaneous lumbar laser discectomy comes from 15 observational studies (148,150,160,164,168,170,173,177,178,188,194,197-200,207,211,217). Overall, among 3,171 patients evaluated, 75% of patients experienced positive results for at least one-year.

Without evidence derived from randomized controlled trials, percutaneous disc decompression procedures have been labeled as experimental (5).Despite this, the utilization of intradiscal therapies and percutaneous disc decompression techniques continues to increase (39-42,47,52). Presently, it is believed the potential medical and economic benefits of percutaneous lumbar laser disc decompression are too high to justify discarding it as experimental or ineffective on the sole basis of insufficient scientific proof (40,44). Well-designed research studies of sufficient scientific strength, comparing percutaneous lumbar laser disc decompression to conventional surgery, minimally invasive surgery, and conservative management of lumbar disc herniation, are needed to determine whether percutaneous lumbar laser disc decompression deserves a prominent place in the treatment arsenal for lumbar radiculopathy. Such a study is ongoing, and will hopefully clarify some of the issues facing the scientific and clinical community.

The idea of using lasers for the treatment of lumbar disc herniations arose in the early 1980's (44). After a series of in vitro experiments, Choy and colleagues performed the first percutaneous lumbar laser disc decompression on a human patient in February 1986 (218). The FDA approved percutaneous lumbar laser disc decompression in 1991. By 2002, over 35,000 percutaneous lumbar laser disc decompressions had been performed worldwide (230).

The treatment principle of percutaneous lumbar laser disc decompression is based on the concept of the intervertebral disc being a closed hydraulic system. This system consists of the nucleus pulposus, containing a large amount of water, surrounded by the inelastic annulus fibrosis. An increase in water content of the nucleus pulposus leads to a disproportionate increase of intradiscal pressure. In vitro experiments have shown that an increase of intradiscal volume of only 1.0 mL causes the intradiscal pressure to rise by as much 312 kPa or 2340 mmHg (218). On the other hand, a decrease in intradiscal volume can cause a disproportionately large decrease in intradiscal pressure. A reduction of intradiscal pressure causes the herniated disc material to recede toward the center of the disc, thus leading to reduction of nerve root compression and relief of radicular pain. In percutaneous lumbar laser disc decompression, this reduction is achieved by application of laser energy to evaporate water in the nucleus pulposus. The evaporation of water and the increase in temperature causes protein denaturation and subsequent renaturation, causing a structural change in the nucleus pulposus. This in turn limits its capability to attract water, therefore leading to a permanent reduction of intradiscal pressure by as much as 57% (218).

Seventeen clinical studies (148,150,160, 164,168,170,173,177,178,188,194,197-200,207,211,217) were included in this systematic review, representing a total of 3,171 patients. Studies were only included if they met all inclusion criteria. Schenk et al (44) included

16 clinical studies representing a total of 1,579 patients. However, since it was a narrative review, the criteria were different. They included studies only if they provided enough information on the techniques used during the procedure (laser type, parameters used, etc.), and no additional techniques such as endoscopy were used. In this systematic review, we also excluded studies in which endoscopy was used except with LASE. Schenk et al (44) included only trials when they addressed the outcome of percutaneous lumbar laser disc decompression. In the present systematic review as well as the review by Schenk et al (44), although the basic technique of percutaneous lumbar laser disc decompression appeared to be similar, there was a considerable degree of variation in the way percutaneous lumbar laser disc decompression was performed. Differences could be found in the choice of laser type and parameters used. Whereas most studies used fluoroscopy, some also used additional CT imaging or even MR imaging. In our previous systematic review (40), 10 clinical studies were included representing 2,447 patients. In contrast, the present systematic review included 15 clinical studies (148,150,160,164,168,170,173,177,178,188,194,197-200,207,211,217) encompassing 3,171 patients. In contrast to automated percutaneous lumbar discectomy (APLD) (39), there were multiple studies published after 2000. In the eight studies published since the turn of the millennium, all demonstrated positive results (148,150,160,164,168,170,173,177,178). The most recent study by and Duarte and Costa published in 2012 (148) was a prospective, open-label, uncontrolled study extending from June 2006 through July 2009 performed in 205 patients, 67% of whom experienced good results based on MacNab criteria.

