

Current Concepts in Intradiscal Percutaneous Minimally Invasive Procedures for Chronic Low Back Pain

Abstract

Study Design: A systemic review of thermal annular procedures (TAPs) and percutaneous disk decompression procedures (PDDPs) for the treatment of discogenic chronic low back pain (CLBP) was conducted. **Objective:** The objective of this review is to evaluate and to compare the effectiveness of TAPs and PDDPs in treating discogenic CLBP and to assess the frequency of complications associated with those procedures. **Materials and Methods:** English-language journal articles were identified through computerized searches of the PubMed database and bibliographies of identified articles and review papers. Articles were selected for inclusion if percutaneous minimally invasive procedures were the treatment options for patients with CLBP and if follow-up outcome data included evaluations of back pain severity, functional improvement, and/or incidence of complications. For this review, 27 studies were included. **Results:** Intradiscal electrothermal therapy (IDET) procedure in properly selected patients may eliminate or delay the need for surgical intervention for an extended period, whereas few adverse effects have been reported. In contrast to IDET, there is far less literature on the effectiveness of radiofrequency annuloplasty and intradiscal biacuplasty procedures. Nucleoplasty is a potentially effective treatment option for patients with contained disc herniation, while the procedure is well tolerated. Increased success rates have been found for percutaneous laser disc decompression and automated percutaneous lumbar discectomy in strictly selected patients. **Conclusions:** These procedures can be effective and may obviate the need for surgery completely. Further prospective randomized sham-controlled trials with higher quality of evidence are necessary to confirm the efficacy of these procedures.

Keywords: Annular tears, chronic low back pain, disc herniation, discogenic pain, intradiscal minimally invasive interventions

Introduction

Low back pain (LBP) is related to disability, work absence, and extensive costs for the health system in societies.^[1-3] Point prevalence of LBP ranges from 12% to 33%, 1-year prevalence of LBP ranges from 22% to 65%, and the lifetime prevalence of LBP is up to 84%.^[4-7] The classification of LBP is based on the duration of the symptoms.^[8] It is defined as acute when it persists for <6 weeks, subacute between 6 weeks and 3 months, and chronic when it lasts longer than 3 months.^[9] Most commonly, in about 85% of the patients, specific causative factors (e.g., infection, tumor, osteoporosis, fracture) cannot be found and the LBP is defined as nonspecific.^[10,11]

The clinical course of an episode of acute LBP is characterized by fluctuation over time with frequent recurrences

or exacerbations, rather than an acute, self-limiting course.^[12,13] Hestbaek *et al.* in a systemic review pointed out that after the first episode of LBP, about 62% of patients were still experiencing pain after 12 months.^[14] The estimated prevalence of chronic low back pain (CLBP) ranging from 35% to 75% at 12 months after the onset of pain.^[14-20] Many sources of persistent LBP have been identified, with lumbar intervertebral discs, facet joints, and sacroiliac joint being the most common.^[6] Intervertebral discs have been found to be the main source of CLBP with a percentage between 7% and 39%.^[21-23]

Until a few years ago, surgical intervention was the only treatment option for discogenic pain in patients unresponsive to conservative therapy.^[24] Surgical treatments include disc excision with laminectomy, open discectomy, microdiscectomy, spinal fusion, and artificial disc replacement.^[25]

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Altered bladder function and progressive muscle weakness are considered as absolute indications for surgery, but these are rare.^[26] The reported effectiveness and the incidence of complications vary with surgical procedures.^[27,28] Complication rate postsurgically has been reported to be around 17%–18%, including 20% risk of the failed back surgery syndrome,^[29,30] and a 6%–22% re-intervention rate.^[9,31] According to the literature, poor patient selection is consistently reported as one of the causes for failed back surgery syndrome.^[32,33]

More recently, minimally invasive intradiscal procedures have been considered as an alternative treatment approach for CLBP. The reported complication rate is low, the native disc structure is preserved, and the surrounding tissues are less affected with these procedures.^[34] The main purpose of the minimally invasive procedures is to avoid the major disadvantages of using surgical procedures, such as tissue trauma, high incidence of complications, and repeated surgeries.^[35]

Materials and Methods

We reviewed the international literature concerning the intradiscal therapies. The included articles were found through computerized searches in the electronic database of PubMed. The included papers were either reviews or original articles. The included studies were written in English language. Moreover, the articles were selected if percutaneous minimally invasive procedures were used as a treatment option in patients with CLBP. The follow-up in the selected papers included evaluation of back pain severity, functional improvement of the patients, as well as incidence of complications that presented. In total, this review study included 27 studies.

