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Systematic Review

Automated Percutaneous Lumbar Discectomy for the Contained Herniated Lumbar Disc: A Systematic Assessment of Evidence

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Background: Lumbar disc prolapse, protrusion, and extrusion account for less than 5% of all low back problems, but are the most common causes of nerve root pain and surgical interventions. The typical rationale for traditional surgery is an effort to provide more rapid relief of pain and disability. It should be noted that the majority of patients will recover with conservative management. The primary rationale for any form of surgery for disc prolapse associated with radicular pain is to relieve nerve root irritation or compression due to herniated disc material. The primary modality of treatment continues to be either open or microdiscectomy, but several alternative techniques including automated percutaneous lumbar discectomy (APLD) have been described. However, there is a paucity of evidence for all decompression techniques, specifically alternative techniques including automated and laser discectomy.

Study Design: A systematic review of the literature.

Objective: To determine the effectiveness of APLD.

Methods: A comprehensive evaluation of the literature relating to automated lumbar disc decompression was performed. The literature was evaluated according to Cochrane review criteria for randomized controlled trials (RCTs), and Agency for Healthcare Research and Quality (AHRQ) criteria was utilized for observational studies.

A literature search was conducted of English language literature through PubMed, EMBASE, the Cochrane library, systematic reviews, and cross references from reviews and systematic reviews.

The level of evidence was classified as Level I, II, or III with 3 subcategories in Level II based on the quality of evidence developed by the United States Preventive Services Task Force (USPSTF).

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 one-year or less, whereas, long-term effectiveness was defined as greater than one-year.

Results: Based on USPSTF criteria, the indicated evidence for APLD is Level II-2 for short- and long-term relief.

Limitations: Paucity of RCTs in the literature.

Conclusion: This systematic review indicated Level II-2 evidence for APLD. APLD may provide appropriate relief in properly selected patients with contained lumbar disc prolapse.

Key words: Intervertebral disc disease, chronic low back pain, mechanical disc decompression, automated percutaneous lumbar discectomy, internal disc disruption, radiculitis.

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Lumbar disc prolapse, protrusion, and herniation account for less than 5% of all low back problems, but are the most common causes of nerve root pain. Absolute indications for surgery include altered bladder function and progressive muscle weakness, but these are rare (1). The usual indication for surgery is to provide more rapid relief of pain and disability in the minority of patients whose recovery is unacceptably slow (1). The primary goal of surgical treatment for disc prolapse, protrusion, or extrusion is the relief of nerve root compression by removing the herniated nuclear material. The primary modality of treatment has been open discectomy. However, herniated discs are of 2 basic types: contained and non-contained. Contained herniated discs have an intact outer annulus with displaced disc material being held within the outer annulus of the contained herniated disc. In contrast, non-contained herniated disc has localized displacement of disc material beyond the intervertebral disc space and a breach in the outer annulus (2).

There are several treatment approaches for patients with nerve root compression due to a herniated disc have been reported. Besides the risk of the development of a failed back surgery syndrome (FBSS), the complication rates of this operative therapy are substantial (3-10). By 1939, Love (11) was advocating a much more limited approach using a hemilaminectomy. Due to the radiographic evaluation of the ruptured disc being so troublesome secondary issues related to myelography (12), Semmes (13) advised 2-level explorations using the laminotomy approach as being less morbid than myelography. Smith (14) introduced chemonucleolysis, which was later withdrawn due to devastating complications. Minimally invasive surgical approaches were described by Hijikata (15) and Williams (16) in the 1970s. Following the tendency towards a progressively more discreet approach to the herniated disc, the innovation of a suction-cutting probe placed into the disc space has emerged (12). Onik, a radiologist, recognizing the similarity between vitreous material of the eye and the nucleus of the disc, proposed the use of redesigned ophthalmic equipment for this purpose, now known as Nucleotome (17,18).

Minimally invasive treatments for the disc protrusions have faced fierce opposition from elements of the surgical community. That despite enjoying a high level of psychological acceptance by patients (19,20). Consequently, claims have been made in the literature over the last 30 years that automated percutaneous lumbar discectomy (APLD) can produce satisfactory results with small wounds and fewer serious complications (14-50). However, these claims remain controversial (1,51-57). Despite that, utilization of intradiscal therapies and all types of percutaneous mechanical disc decompression techniques continues to increase (58-63).

Gibson and Waddell (1) in the Cochrane Collaboration review presented the results from 40 randomized controlled trials (RCTs). However, this review indicated that the place for forms of discectomy other than traditional open discectomy is unresolved. Trials of percutaneous 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 (1). They also concluded that there is considerable evidence that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica due to lumbar disc prolapse that fails to resolve with conservative management. Discectomy provides faster relief from the acute attack of sciatica, although any positive or negative effects on the long-term natural history of the underlying disc disease are unclear. In addition, they noted that the choice of micro- or standard discectomy at present probably depends more on the training and expertise of the surgeon, and the resources available, than on scientific evidence of efficacy. However, these authors note that, at present, unless or until better scientific evidence is available, APLD should be regarded as a research technique.

In a technology assessment report (54), 4 randomized published studies were included (21,51-53) and all of them showed negative results. Boswell et al (55) in evidence-based guidelines of spinal interventional techniques showed that evidence was moderate for short-term and limited for long-term relief for automated discectomy.

This systematic review is undertaken to evaluate the current evidence of APLD.

Methods

Literature Search

Databases reviewed were PubMed, EMBASE, the Cochrane Library, and the Database of Reviews of Effectiveness (DARE). Bibliographies of reviewed papers were also examined. In addition, authors known to be active in the field were contacted. The time frame cov-

ered was 1966 to April 2009.

Inclusion criteria were:

1. Lumbar disc related pain of at least 3 months duration.
2. Treatment with APLD.
3. Minimum of 12-month follow-up.
4. At least 50 patients included in observational studies.