One of the 8 studies published after 2000 was a prospective uncontrolled study by Duarte and Costa (148) that evaluated percutaneous lumbar laser disc decompression performed under CT guidance and local anesthetic. This study utilized appropriate selection criteria involving only a single nerve root. Utilizing MacNab criteria to include functional recovery, pain reduction and absence of drug dependency, the authors reported that 67% of patients experienced good results and 9% acceptable outcomes.

In 2011, Menchetti et al (150) published a multicenter retrospective study evaluating percutaneous lumbar laser disc decompression. The authors reported a 70% success rate utilizing MacNab criteria at mean follow-up of 5 years (range 2 to 6 years), with a very low complication rate. Tassi (164,170) published 2 reports in 2004 and 2006 comparing percutaneous lumbar laser disc decompression with microdiscectomy. This study utilized identical selection criteria (i.e. pain from herniated disc at 1 or 2 levels unresponsive to conservative management) and MacNab outcome criteria. The success rates were comparable in both groups (84% in laser decompression group and 86% in the microdiscectomy group, with a lower complication rate reported with laser surgery (0% vs. 2.2%). In uncontrolled studies by Choy (173) and Gronemeyer (177) reported success rates of 83% and 74%, respectively.

Several studies have attempted to identify outcome predictors for laser disc decompression. Iwatsuki et al (160) published an observational study that demonstrated a success rate of 80% using MacNab criteria in patients with a positive Lasègue's sign in 80% versus a success rate of only 5% in those with a negative Lasègue's sign. In a case-control study by Zhao et al (168), the authors found that 82% of patients with a "good" indication experienced either a good or excellent treatment response, which favorably compared to 56% of patients who had less than a good indication.

The success rate of laser decompression appears relatively stable. In an observational study by Knight and Goswami (178), the authors reported good (60%) or satisfactory (20%) results in 80% of patients at the end of the first year, which had declined only slightly to 73% (51% good, 22% satisfactory) after 3 years. Four patients developed aseptic discitis, 2% experienced a recurrent disc prolapsed, and 17% required additional surgery.

The main limitations of this systematic review are the lack of standardization of selection and outcome criteria, and the absence of randomized studies. However, there were a number of observational studies, with approximately half published after 2000. Despite several studies utilizing strict selection criteria, the lack of a control group limits the conclusions one can draw regarding efficacy. The strict selection criteria we used resulted in the exclusion of a number of studies which have been included in other studies. RCTs, specifically using a placebo control, can be challenging to design. This has led to many misconceptions regarding the interpretation of evidence (61,253,254). These difficulties are perhaps best illustrated when evaluating controlled studies and review articles for other interventional procedures, ranging from facet blocks to open spine surgery (9,10,57,254-260). Many studies which were intended to be "placebo-controlled" in an interventional pain management settings, are

in fact "comparative-effectiveness" trials in which a local anesthetic "control" injection may afford some benefit (55,61,254-269). A recurring issue that arises during the design of interventional studies relates to non-analgesic solutions (e.g., saline) injected into painful structures. These have been shown to only provide significant pain relief spinal pain, but also for multiple other painful conditions (270-280). The misinterpretation of interventional clinical trial results may in part be due to a lack of understanding about the scientific basis for placebo and nocebo effects (273,281-296). In recent years, placebos have been classified into pure or true placebos, and impure placebos. Whereas pure placebos lack any pharmacological activity, impure placebos do possess pharmacological effects, albeit for either a different purpose or at a higher dose (297).

The pitfalls of evidence-based medicine and the consequences resulting from a lack of understanding the issues have been well described in the literature (298). In interventional pain management, particularly when the procedure involves a major intervention such as percutaneous disc decompression, it is essential to understand not only the study design and technical aspects, but how placebo and nocebo effects can influence outcomes. It has been widely reported by Cochrane reviewers and others that placebo effect studies are susceptible to response bias and other types of biases. Hróbjartsson et al (299) reviewed the complex relationship between the placebo effect and bias. Since the concept of the placebo was brought to the attention of the medical community by Beecher (300) in his classic 1955 JAMA article, "The Powerful Placebo," it has been argued that the improved condition of patients receiving placebo was caused by the placebo intervention itself. Beecher's analysis includes the fallacy that underlies the need for controlled trials. It is not well-established that the observed response in randomized trials does not itself provide any reliable, unbiased, evidence of a placebo effect —an outcome caused by receiving a sham treatment disguised to be indistinguishable from an active medical intervention. Furthermore, an unbiased assessment of the placebo effect would require a comparison of placebo interventions with a suitable control group in order to distinguish the effect of the placebo intervention from confounding factors (e.g. the natural course of the condition or regression to the mean (301). Despite Beecher's approach being recognized as flawed in the late 1990's (302), by that time the notion of 'powerful placebo' had become deeply rooted. Methodologists haven't consistently been able to tease out the contributions of the placebo effect, natural history and regression to the mean, to study results.