Thermal annular procedures

Internal disc degeneration (IDD) is considered as the causative factor in about 39% of total CLBP cases in adult population.^[22,36] Radial tears or fissures in the annulus can be caused by these degenerative changes. Disc material from the nucleus migrates outward through these rents, causing inflammation.^[37]

Thermal annular procedures (TAPs) are an alternative option between pharmacologic and surgical treatment for patients suffering from IDD.^[6] Three minimally invasive procedures have been developed: intradiscal electrothermal therapy (IDET), radiofrequency annuloplasty (RFA), and intradiscal biacuplasty (IDB).^[37] Heat is delivered by these procedures to the damaged annulus, leading to denervation of the annulus and pain relief.^[38] Heat-induced denaturation of collagen fibers is thought to stabilize the disc and potentially seal annular fissures.^[39,40]

The effectiveness of TAPs is based on the strict and careful patient selection.^[37] The ideal patient^[41] has LBP for at least 6 months, has back pain greater than leg

pain, and is unresponsive to conservative treatment. Back pain is exacerbated by sitting or standing and is relieved by lying down. Moreover, positive well-performed discography, presence of an annular tear, and one or two affected intervertebral discs with at least 50% remaining disc height and disc bulges ≤ 5 mm are associated with favorable outcomes.^[37] Compressive radiculopathy and abnormal neurological examination are considered as contraindications for TAP.

Intradiscal electrothermal therapy

In IDET, a navigable intradiscal catheter that is radiologically guided into the outer posterior or posterolateral annulus is utilized and the produced heat is delivered to the affected disc while the patient is under conscious sedation lying prone.^[42,43] Temperature is thought to cause local denaturation of collagen fibrils, cauterization of granulation tissue, and coagulation of nerve fibers.^[44-46] Favorable outcomes in pain and disability can be achieved, when patients are selected correctly^[42,43] [Table 1].

Meta-analyses assessing the efficacy of IDET procedure were conducted by Freeman^[47] and Appleby *et al.*^[48] They reported a mean improvement in visual analog scale (VAS) for back pain of 3.4 and 2.9 points, respectively. In Oswestry disability index (ODI), the improvement was 5.2 and 7 points, respectively. In Appleby *et al.*'s^[48] survey, the mean decrease in SF-36 physical function was 21.1 points and the mean decrease in SF-36 bodily pain was 18 points, all of which were statistically significant. The estimated incidence of complications was 0.8%. Freeman evaluated five retrospective studies with a total of 379 patients and between 13% and 23% of patients underwent surgery for persistence LBP after IDET procedure. He concluded that the evidence for the efficacy of IDET remains limited.^[47] However, in contrast to Freeman's conclusion, Appleby *et al.* pointed out that the effectiveness and the safety of the procedure have been confirmed by the outcomes of the published surveys.

The two randomized sham-controlled trials (RCTs) of the IDET procedure have conflicting findings. In a double-control trial,^[49] a total of 57 patients were

Table 1: Intradiscal electrothermal therapy indications

N	Indication
1	Persistent symptoms of axial low back pain±leg pain for at least 6 months duration. Without marked lower extremity neurological deficit
2	Failure to improve with a minimum of 6 weeks of conservative treatment (including pain medication and physical therapy)
3	One to three desiccated discs with or without small, contained herniated nucleus pulposus evidenced by T2-MRI
4	Present with predominant low back pain with or without referred leg pain

MRI – Magnetic resonance imaging

randomized with 2:1 ratio, 38 being included in IDET group and 19 being included in sham procedure. The mean LBP outcome score for the IDET group was 39.51 at baseline and 38.31 at 6 months and that of for placebo group was 36.71 and 37.45, respectively. The mean ODI for the IDET group was 41.42 at baseline and 39.77 at 6 months and for the placebo group was 40.74 and 41.58, respectively. Outcome measures were not significantly improved after IDET or placebo treatment. In contrast to these findings, Pauza *et al.*^[41] demonstrated better outcomes for patients treated with IDET. Sixty-four patients included in the survey group and 37 were located to IDET group and 27 to sham treatments. They reported that patients in both groups improved in SF-36 score, whereas pain relief and ODI were improved significantly greater in IDET group than in sham group. They found that in patients who were presented with VAS <7, SF-36 <55, or ODI >40, IDET procedure was significantly more effective. Furthermore, >50% pain relief occurred only in 40% of patients treated with IDET and in 33% of participants in placebo group.