Search terms included intervertebral disc, degenerative disc disease, disc herniation, disc protrusion, disc extrusion, disc prolapse, disc displacement, APLD, percutaneous lumbar discectomy/diskectomy/nucleotomy/ and mechanical disc decompression.

Only articles in English or with English abstracts, systematic reviews, RCTs, and observational studies were reviewed. Discrepancies in rating were resolved by adjudication by a third reviewer. If there was a conflict of interest with the reviewed manuscripts such as authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence.

Methodologic Quality Assessment

The method of quality assessment was a function of the type of study. For RCTs, the Cochrane review criteria were used (64). Assessment of study quality for observational studies was done according to the Agency for Healthcare Research and Quality (AHRQ) criteria (65). Both the RCTs and observational forms provide a maximum of 100 points; only studies with scores of over 50 points were included. Consensus-based weighted scoring developed by the guidelines committee of the American Society of Interventional Pain Physicians (ASIPP) was utilized. The same scoring system has been used in multiple evaluations (66-82).

Outcome Measures

Pain relief was the primary outcome measure. Other outcome measures were functional improvement, improvement of psychological status, and return to work.

A decrease of either 2 points or 30% of pain scores provides a useful benchmark of clinical importance to assess effectiveness (83,84). Similarly, a 10% improvement in functioning outcomes provides an accepted benchmark of clinically useful benefit (85). However, in interventional pain management settings, a significant improvement has been defined as 50% or more relief, whereas significant improvement in disability has been defined as a 40% or more decrease in disability scores in multiple publications (86-95). Inclusion of the observational studies improves generalizability (86-88,96,97).

Significant pain relief (≥ 50%) of short-term (≤ 12 months) and long-term (> 12 months) was the primary outcome measure. Secondary outcomes included functional or psychological improvement, improvement in work status, and complications.

Analysis of Evidence

Level of evidence was determined based on the United States Preventive Services Task Force (USPSTF) criteria using 5 levels of evidence, ranging from Level I to III with 3 subcategories in Level II, as illustrated in Table 1 (98).

Recommendations

Recommendations for effectiveness were made according to Guyatt et al's criteria (99) (Table 2).

Results

The results of literature search for APLD are illustrated in Fig. 1. A total of 80 articles (14-53,100-139) were located in the literature search. Of these, 4 were RCTs (21,51-53).

Table 1. *Quality of evidence developed by USPSTF.*

I:	Evidence obtained from at least one properly randomized controlled trial
II-1:	Evidence obtained from well-designed controlled trials without randomization
II-2:	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
II-3:	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence
III:	Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees

Adapted from the U.S. Preventive Services Task Force (USPSTF) (98).

Table 2. *Grading recommendations*.

Grade of Recommendation/ Description	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A/strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B/strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C/strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A/weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C/weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Adapted from Guyatt G et al. Grading strength of recommendations and quality of evidence in clinical guidelines. Report from an American College of Chest Physicians task force. *Chest* 2006; 129:174-181 (99).

Randomized Controlled Trials

Methodologic Quality Assessment

Of the 4 RCTs (21,51-53), 2 trials (21,53) met inclusion criteria and 2 studies were of short-term follow-up (51,52). Thus methodologic quality assessment as shown in Table 3 was performed for 2 trials (21,53). Only one study met inclusion criteria with a score of 70 by Revel et al (53), whereas the study by Krugluger and Knahr (21) achieved a score of 33.

Study Characteristics

Among the published randomized trials, 2 trials (21,53) compared APLD and chemonucleolysis. Revel et al (53) randomized patients with sciatica caused by a disc herniation to undergo as an APLD or chemonucleolysis. The trial included 72 chemonucleolysis and 69 APLD patients of whom 43% of chemonucleolysis patients and 26% of APLD patients were considered sedentary subjects, and the disc appeared degenerated more often in the chemonucleolysis group (92%) than in the APLD group (76%). The study had 32 patients withdrawing during trial as therapeutic failures. They concluded that the results of both chemonucleolysis and APLD were generally disappointing, because 48% of the overall population entering the study considered treatment a failure and 20% submitted to open laminectomy within 6 months. They further described that while the failure rate of chemonucleolysis was similar to that observed in various controlled studies, the results observed in the APLD group were strikingly different from most reported previous uncontrolled series. They also postulated that the success rate of APLD in this study approached that observed in the placebo groups in the chemonucleolysis trials. At one-year follow-up, overall success rates were 66% in the chemonucleolysis group and 37% in the APLD group.

Many aspects of Revel et al's study (53), such as patient selection criteria, which led to poor results, have been criticized (51). The size of the disc herniation was an issue because for APLD it should not occupy more than 30% of the spinal canal, whereas in