However, Krogsbøll et al's (303) reference to spontaneous improvement in randomized clinical trials and meta-analyses of 3-armed trials comparing no treatment and placebo to an active intervention, has done a great deal to dispel these myths. They showed that the conditions associated with the most pronounced spontaneous improvement were nausea 45%, smoking 40%, depression 35%, phobia 34%, and acute pain 25%. These results are consistent with studies demonstrating a very powerful placebo effect in psychiatric and pain conditions associated with cognitive processes, and underscore the strong parallels between pain and psychopathology. The authors also showed that overall, across all conditions, there was statistically significant improvements noted in all 3 study arms. For chronic pain, receiving no treatment was associated with only a very small improvement, the placebo response was associated with modest benefit (< 30%), whereas the active treatment resulted in pain reduction of around 60%. Consequently, the authors concluded that both spontaneous improvement and the placebo effect are important contributors to the observed treatment effect in actively treated patients, though the relative importance of these factors differs according to clinical conditions and context.

In 2001, the power of placebo was challenged by a systematic review (304) evaluating 114 randomized clinical trials that reported no significant overall placebo effects of placebo for objective and binary outcomes, and only a small and likely clinically irrelevant effect for continuous subjective outcomes, such as pain. These findings are incompatible with Beecher's classic position and present a methodologist's perspective for the reasons for improvement. Although some academicians either pointed out that worthwhile effects could still exist in some settings (305), or saw the review as a necessary scientific correction to set the bar differently for claims concerning placebo (306), some media commentators interpreted the result as demonstrating the placebo effect to be a myth (307). An updated review published in 2004 showed similar findings (308), though the latest update from 2010 reported more multifaceted results (309). This latest systematic review demonstrated that large analgesic effects from placebo interventions were found in several well-conducted trials and that considerable variations in effect could in part be explained by differences in trial design (i.e. the

effect of placebo was larger when the intervention was a device versus a pill).

Popular fascination with the placebo effect, specifically for methodologists who do not like any type of interventions in medicine, has helped contribute to unrealistic assessments regarding its therapeutic effects, though many continue to believe in its benefit (310). Consequently, estimating the size of the placebo effect is not only subject to considerable uncertainty, but may be nearly impossible. In their methodological analysis and discussion of placebo effect studies and their susceptibility to bias, Hróbjartsson et al (299) showed that one challenge in evaluating interventional trials is how to reconcile response bias in trials in which outcomes are based on patient's reports. Other biases can include differential co-interventions, patient drop-outs, publication bias, and outcome reporting bias. As a result, extrapolation of study results to clinical settings can be fraught with difficulties. When designing interventional studies creative experimental efforts are needed to rigorously assess the clinical significance of placebo interventions, and explore the component elements that may contribute to therapeutic benefit (299).

In summary, this systematic review showed there is limited evidence that percutaneous lumbar laser disc decompression may provide appropriate relief in properly selected patients with a contained disc herniation.

5.0 Conclusion

This systematic review shows limited short-term and long-term evidence term for percutaneous lumbar laser disc decompression. However, based on the evidence from a large number of observational studies, laser disc decompression may provide appropriate relief in properly selected patients with contained disc herniation.

Acknowledgments

The authors wish to thank Vidyasagar Pampati, MSc, for statistical assistance, Sekar Edem for assistance in the search of the literature; Alvaro F. Gómez, MA, and Laurie Swick, BS, for manuscript review; and Tonie M. Hatton and Diane E. Neihoff, transcriptionists, for their assistance in preparation of this manuscript. The authors also thank Pain Physician for permission to reproduce Singh et al's manuscript from 2009 (40). We would like to thank the editorial board of Pain Physician for review and criticism in improving the manuscript.

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