Both RCTs have been criticized. In Pauza *et al.*'s survey,^[41] extensive placebo effect has been reported, whereas the implementation of strict criteria in patient selection has led to outcomes which are uncertain if they could be extrapolated to clinical practice. On average, patients selected in the study were not disabled, with high scores for most of the subscales of the SF-36. Freeman's survey has been criticized for the failure of having a placebo effect. In contrast to the literature, Freeman's study has failed to demonstrate any beneficial outcome to IDET or sham group. The absence of placebo response suggests an undefined methodological error, and according to Helm *et al.*,^[37] the study is nonresponsive in evaluating the null hypothesis that IDET is as effective as placebo in the treatment of CLBP. Furthermore, Freeman *et al.*^[49] included in their survey patients with marked functional limitations, whereas participants in Pauza *et al.*' survey^[41] were less disabled and comparatively healthier.

Clinical outcomes of IDET procedure were compared with the outcomes of spinal fusion in a systemic review of Andersson *et al.*^[50] The overall median improvement after spinal fusion was 50% in VAS for pain, 42% in ODI, and 46% in SF-36. After IDET, the improvement was 51%, 14%, and 43%, respectively. The authors pointed out that perioperative complications were commonly associated with surgical intervention and concluded that IDET could be used before spinal fusion among eligible patients.

Radiofrequency annuloplasty

Radiofrequency thermal energy is delivered by RFA to the affected disc to treat LBP.^[43] Through an electrode, an alternating current (frequency, 250–500 kHz) is produced by a radiofrequency generator, causing ionic movements in the tissue directly surrounding the active tip.^[51] Molecular friction and heating of the tissue occur within a limited

distance of the electrode.^[52] Cosman and Cosman,^[53] as well as Kline,^[52] reported that RFA's efficacy is caused by de-activating the nerves suspected of contributing to pain, by applying an electrical current to coagulate the sensory nerves, and by preventing conduction of nociceptive impulses.

Clinical effectiveness of RFA procedure is reported in a prospective case–control study by Finch *et al.*^[54] Thirty-one participants underwent RFA in a single-level painful annular tear, and 15 patients continued conservative treatment. In treatment group, VAS and ODI were decreased significantly, whereas in control group, both outcome measures were unchanged over 12 months of follow-up.

Two RCTs for RFA have been conducted and showed no beneficial outcomes from the procedure. In Kvarstein *et al.*'s survey,^[55] 20 patients were distributed in treatment and sham group with a ratio of 1:1. Pain intensity scores and secondary outcome measures (ODI, SF-36, the percentage of patients' pain relief, and brief pain inventory) showed no significant differences between the groups neither at 6 months nor at 12 months follow-up. Five patients treated with RFA reported >50% pain relief at 12 months compared to only one patient in sham group. However, four patients in RFA group presented with worse or unchanged pain intensity in final follow-up, whereas in sham group, seven patients reported deterioration. In Barendse *et al.*'s^[56] RCT, 13 patients were allocated in treatment group and 15 in sham group. No differences were reported in VAS for pain, global perceived effect, and ODI between the two groups 8 weeks after treatment.

In contrast to the results of Kvarstein *et al.* and Barendse *et al.*, Oh *et al.*^[57] conducted an RCT and demonstrated clinical improvement postoperatively. In this survey, 49 patients were included suffering from CLBP for >1 year and whose pain continued after undergoing IDET. The control group patients each received an injection of lidocaine without RFA. At 4-month follow-up, in treatment group, VAS for pain and bodily pain and physical function subscales of SF-36 were significantly improved compared to control group. In control group, significant differences in these outcome measures were not found.

IDET and RFA procedures were compared in a prospective-matched control trial study by Kapural *et al.*^[58] Twenty-one patients were allocated to either group. Before treatment, statistically significant differences in VAS or pain disability index (PDI) were not found between the two groups. From the 3rd-month to the 12th-month postprocedure, participants in the IDET group were improved significantly greater in VAS and PDI than patients in RFA group.

Intradiscal biacuplasty

In IDB, two cooled RF electrodes, which are included in a bipolar system, are placed on the posterolateral annulus fibrosus.^[24] The suggested process with regard to IDB

is the coagulation of nociceptors within the posterior aspect of the disc. The produced temperature maintains a safe environment for the surrounding tissues, and at the same time, neural ablation is caused.^[59] Safety profile of the procedure and the absence of perioperative and postoperative complications have been reported in many studies in the literature.^[60-63]

The effectiveness of IDB procedure was compared to that of a placebo intervention in Kapular *et al.*'s double-blinded RCT.^[60] At 6-month follow-up, physical function, pain, and disability were significantly improved in treated patients ($n = 27$) compared to patients in the sham group ($n = 28$). In IDB group, significant improvement was found in physical function and pain at 12-month follow-up. Participants with single-level disc degeneration appeared with better outcomes posttreatment compared to patients with two-level disc degeneration. At 6-month follow-up, patients in sham group were offered IDB and the improvement in physical function, pain, disability, and opioid usage at final follow-up was similar to those of patients who received IDB at inception. The authors provided evidence that IDB could be a minimally invasive option treatment in carefully selected patients and helped validate results of efficacy seen in earlier uncontrolled studies.^[24,64,65]