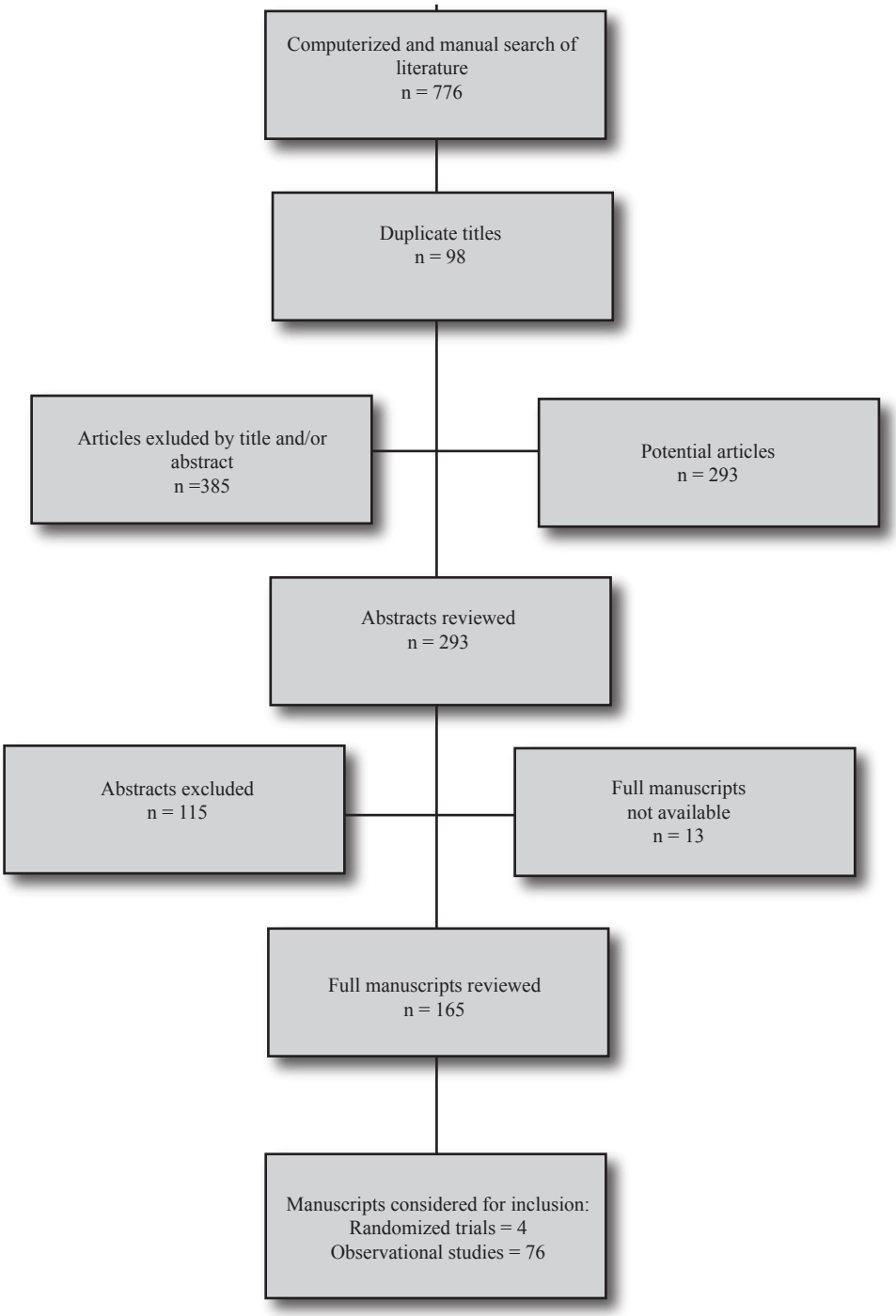

Fig. 1. *The flow diagram illustrating studies evaluating APLD.*

Table 3. *Methodological assessment of randomized clinical trials evaluating the effectiveness of APLD.*

CRITERION		Weighted Score (points)	Revel et al (53)	Krugluger & Knahr (21)
Study population				
A	Homogeneity	2	2	–
B	Comparability of relevant baseline characteristics	5	4	5
C	Randomization procedure adequate	4	4	–
D	Drop-outs described for each study group separately	3	3	3
E	< 20% loss for follow-up	2	2	–
	< 10% loss for follow-up	2	2	–
F	> 50 subject in the smallest group	8	8	–
	> 100 subjects in the smallest group	9	–	–
Interventions				
G	Interventions included in protocol and described	10	10	5
H	Pragmatic study	5	5	5
I	Co-interventions avoided or similar	5	5	5
J	Placebo-controlled	5	–	–
Effect				
K	Patients blinded	5	–	–
L	Outcome measures relevant	10	10	5
M	Blinded outcome assessments	10	–	–
N	Follow-up period adequate	5	5	5
Data-presentation and analysis				
O	Intention-to-treat analysis	5	5	–
P	Frequencies of most important outcomes presented for each treatment group	5	5	–
	TOTAL SCORE	100	70	33

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (64).

Revel et al's study (53) in 59% of APLD and 64% of chemonucleolysis patients the disc herniation covered between 25% and 50% of the spinal canal. Further, in 71% of the APLD patients and 79% of chemonucleolysis patients, the disc herniation had migrated up to 5 mm cranially or caudally to the endplate levels, which is considered a contraindication of APLD. Other factors included that at discography, 39% of the tested discs showed epidural leakage, 76% of the discs were severely degenerated (APLD is not effective in diffuse annular bulging), 9% had marked disc space narrowing, and 21% of patients had severe back pain, but no correlation to leg pain was made.

Krugluger and Knahr (21) also conducted a study comparing APLD with chemonucleolysis. The study initially selected 29 patients with symptomatic disc lesion confirmed by discography, however, due to epidural leakage of contrast material, 7 patients were excluded with 22 patient randomized to either chemonucleolysis or APLD. The results showed that at 6 weeks, both groups showed significant improvement in neurological deficits and Oswestry score. However, the differences between groups were not statistically significant at the 12-month follow-up.

This study failed to meet inclusion criteria based on Cochrane methodologic quality criteria. The total score was 33 of 100. The study suffers with multiple shortcomings, including lack of homogeneity, inadequate randomization procedure, loss of follow-up of > 20%, less than 50 subjects even in the largest group, not placebo-controlled, patients were not blinded, outcomes of assessments were not blinded, intention-to-treat analysis was not performed, and frequencies of most important outcomes presented for each treat-

ment group were not described.