Safety and clinical effectiveness of IDB were demonstrated in Desai *et al.*'s^[63] prospective, randomized study. The authors compared IDB and conventional medical management (CMM) (29 participants) with CMM-alone (34 participants). After 6 months, 89% of CMM-alone participants opted to receive IDB in addition to CMM. At 6-month and 12-month follow-up, patients in the original IDB + CMM group showed statistically significant pain relief and 55% of them presented with improvement in VAS >2 points. VAS score decreased >50% was documented in 41% of the patients, whereas physical function, ODI, and quality of life were improved significantly. At 6 months, none of the CMM-alone group average outcome scores were improved significantly. In cross-over group, the results at 6 months were more favorable than those observed in the CMM-alone group and were similar to the 6-month recorded outcomes in the originally treated IDB + CMM group.

A systemic review of the literature regarding the outcomes of TAPs for the treatment of CLBP was performed by Helm *et al.*^[6] Twelve observational studies and three RCTs were included in their survey. As mentioned above, RCTs of Pauza *et al.*^[41] and Freeman *et al.*^[49] had conflicting outcomes, whereas four observational studies^[66-68] showed positive results for IDET, one observational study^[69] showed negative results, and another showed undetermined results.^[70] Consequently, authors pointed out that IDET has an effect on health outcomes and they mentioned the necessity for further studies to determine the efficacy of the

procedure. The authors included only one study for RFA,^[55] which showed no benefit, so the evidence for the efficacy of the procedure is poor. Investigators pointed out the insufficient evidence for the effectiveness of IDB.

Percutaneous disc decompression

Contained disc herniation in patients without abnormal neurological examination can be treated with percutaneous disc decompression (PDD).^[71] Open discectomy has been the primary modality for many years and is indicated in the minority of patients with persistent symptomatology.^[72] Hakkinen *et al.*^[73] estimated that the reoperation rate for lumbar disc herniation was 10% at 5-year follow-up, whereas Atlas *et al.*^[31] and Osterman *et al.*^[74] reported a 25% reoperation rate at 10-year follow-up. Open discectomy appears to have limited success rate in patients with small contained disc herniations, with recurrence of sciatica of 37.5% and reherniation rate of 12.5%.^[75-78] In contrast, open discectomy appears beneficial in patients with noncontained disc herniations.^[79]

In PDD procedures, pain improvement is achieved by the relief of intradiscal pressure while the integrity of the surrounding tissues is preserved.^[80] As a consequence of intradiscal pressure reduction, inflammatory mediators' release is limited, whereas a reduction in disc size and an initiation of healing progress occur.^[81] Important predictive factor for the success of the PDD is to determine whether the disc herniation is still contained by intact fibers of the outer annulus and posterior longitudinal ligament.^[25]

Techniques included in PDD are chymopapain chemonucleolysis, which produces an enzymatic break of the nucleus, PDD (nucleoplasty), percutaneous laser disc decompression (PLDD), and automated percutaneous lumbar discectomy (APLD).^[25,43,82] Chymopapain is no longer used due to the increased risk for fatal anaphylaxis, cartilaginous endplate damage, and hemorrhage.^[83-85] The effectiveness of PDD is based on the strict and careful patient selection [Table 2].

Table 2: Indications and contraindications for percutaneous disk decompression

Indications for PDD	Contraindications for PDD
Contained disc herniation and annular integrity	Large, noncontained disc herniation, sequestration or extrusion
Radicular pain (greater than axial pain) for at least 6 months	Infection
Patient unresponsive to conservative treatment	Cauda equina syndrome or newly developed signs of neurological deficit
50% of disc height is preserved	Uncontrolled coagulopathy and bleeding disorders. Structural deformities

PDD – Percutaneous disk decompression

Percutaneous disc decompression (nucleoplasty)

Disc nucleoplasty (RF coblation or plasma discectomy) is a method of PDD using coblation technology. RF energy is produced through a 1-mm diameter bipolar instrument. Intradiscal pressure is reduced by removing approximately 1 cm \geq of the nucleus pulposus, and the causing elimination in disc protrusion, as well as the decompression of the nerve root, has a good effect in pain relief.^[43,86,87] This technique preserves the integrity of the surrounding tissues, without direct mechanical or thermal damage.^[80] Consequently, risks associated with open surgery, such as fibrosis and infection, have been minimized.^[88,89] The most significant side effect is temporary soreness at the point of needle insertion,^[90] whereas discitis, both aseptic and septic, occur with rates between 0% and 1.2%.^[34]

Beneficial results of nucleoplasty were documented in Al-Zain *et al.*'s^[86] prospective survey. Participants ($n = 69$) had a VAS score of 6.59 for back pain preoperatively and 3.36 after 1 year, whereas for radicular pain, the score was 5.68 and 2.5, respectively. These findings were statistically significant. At least 50% pain relief was reported in 58% of the participants. Similarly, clinical improvement postnucleoplasty was documented in Nedeljkovic's systematic review.^[80] Fourteen studies were included in the survey. Fifty-three percent of the patients reported >50% pain relief. The median percentage of improvement of VAS from baseline was 38.5%, with a range of 11%–72%. All studies reported improvement in VAS postnucleoplasty, but in nine studies, the improvement was statistically significant. Three studies assessed patients' functional improvement and concluded that over 50% of the participants were presented with improvement in the final follow-up.

A comprehensive meta-analysis was conducted to analyze the effectiveness and safety of the procedure in treating lumbar and cervical disc herniations. Eichen *et al.*^[91] evaluated 27 studies, with a total of 3211 patients, and concluded that procedure reduces pain in the long term and increases patients' functional mobility. In 17 studies, VAS and numeric pain scale were utilized as outcome measures, and nucleoplasty led to statistically significant pain reduction compared to baseline at every measurement time point. Four studies had control groups and nucleoplasty was found to be more effective than conservative treatment after 6 weeks and 3 months. ODI was decreased significantly compared to baseline across all time points.

Effectiveness of nucleoplasty against fluoroscopy-guided transforaminal epidural steroid injection (TFESI) was tested in an RCT.^[71] Forty-six participants were allocated in PDD group and 44 in TFESI group. VAS for leg pain, ODI, and SF-36 were improved significantly greater in nucleoplasty group compared to those in TFESI group. During the 2-year follow-up period, 25 (56%) patients in nucleoplasty group and 11 (28%) in the TFESI group have not undergone a secondary procedure.

It has been mentioned that nucleoplasty and PDD techniques are indicated in patients with contained disc herniation.^[89] The assumption that patients with larger protrusion will have less favorable outcomes from nucleoplasty was assessed in a prospective, nonrandomized, cohort study.^[87] Three groups of patients were evaluated. In Subgroup 1A, 24 patients were included with a disc protrusion ≤ 5 mm; in Subgroup 1B, those with a disc protrusion size 6 mm–9 mm are included, and in Group 2, 27 patients were allocated with a disc extrusion. All of them were treated with nucleoplasty. Sixty-five patients with disc extrusion were allocated in Group 3 and were treated with microdiscectomy. Comparing Subgroup 1A with Subgroup 1B, it was found that both subgroups were equal concerning pain severity and disability after 1-year follow-up. In Group 2, statistically significant exacerbation of pain severity and disability was documented during the first 3 months, and a further stabilization of patients' condition was found during the next follow-ups. In Group 3, during the first 6 months, pain intensity and disability were decreased significantly. The authors concluded that total annulus disruption in cases of disc extrusion is associated with poor results and less pain relief when treated with nucleoplasty. On the contrary, nucleoplasty appeared to have beneficial outcome for contained disc herniations up to 9 mm.

Percutaneous laser disc decompression

PLDD is one minimally invasive treatment modality for contained lumbar disc herniation, which has been approved by Food and Drug Administration since 1991.^[34] In PLDD, laser energy is delivered by a laser fiber through a hollow needle placed into the nucleus pulposus via a percutaneous approach under local anesthesia.^[92] Water content of the nucleus pulposus is vaporized due to laser energy, causing a decrease in intradiscal volume and a subsequent reduction in intradiscal pressure.^[93–96] In Hellinger's survey, 3377 patients were evaluated and a complication rate of 0.5% was reported.^[97] One case of infectious discitis was documented among 377 PLDD procedures,^[96] whereas three cases of abdominal perforation and one of partial cauda equina syndrome were caused due to PLDD according to Quigley's study.^[98]

The limited evidence for the short-term and long-term effectiveness of PLDD has been reported in systemic reviews.^[34,92] In Singh *et al.*'s^[34] study, among 3171 patients, 75% experienced clinical improvement for at least 1 year. In Schenk *et al.*'s^[92] review, 16 clinical trials were included with a total of 1579 patients. Schenk *et al.*, as well as Singh *et al.*, concluded that PLDD may be effective in properly selected patients and mentioned the paucity of RCTs.