Randomized trials of APLD and microdiscectomy included Chatterjee et al (51) and Haines et al (52,119). Both of these studies failed to meet inclusion criteria due to lack of one-year follow-up. Chatterjee et al (51) compared APLD to microdiscectomy in the treatment of contained lumbar disc herniation in a randomized study with blind assessment. The study included 71 patients with radicular pain as their dominant symptom after failure of conservative therapy for at least 6 weeks and contained disc herniation at a single level with a disc bulge of less than 30% of the canal size demonstrated with MRI. The study excluded patients with dominant symptoms of low back pain, disc extrusion, sequestration, subarticular or foraminal stenosis, and multiple levels of herniation. The results showed satisfactory outcomes in 29% of the patients in APLD group and 80% in the microdiscectomy group. They concluded that the APLD was ineffective as a method of treatment for small, contained lumbar disc herniations. The authors were criticized in that they failed to utilize CT discography.

Haines et al (52) also compared APLD to conventional discectomy as a first line treatment for herniated lumbar discs. The primary endpoint was the patients' outcome ratings 12 months after surgery. The study included patients with unilateral leg pain or paresthesia with no history of lumbar spinal surgery, whereas exclusions included moderate or advanced lumbar spondylosis, spondylolisthesis, lateral restenosis, herniated disc fragment occupying more than 30% of the AP diameter of the spinal canal, herniated disc fragment migrating more than 1 mm above or below the disc space, calcified disc herniation, lateral disc herniation, and posterior disc space height less than 3 mm. The success rate of APLD was 41% compared to 40% for conventional discectomy. However they concluded that the study did not have the power to identify clinically important differences because of insufficient patient enrollment.

Observational Studies

Methodologic Quality Assessment

Several studies were identified describing APLD (14-20,22-50,100-139). Multiple studies as shown in Table 4 are excluded due to reasons as described. Overall 12 observational studies met the inclusion criteria for methodologic quality assessment (22,23,25-30,35-37,124). Methodologic quality scores are described in Table 5, ranging from 45 to 71. Of these, 10 studies scored 50 or above (22,23,26-28,30,35-37,124), meeting the methodologic quality assessment criteria for evidence synthesis and 2 studies (25,29) scored below 50.

There are a large number of studies that attest to the success of APLD. The results are consistent in the studies with an approximately 75% success rate. Further, the risk factors reported have been low. In addition, throughout the reviewed literature, APLD always appears to be performed on an outpatient basis with return to activities immediately. APLD has been compared to alternative forms of treatments, including open discectomy, microdiscectomy, and chymopapain injection.

Study Characteristics

Onik et al (22) carried out a prospective multi-institutional study to evaluate automated percutaneous discectomy in the treatment of lumbar disc herniation. From 1984 through 1987, 506 APLDs were performed by 18 different surgeons within this prospective multi-institutional study. Of these, 327 patients met the prospective study criteria. The remaining 168 patients also underwent the study group. Of the 327 patients who were followed for one year or longer within the protocol, the success rate was 75.2% (n = 246) of the procedures done in patients outside the protocol, 49.4% were successful (n = 83). Of the 81 patients within the protocol in whom the procedure was considered to have failed, 41 patients underwent either a laminectomy, a microdiscectomy, or a fusion. Nineteen patients had second percutaneous discectomy with 3 of them requiring an open procedure and 21 patients have not had any other procedures as of the report date. They reported 2 cases of discitis, one psoas hematoma and one patient who had vasovagal attack. Further, of the 44 patients who underwent a subsequent open procedure, 30 had free disc fragments that were not seen on preoperative imaging studies, 6 patients had spinal stenosis, one patient had a vertebral fracture, and the remaining patients had bulging discs with no evident cause for failure. These authors believe that APLD is not appropriate for all patients with a herniated disc and should be used only for those patients with a contained herniation, that is, with the annulus and/or posterior longitudinal still intact and without evidence of migration from the disc space. Nearly 70% of patients in whom the treatment failed and who subsequently had surgery had unrecognized sequester of free disc fragments. This remains

Table 4. *Reasons for exclusion of observational studies of APLD.*

STUDY	REASON FOR EXCLUSION
Savitz et al (111)	Endoscopic surgery
Lee et al (113)	Endoscopic diskectomy < 50 patients
Simons et al (123)	Short-term follow-up
Pfeiffer et al (122)	Cadaver study
Goldstein et al (40)	< 50 patients with short-term follow-up
Pitto et al (41)	Short-term follow-up
Ramberg & Sahlstrand (42)	< 50 patients (30 patients)
Moon et al (137)	Discographic CT evaluation and short-term follow-up
Stevenson et al (135)	Cost-effectiveness study with short-term follow-up
Yeo & Tay (43)	Short-term follow-up and < 50 patients
Castro et al (116)	Short-term follow-up
Onik et al (136)	Cauda equina syndrome due to Nucleotome probe
Onik et al (47)	< 50 patients (36 initial report)
Taşdemiroğlu et al (134)	Spondylodiscitis – review of reports of complications
Sahlstrand & Lönntoft (125)	< 50 patients (20 patients)
Gill (133)	Retroperitoneal bleeding
Onik (132)	APLD in infectious discitis
Fencl & Kozler (131)	< 50 patients (45 patients)
Onik et al (44)	< 50 patients (4 patients) Description of far-lateral disk herniation
Theron et al (130)	6-week follow-up in 44 patients
Maroon et al (39)	Review
Davis & Onik (31)	Short-term follow-up
Shea et al (129)	Basic science study
Mirovsky et al (45)	< 50 patients (24 patients)
Gill (128)	Onset of sciatic after automated percutaneous discectomy
Kornberg (46)	< 50 patients (21 patients)
Gunzburg et al (127)	Experimental study
Onik & Helms (126)	Review article
Castro et al (139)	Study of biomechanics
Swiecicki (32)	Percutaneous technique – but, not APLD
Hijikata (100)	Percutaneous technique – but, not APLD
Schreiber et al (101)	Percutaneous technique – but, not APLD
Kambin & Schaffer (102)	Percutaneous technique – but, not APLD
Sakou & Masuda (103)	Percutaneous technique – but, not APLD
Hoppenfeld (104)	Percutaneous technique – but, not APLD
Onik and Helms (112)	Review
Hammon (34)	Presentation at a society meeting
Gobin et al (110)	< 50 patients (39 patients)
Delamarteret et al (109)	Imaging study in < 50 patients (30 patients)
Mathews et al (24)	< 50 patients (45 patients)
Gill (108)	Review
Bonaldi (19)	Short-term follow-up
Du Bois et al (107)	Cost effectiveness study
Morris (117)	Review
Maroon et al (118)	Review
Onik (115)	Review
Gill & Blumenthal (33)	Preliminary report of Gill and Blumenthal (29)
Onik et al (114)	Description of controversy
Benz & Garfin (106)	Review
Mink (105)	Imaging evaluation
Onik et al (17)	Probe description
Onik et al (18)	Cadaver study
Smith (14)	Chemonucleolysis study
Williams (16)	Microdiscectomy
Lucas (20)	Review article
Kambin & Schaffer (38)	Comment on endoscopic diskectomy
Maroon (120)	Review of current concepts
Hijikata (15)	Described experience of his technique
Negri & Belledi (48)	Full manuscript not available
Fiume et al (49)	Full manuscript not available
Dullerud et al (50)	Full manuscript not available
Chen et al (121)	Nucleoplasty histologic study

Table 5. *Methodological assessment of observational studies evaluating the effectiveness of APLD.*

CRITERION	Weighted Score (points)	Shapiro (27)	Grevitt et al (26)	Onik et al (22)	Davis et al (36)	Maroon & Allen (35)
1. Study Question	2	2	2	2	2	2
• Clearly focused and appropriate question						
2. Study Population	8	5	5	5	5	5
• Description of study population	5	5	5	5	5	5
• Sample size justification	3	-	-	-	-	-
3. Comparability of Subjects	22	11	11	17	11	11
• Specific inclusion/exclusion criteria for all groups	5	5	5	5	5	5
• Criteria applied equally to all groups	3	-	-	3	-	-
• Comparability of groups at baseline with regard to disease status and prognostic factors	3	-	-	3	-	-
• Study groups comparable to non-participants with regard to confounding factors	3	3	3	3	3	3
• Use of concurrent controls	5	-	-	-	-	-
• Comparability of follow-up among groups at each assessment	3	3	3	3	3	3
4. Exposure or Intervention	11	8	8	11	8	8
• Clear definition of exposure	5	5	5	5	5	5
• Measurement method standard, valid and reliable	3	3	3	3	3	3
• Exposure measured equally in all study groups	3	-	-	3	-	-
5. Outcome measures	20	11	15	15	15	10
• Primary/secondary outcomes clearly defined	5	3	5	5	5	3
• Outcomes assessed blind to exposure or intervention	5	-	-	-	-	-
• Method of outcome assessment standard, valid and reliable	5	3	5	5	5	2
• Length of follow-up adequate for question	5	5	5	5	5	5
6. Statistical Analysis	19	-	11	-	-	-
• Statistical tests appropriate	5	-	5	-	-	-
• Multiple comparisons taken into consideration	3	-	3	-	-	-
• Modeling and multivariate techniques appropriate	2	-	-	-	-	-
• Power calculation provided	2	-	-	-	-	-
• Assessment of confounding	5	-	3	-	-	-
• Dose-response assessment if appropriate	2	-	-	-	-	-
7. Results	8	8	8	8	8	8
• Measure of effect for outcomes and appropriate measure of precision	5	5	5	5	5	5
• Adequacy of follow-up for each study group	3	3	3	3	3	3
8. Discussion	5	5	5	5	5	5
• Conclusions supported by results with possible biases and limitations taken into consideration	5	5	5	5	5	5
9. Funding or Sponsorship	5	5	5	5	5	5
• Type and sources of support for study	5	5	5	5	5	5
TOTAL SCORE=	100	55	70	68	59	54

Adapted and modified from West S et al. *Systems to Rate the Strength of Scientific Evidence*, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (65).

Table 5 (continued). *Methodological assessment of observational studies evaluating the effectiveness of APLD.*

CRITERION	Weighted Score (points)	Teng et al (28)	Bonaldi et al (30)	Degobbis et al (37)	Gill & Blumenthal (29)
1. Study Question	**2**	**2**	**2**	**2**	**2**
• Clearly focused and appropriate question					
2. Study Population	8	5	**5**	**5**	**5**
• Description of study population	5	5	5	5	5
• Sample size justification	3	-	-	-	-
3. Comparability of Subjects	22	**14**	**14**	**11**	**8**
• Specific inclusion/exclusion criteria for all groups	5	5	5	5	5
• Criteria applied equally to all groups	3	3	3	-	-
• Comparability of groups at baseline with regard to disease status and prognostic factors	3	-	-	-	-
• Study groups comparable to non-participants with regard to confounding factors	3	3	3	3	-
• Use of concurrent controls	5	-	-	-	-
• Comparability of follow-up among groups at each assessment	3	3	3	3	3
4. Exposure or Intervention	**11**	**11**	**11**	**11**	**8**
• Clear definition of exposure	5	5	5	5	5
• Measurement method standard, valid and reliable	3	3	3	3	3
• Exposure measured equally in all study groups	3	8	3	3	-
5. Outcome measures	20	8	8	8	**6**
• Primary/secondary outcomes clearly defined	5	3	3	3	3
• Outcomes assessed blind to exposure or intervention	5	-	-	-	-
• Method of outcome assessment standard, valid and reliable	5	-	-	-	-
• Length of follow-up adequate for question	5	5	5	5	3
6. Statistical Analysis	**19**	**13**	**-**	**-**	**-**
• Statistical tests appropriate	5	5	-	-	-
• Multiple comparisons taken into consideration	3	3	-	-	-
• Modeling and multivariate techniques appropriate	2	-	-	-	-
• Power calculation provided	2	-	-	-	-
• Assessment of confounding	5	5	-	-	-
• Dose-response assessment if appropriate	2	-	-	-	-
7. Results	**8**	**8**	**8**	**8**	**6**
• Measure of effect for outcomes and appropriate measure of precision	5	5	5	5	3
• Adequacy of follow-up for each study group	3	3	3	3	3
8. Discussion	**5**	**5**	**5**	**5**	**5**
• Conclusions supported by results with possible biases and limitations taken into consideration	5	5	5	5	5
9. Funding or Sponsorship	**5**	**5**	**5**	**5**	**5**
• Type and sources of support for study	5	5	5	5	5
TOTAL SCORE=	**100**	**71**	**58**	**55**	**45**