The first RCT comparing the effectiveness of PLDD to conventional surgery in patients with lumbosacral radicular syndrome was conducted by Brouwer *et al.*^[99] Fifty-seven patients were included in PLDD group and 58 patients

allocated in surgery group. Statistically significant differences were not found in outcome measures (Roland–Morris disability questionnaire, VAS for pain, and seven-point Likert scale) between the two groups, except for a faster recovery for patients underwent surgery. In PLDD group, 24 patients (44%) had undergone to additional surgical intervention during the 1st year, whereas nine of the patients (16%) had undergone surgery needed a reoperation. Surgery group demonstrated more complications (11%) compared to PLDD group in which complications occurred less commonly (5%). The authors concluded that PLDD, with additional surgery when needed, can be a treatment option with effectiveness similar to surgical intervention.

The same conclusion was led by Tassi,^[35] who compared microdiscectomy to PLDD, in a 2-year follow-up. In microdiscectomy group ($n = 500$), clinical improvement occurred in 85.7% of the patients, whereas the remaining patients (14.3%) deteriorated or did not improve. In PLDD group ($n = 500$), the percentages were 83.8% and 16.2%, respectively. Clinical improvement occurred more quickly in surgery group, whereas recovery time was significantly shorter in PLDD group. Complication rate in microdiscectomy group was 2.2%, whereas in PLDD group, complications did not occur.

Automated percutaneous lumbar discectomy

A pneumatically driven, suction-cutting probe is utilized in APLD and is placed in the affected disc through a cannula that has a 2.8-mm outer diameter.^[100] Three grams of disc material is removed 1 cm anterior to the herniation, thus leading to reduction of intradiscal pressure and decompression of the nerve root.^[100]

In a prospective multi-institutional study,^[101] the results of 1582 APLD procedures from 1992 to 1994 were evaluated. The reported success rate was 83% at 1 year. Similarly, in Manchikanti *et al.*'s^[102] review, positive results occurred in 80% of the patients. Patients with disc protrusion improved significantly greater compared to patients with disc sequestration and to patients with <2 years symptoms duration.^[101] In contrast to the common philosophy, Teng *et al.*^[101] reported that patients with LBP as a predominant symptom improved significantly greater than those with classic sciatica.

In a comparative study by Liu *et al.*,^[103] 104 patients were treated with APLD and 82 patients were treated with microendoscopic discectomy (MED) with a mean follow-up period of 6 years. According to MacNab criteria, success rate of 75.96% in APLD group and 84.15% in the MED group was reported. Patients treated with MED had significantly greater improvement in ODI and SF-36 scores of social functioning and bodily pain than those in APLD group. Eight patients (7.69%) in the APLD group and two patients (2.44%) in the MED group underwent open surgical discectomy. While long-term postprocedural

satisfaction is greater in patients underwent MED, incidence of complications, duration of hospitalization, and costs are lower for patients in APLD group.

Two RCTs have been performed to evaluate the effectiveness of APLD, but the quality and the results of the studies have been criticized. Chatterjee *et al.*^[104] conducted an RCT comparing APLD to microdiscectomy. Twenty-nine percent of patients in APLD group and 80% of patients in microdiscectomy group showed beneficial outcomes. The authors have been criticized for poor selection criteria, for unreasonably low success rate with APLD, which may be even less than with placebo, and for not using CT discography. The absence of control group limits the quality of the RCT. The second RCT was conducted by Haines *et al.*^[105] and compared the effectiveness of APLD to the effectiveness of conventional discectomy. According to Macnab criteria, the success rate of APLD was 41% of the percutaneous discectomy patients and 40% of the conventional discectomy. Haines *et al.*^[105] failed to recruit sufficient number of participants and only 34 patients were included in the survey.

Characteristics and results of the published surveys for intradiscal minimally invasive procedures are presented in Table 3.

Conclusions

Patients who underwent IDET procedure presented 51% improvement in VAS score, 14% in ODI, and 46% in SF-36, whereas the complications were approximately 0.8%.^[47,50] Concerning RFA, it seems that the results are not so beneficial.^[55] IDB in combination with CMM showed 55% pain relief,^[63] whereas disc showed relief of the pain in 58% of the patients. PLDD results have been reported beneficial in 75% of the patients.^[34]

In the Swedish Lumbar Spine Study^[27] at 2-year follow-up, the mean decrease in back pain was 33% in the surgical group and 7% in the nonsurgical group. In the Norwegian study,^[106] at 1-year follow-up, improvement in back pain was not different between lumbar fusion group and control group. In the UK Medical Research Council trial,^[107] spinal fusion was compared to an intensive program of exercise therapy, spine stabilization exercises, and education using cognitive-behavioral principals. At a 2-year follow-up, it was found that pain, ODI, quality of life, or SF-36 physical or mental components did not statistically differ between the two treatment approaches. The European guidelines support that fusion surgery cannot be recommended unless 2 years of conservative treatment or minimally invasive procedures have failed.^[9]