Adapted and modified from West S et al. *Systems to Rate the Strength of Scientific Evidence*, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (65).

Table 5 (continued). *Methodological assessment of observational studies evaluating the effectiveness of APLD*

CRITERION	Weighted Score (points)	Rezaian & Ghista (25)	Marks (23)	Bernd et al (124)
1. Study Question	2	2	2	2
• Clearly focused and appropriate question				
2. Study Population	8	5	5	5
• Description of study population	5	5	5	5
• Sample size justification	3	-	-	-
3. Comparability of Subjects	22	11	14	14
• Specific inclusion/exclusion criteria for all groups	5	5	5	5
• Criteria applied equally to all groups	3	3	3	3
• Comparability of groups at baseline with regard to disease status and prognostic factors	3	-	-	-
• Study groups comparable to non-participants with regard to confounding factors	3	-	3	3
• Use of concurrent controls	5	-	-	-
• Comparability of follow-up among groups at each assessment	3	3	3	3
4. Exposure or Intervention	11	8	11	11
• Clear definition of exposure	5	5	5	5
• Measurement method standard, valid and reliable	3	3	3	3
• Exposure measured equally in all study groups	3	-	3	3
5. Outcome measures	20	7	8	10
• Primary/secondary outcomes clearly defined	5	3	3	3
• Outcomes assessed blind to exposure or intervention	5	-	-	-
• Method of outcome assessment standard, valid and reliable	5	2	-	2
• Length of follow-up adequate for question	5	2	5	5
6. Statistical Analysis	19	-	11	11
• Statistical tests appropriate	5	-	5	5
• Multiple comparisons taken into consideration	3	-	3	3
• Modeling and multivariate techniques appropriate	2	-	-	-
• Power calculation provided	2	-	-	-
• Assessment of confounding	5	-	3	3
• Dose-response assessment if appropriate	2	-	-	-
7. Results	8	5	5	5
• Measure of effect for outcomes and appropriate measure of precision	5	3	2	2
• Adequacy of follow-up for each study group	3	2	3	3
8. Discussion	5	5	5	5
• Conclusions supported by results with possible biases and limitations taken into consideration	5	5	5	5
9. Funding or Sponsorship	5	5	5	5
• Type and sources of support for study	5	5	5	5
TOTAL SCORE=	100	48	66	68

Adapted and modified from West S et al. *Systems to Rate the Strength of Scientific Evidence*, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (65).

the major inherent limitation of this approach to the treatment of herniated lumbar discs. However, with advances in imaging, this may not be a problem in modern times. They also described that the size of the herniation appears to be an important criterion in excluding patients with free fragments. They concluded that percutaneous discectomy is more efficacious for small-to-moderate sized disc herniations similar to chemonucleolysis (140). This study also included extensive conservative management and all the patients were facing open surgery as they failed to respond to conservative management. Thus, natural healing and improvement is not an issue.

Maroon and Allen (35) examined the results of 1,054 patients who had undergone APLD procedures from January 1987 to February 1988 at 35 U.S. hospital facilities. The primary goal of the study was to determine the net clinical results of the procedure when performed by private, non-academically based surgeons. Further, they also evaluated the impact of multiple factors on clinical results including the patient's age, gender, disc level, amount of material resected, and surgeon training. Of the 1,054 cases done, 865 or 82.9% were considered to have a successful result, both by the treating physician and the patient. There was no significant correlation between the disc level and success. However, the primary cause of the failure was the preoperative non-discernible presence of free disc fragments. Further, no other pathology appeared to impact the failure rate. They removed an average of 2.4 grams of nucleus pulposus material from the disc ranging from 1 gram to 8 grams with no correlation with the outcomes. They reported only 3 postoperative complications in the study group with 2 patients having disc infections and one patient with muscular hematoma with an overall complication rate of 0.002%.

Teng et al (28) utilizing an APLD technique with Teng's instrument, which was modified from Onik's instrument in China, reported results of 1,582 APLD procedures in a prospective study in 10 independent hospitals from 1992 to 1994. The success rate was 83% at one year, which was significantly greater for protrusion versus sequestration (86% vs 72%, $P < 0.01$); for back pain alone versus leg and back pain (89% vs 80%, $P < 0.005$); for duration of symptoms less than 2 years versus more than 2 years (85% vs 79%, $P < 0.005$); and for age younger than 60 years versus older than 60 years (84% vs 76%, $P < 0.01$). They also reported a 77% success rate among post surgical patients in 17 of 22 patients. The only complication was discitis (0.06%) in 9 patients. They reported that good results were obtained in patients considered to have contraindications by other authors. These contraindications included extrusion/sequestration type of herniation, long-term duration of the symptoms, old age, calcification of longitudinal ligaments, interspaces and disc, and previous surgical discectomy. They also reported that patients who had only low back pain with little or no leg pain had significantly better results than those with classical sciatica in contradiction to reported indications and other reports. They recommended that patients who failed to respond to conservative treatment for 2 months or longer should be considered as candidates for APLD, even with low back pain, as long as the clinical findings correlate with the images. Further, 33% of the patients had more than one level involved with similar results, either with a multilevel treatment or a single level treatment. However, they felt that the superior results were due to wider and more effective disc removal with the Teng Nucleotome.

Davis et al (36) reported results in 518 compensation patients, elderly patients, and patients with previous surgery who were treated successfully using percutaneous discectomy on an outpatient basis. They reported no intraoperative or postoperative complications. A total of 439 patients or 85% were treated successfully with a 15% failure rate. The successful criteria included at least moderate to complete pain relief, not receiving narcotic medications, a return to the pre-injury functional status, and to minimize the bias of the investigators, the patient had to be satisfied with the results of the procedure. The results showed that in 427 non-compensation cases, there was a 87% success rate with a 13% failure rate, whereas of 91 compensation patients, the success rate was 74%. Of the 79 patients considered failures, 33 were found to have extruded disc fragments outside the interspace with subsequent microdiscectomy and successful results. Five patients had spinal stenosis sufficient to deny pain relief from the percutaneous discectomy, and later, surgery was successfully performed. The 41 patients who failed and later underwent extensive diagnostic investigation were either found to have no sufficient anatomic explanation for their pain or refused further surgery and were considered failures. In addition, there were 44 patients in the original group of 518 who had previous laminectomy for a herniated disc. The results 6 months after surgery revealed 40 of these patients

were successful, and 4 were failures, undergoing further open surgery. Among the patients over the age of 60 years, a successful result was obtained in 70% of the patients. Of all successfully treated patients, 70% returned to work in less than 2 weeks. They reported no intraoperative or postoperative complications, specifically with no disc space infection, no nerve damage, no vascular damage, and no damage to the dura. The average amount of disc material removed by the procedure was 2.1 gram.

Bernd et al (124) reported the results of 238 patients operated by APLD between 1988 and 1990. They had a written questionnaire response of 76.4% with a mean follow-up of 2.5 years. Overall, 60% reported pain relief and 52% were satisfied with APLD. The only significant parameters for improvement in condition and pain relief was age, where patients younger than 41 did better. Risk factors for re-operation were a positive Lasègue's sign and over 41 years of age. Patient satisfaction was significantly higher for patients without sensory deficit preoperative.

Grevitt et al (26) treated 137 patients with symptomatic lumbar disc prolapse by APLD. At a mean follow-up of 55 months, of those 72% reported an excellent or good result when reviewed at one year follow-up. There were no correlation between the success rate and the volume of disc material removed.

Shapiro (27) provided long-term follow-up results of 57 patients undergoing APLD. All 57 patients had unilateral sciatica with a mean follow-up period of 27 months, ranging from 6 to 45 months, 33 patients or 58% showed improvement in their sciatica, but only 3 (5%) were completely pain free. Of the 17 patients presenting with recurrent sciatica, 11 patients have undergone microdiscectomy, with 8 showing improvement. They removed on average 3.5 grams of disc material without any significant complications.

Marks (23), using a relatively novel approach, evaluated the role of percutaneous discectomy as a surgical option for treating lumbar internal disc derangement. One hundred three patients with low back pain with or without radiation to one or both lower extremities and an unsuccessful rigorous trial of conservative care, underwent APLD. Internal disc derangement was defined either by discographic fissuring of the annulus with pain production and/or desiccation on MRI with or without disc bulging, protrusion, or herniation, in combination with intractable back or leg pain or both. The overall subjective rating was excellent in 33%, good in 30%, fair in 20%, and poor in 17%. Of patients less than 45 years old, 65 patients had an excellent or good subjective outcome, compared with 54% of patients 46 and older. The factors of gender, levels of disc surgery involved, and workers' compensation status had no statistically significant effect on the subjective rating outcome. For patients receiving workers' compensation, 55% returned to work at the same level, and 27% of patients returned to lighter duty work, which compared similarly to patients not receiving workers' compensation. Regressional analysis of all factors found that age was a statistically significant factor (P = 0.367). Of the 17 patients whose results were rated as poor, 10 required subsequent surgery for continued symptoms.

Bonaldi et al (30) evaluated a total of 234 patients treated by percutaneous discectomy at 237 levels and followed-up between 11 months and 3 years 4 months who showed an overall success rate of about 75%. In a subgroup of 112 of these patients were checked for a second time, the clinical results remain consistently good even 24 months after surgery. In a special group of 28 patients who complained only of low back pain, percutaneous discectomy achieved a success rate of 85.7%. Complications consisted of one disc infection which cleared without clinical or radiological sequelae (0.26%)

Degobbis et al (37), between October 1989 and December 2003, performed 506 automated percutaneous nucleotomies according to Onik for the treatment of lumbar disc hernia. The survey of 50 reviewed cases after evaluation of the subjective and objective clinical pictures according to the Cabot method allowed them to come to the conclusion that percutaneous methodology is suitable to relieve damaged discs from compression. It is also well accepted by patients because it is not too traumatic, it requires short-term hospitalization, presents no risk of postoperative fibrosis, and does not create complications for the eventual traditional operation when unsuccessful. It is extremely important to accurately select the candidates, keeping in mind the original indications given by Onik for percutaneous discectomy for which—in case of contained disc herniation—leg pain (sciatalgia) is more severe than low back pain affecting the lumbar region.

Table 6 illustrates summary results of eligible studies of APLD included in this systematic review.