Therefore, the short-term indication for medications, as well as the increased complication rate and the variable success rate of surgery, leads to an increased interest for minimally invasive procedures. Since 1998, IDET procedure has been performed and the reported incidence of complications

Table 3: Clinical surveys published concerning intradiscal therapies

Study	Study characteristics	Technique	Outcomes	Complications	Conclusions
Appleby <i>et al.</i> (2006)	Meta-analysis 17 studies	IDET	VAS for back pain, ODI, SF-36 bodily pain, and SF-36 physical function were improved 2.9, 7, 18, and 21.1 points, respectively	The overall incidence of complications was 0.8%	The pooled results of the published studies provide compelling evidence of the relative efficacy and safety of the IDET procedure
Andersson <i>et al.</i> (2006)	Systemic review 33 spinal fusion articles 18 IDET articles	Spinal fusion IDET	Spinal fusion: VAS was improved 50%. ODI was improved 42%. SF-36 was improved 46% IDET: VAS was improved 51%. ODI was improved 14%. SF-36 was improved 43%	14% perioperative complications for spinal fusion. Rare adverse events with IDET	IDET could be used before spinal fusion among eligible patients
Freeman <i>et al.</i> (2005)	Randomized, double-blind, placebo-controlled trial 38 patients in IDET group 19 patients in sham group	IDET	IDET group: LBOS was 39.51 at baseline and 38.31 at 6 months. ODI was 41.42 and 39.77, respectively Sham group: LBOS was 36.71 at baseline and 37.45 at 6 months. ODI was 40.74 and 41.58, respectively	Transient radiculopathy (<6 weeks) in four patients in IDET group and in one participant in sham group	No subject in either arm showed clinically significant improvements 6 months following treatment IDET is no more effective than placebo for the treatment of CLBP
Pauza <i>et al.</i> (2003)	Randomized, placebo-controlled, prospective trial 37 patients in IDET group 27 patients in sham group	IDET	Mean improvements in pain, disability, and depression were significantly greater in the group treated with IDET. In IDET group, 40% of patients achieved greater than 50% pain relief, whereas 50% of patients do not benefit appreciably	No adverse effects attributable to treatment	A needed-to-treat value of five, for achieving 75% relief of pain, indicates that it is a worthwhile intervention for highly selected patients
Finch <i>et al.</i> (2005)	Prospective case-control study 31 patients underwent RFA 15 patients continued conservative treatment	RFA	VAS and ODI were decreased significantly, whereas in control group, both outcome measures were unchanged over the 12 months of follow-up	No complications or adverse events	The improvement gained by RFA is significantly better than that obtained from conservative management

Contd...

Table 3: Contd...

Study	Study characteristics	Technique	Outcomes	Complications	Conclusions
Kvarstein et al. (2009)	Prospective, randomized, double-blind placebo-controlled study 10 patients in RFA group 10 patients in sham group	RFA	Pain intensity scores and secondary outcome measures (ODI, SF-36, the percentage of patients' pain relief, and BPI) showed no significant differences between the groups neither at 6 months nor at 12 months follow-up. Five patients in RFA group reported greater than 50% pain relief	Adverse effects were not reported	The study did not find evidence for a benefit of RFA, although it cannot rule out a moderate effect
Oh et al. (2004)	Randomized control trial 26 patients in RFA group 23 patients received an injection of lidocaine	RFA	At 4-month follow-up, VAS for pain and bodily pain and physical function subscales of SF-36 improved significantly compared to control group. In RFA group, VAS, bodily pain, and physical function improved 46.5%, 49.7%, and 34.8%, respectively	One patient in RFA group complained of mild lower limb weakness, but he completely recovered 15 days	RFA should be considered a treatment option in patients with CLBP
Kapural et al. (2005)	Prospective matched control trial 21 patients in IDET group 21 patients in RFA group	IDET RFA	At 12-month follow-up, in the IDET group, VAS and ODI were improved significantly compared to RFA group	N/A	IDET appears to be more efficacious than RFA based on PDI and VAS scores measured at 1 year following procedure
Kapural et al. (2014)	Randomized sham-controlled study 27 patients in IDB group 28 in sham group	IDB	Pain, disability, and physical function were improved significantly in treatment group compared to sham group	No complications or adverse events	IDB could be a minimally invasive option treatment in carefully selected patients
Helm et al. (2012)	Systemic review 12 observational studies Three RCTs	TAPs	IDET Four observational studies showed positive results One observational study showed negative results One observational study showed undetermined results Two RCTs with conflicting findings RFA One RCT showed no beneficial outcomes	In patients treated with IDET, complications are rare and transient No adverse effects are reported for RFA and IDB	The evidence is fair for IDET and limited (or poor) for RFA and IDB procedures regarding whether they are effective in relieving discogenic CLBP