Table 6. *Summary results of eligible studies of automated percutaneous lumbar discectomy included in this systematic review.*

Study	Study Characteristics	Methodological Quality Scoring	Number of Participants	Pain Relief	Results
				> 12 mos.	Long-term > 12 mos.
Revel et al (53)	RA	70	69 APLD 72 Chemonucleolysis	37% APLD 66% Chemonucleolysis	N
Shapiro (27)	O	55	57	58%	P
Grevitt et al (26)	O	70	137 (115 remained at final follow-up interview)	72%	P
Onik et al (22)	O	68	506	75%	P
Davis et al (36)	O	59	518	85%	P
Maroon & Allen (35)	O	54	1054	85%	P
Teng et al (28)	O	71	1,582	83%	P
Bonaldi et al (30)	O	58	234	75%	P
Degobbis et al (37)	O	55	50	NA	NA
Marks (23)	O	66	103	63%	P
Bernd et al (124)	O	68	238	60%	P

RA = randomized; O = observational; P = positive; N = negative; N/A = not available.

Level of Evidence

The indicated level of evidence based on USPSTF criteria (98) is Level II-2 for short- and long-term relief.

Recommendations

The recommendation is 1C/strong recommendation based on Guyatt et al's (99) criteria.

Discussion

This systematic review evaluated the role of lumbar disc decompression with APLD. The present evaluation of evidence for APLD indicated Level II-2 for short- and long-term relief with a 1C/strong recommendation.

Automated percutaneous lumbar discectomy, or APLD, is performed with a pneumatically driven, suction-cutting probe placed through a cannula that has a 2.8 mm outer diameter. Most of the disc removal occurs one cm anterior to the herniation removing approximately one to 3 grams of disc material with the intent of reducing intradiscal pressure and decompressing nerve roots (17-19,109,126,141). ONik and Helms (126) described APLD in a review article. Since their description in 1990, multiple other studies hae been published. Onik and Helms also outlined various aspects of percutaneous lumbar discectomy, including patient selection. at the time of the writing of the manuscript in 1990, they described that more than 3,000 physicians have been trained to perform the procedure, and over 40,000 cases have been completed worldwide.

Gibson and Waddell (1) concluded that clinical outcomes following APLD are at best fair and certainly worse than after microdiscectomy. They also made a point of the importance of patient selection. Four randomized trials met the inclusion criteria. These 2 trials (21,53) compared APLD and chemonucleolysis, whereas 2 other trials (51,52) compared APLD with microdiscectomy. Revel et al (53) in the randomized trial, even though multiple deficiencies have been pointed out, demonstrated the inferiority of APLD compared to chemonucleolysis. Krugluger and Knahr (21) in their study

showed similar improvement in both groups. However, the study was too small.

Onik and Helms (126) described APLD in a review article. Since their description in 1990, multiple other studies have been published. Onik and Helms also outlined various aspects of percutaneous lumbar discectomy, including patient selection. At the time of the writing of the manuscript in 1990, they described that more than 3,000 physicians have been trained to perform the procedure, and over 40,000 cases completed worldwide.

Among the observational studies, a prospective multi-institutional study (22) evaluated 506 APLD procedures from November 1984 through May 1987 performed by 18 different surgeons. In this study, 327 patients met the protocol and had follow ups of one-year or more, with a success rate of 75%. Further, in those patients outside the protocol, procedures were successful in 49%. They also showed that, of the 44 patients who subsequently underwent an open procedure, 68% had pre-fragment of disc unsuspected by preoperative imaging. In another prospective multi-institutional study conducted in Italy (142), 650 patients were treated with APLD with a 72% success rate, with the selection and success criteria similar to the above study (22).

In a study by Carragee et al (143), they reported that the patients in the fragment-fissure group, who had disc fragment and a small annular defect, had the best overall outcomes and the lowest rates of reherniation (1%) and reoperation (1%). Patients in the fragment-contained group had a 10% rate of reherniation and a 5% of reoperation. Further, patients in the fragment-defect group, who had extruded fragments and massive posterior annular loss, had a 27% rate of reherniation and a 21% rate of reoperation. Finally, patients in the no fragment-contained group did very poorly with 38% having recurrent or persistent sciatica, and the standard outcome scores were less improved compared with those in the other groups ($P < 0.001$). Thus, it is postulated that for patients with contained disc herniation, percutaneous mechanical disc decompression with APLD may be the best choice.

Similarly, the Dewing et al (141) in an evaluation of outcomes of lumbar microdiscectomy showed that patients with sequestered or extruded lumbar disc herniations had significantly better outcomes than did those contained herniations. Contained discs were associated with the poorest outcomes; significantly worse than either extruded or sequestered disc types.

APLD is considered safer than microdiscectomy since it utilizes the Nucleotome probe as the primary instrument used for decompression, limiting the amount of times that the physician needs to enter the disc space for removal of nucleus pulposus. By contrast, microdiscectomy uses manual instruments that may need to reenter the disc several times. Almost definitionally, microdiscectomy is more invasive than APLD.

The effectiveness of APLD appears to compare favorably with the results of chymopapain injection and open discectomy, even though it is very difficult to draw conclusions as these assumptions have not been proven in randomized trials. Further, if optimistic success rates reported for microdiscectomy are considered, the difference in efficacy between open discectomy and APLD appears to be only 10% to 15%. Gibson and Waddell (1) concluded that despite the critical importance of knowing whether surgery is beneficial for disc prolapse, overall, surgical discectomy for carefully selected patients with sciatica due to the prolapsed lumbar disc appears to provide faster relief from the acute attack than non-surgical management. However, positive or negative effects on the lifetime natural history of the underlying disc disease remain unclear. They also concluded that microdiscectomy gives broadly comparable results to standard discectomy. Considering the benign nature of the procedure and cost, it appears APLD is recommended in a selective group of patients meeting the inclusion criteria. As described in the recommendation, best action may differ depending on circumstances or patients' or societal values.

Conclusion

This systematic review indicated Level II-2 evidence, with 1C/strong recommendation for APLD which may provide appropriate relief in properly selected patients with contained disc herniation. APLD is a safe procedure with minimal complications.

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