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Study	Study characteristics	Technique	Outcomes	Complications	Conclusions
Al-Zain <i>et al.</i> (2008)	Prospective study 69 patients were evaluated (1-year follow-up)	Nucleoplasty	VAS for back pain was 6.59 preoperatively and 3.36 after 1 year VAS for radicular pain was 5.68 and 2.5, respectively Statistically significant reduction in analgesic consumption, disability and occupational incapacitation resulted from treatment with nucleoplasty	N/A	Nucleoplasty is an effective therapy for CLBP which results in significant reductions in levels of disability and incapacity for work as well as decreased analgesic consumption
Eichen <i>et al.</i> (2014)	Comprehensive meta-analysis 27 studies were included 3,211 patients	Nucleoplasty	VAS 7.27 at baseline 3.03 at 12 months 3.69 at 24 months ODI 58.95 at baseline 24.43 at 12 months 36.98 at 24 months	Complication rate of 1.8% for lumbar nucleoplasty	Compared to baseline, significant pain reduction and improvement in functional mobility after nucleoplasty were observed at every time point
Frederic <i>et al.</i> (2010)	Systemic review Seven studies were included 717 patients	Nucleoplasty	VAS was improved 38.5% at 12-month follow-up 53% of patients presented with more than 50% pain relief Over 50% of patients presented with functional improvement	The majority of reviewed studies reported no significant complications	The median percentage and range of patients having successful outcomes after nucleoplasty was 62.1%. The recommendation is a level 1C, strongly supporting the therapeutic efficacy of this procedure
Singh <i>et al.</i> (2013)	Systemic review 17 observational studies were included 3,171 patients	Laserdisc decompression	75% of patients experienced clinical improvement	Discitis varies from 0% to 1.2%	Low evidence for short-term and long-term relief in managing disc herniation
Schenk <i>et al.</i> (2006)	Review 16 clinical trials were included 1,579 patients	Laserdisc decompression	Success rates in the larger studies varies from 75% to 87% 4.4%–25% of patients received additional surgical treatment	The reported frequency of discitis varies from 0% to 1.2%	PLDD may provide pain relief in properly selected patients with contained disc herniations and the paucity of RCTs is mentioned
Brouwer <i>et al.</i> (2014)	Randomized prospective trial 57 patients in PLDD group 58 patients in surgery group	Laserdisc decompression and conventional surgery (discectomy)	No statistical differences in RMDQ, VAS and 7-point Likert scale Higher speed recovery in favor of surgery Reoperation rate: 44% in PLDD group, 16% in surgery group	11% for surgery group 5% for PLDD group	PLDD with additional surgery when need, proved to be noninferior compared to surgery at 1-year follow-up

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Study	Study characteristics	Technique	Outcomes	Complications	Conclusions
Liu <i>et al.</i> (2009)	Retrospective comparative study 104 patients in APLD group 82 patients in MED group	APLD MED	MacNab 75.96% in APLD 84.15% in MED ODI Significantly better in MED SF-36 Social functioning, bodily pain significantly better in MED Open discectomy 7.69% in APLD 2.44% in MED	No in APLD group Two patients in MED group (muscle cramping and muscular atrophy in the leg)	Both procedures have long-term efficacy and safety Long-term satisfaction rating in the MED Group is slightly higher than that in the PLD group. Complications, duration of hospitalization, and costs are higher in MED group than that of the PLD group
Manchikanti <i>et al.</i> (2013)	Systemic review 19 observational studies 5,515 patients	APLD	4,412 of the patients presented with positive results ranging from 45% to 88%	Complications are rare	APLD may provide appropriate relief in properly selected patients with contained disc herniation It is a safe procedure with minimal complications

IDET – Intradiscal electrothermal therapy; VAS – Visual analog scale; ODI – Oswestry disability index; SF – Short-form; LBOS – Low back pain outcome score; CLBP – Chronic low back pain; RFA – Radiofrequency annuloplasty; BPI – Brief pain inventory; N/A – Not available; PDI – Pain disability index; IDB – Intradiscal biacuplasty; RCTs – Randomized sham-controlled trials; TAPs – Thermal annular procedures; PLDD – Percutaneous laser disc decompression; MED – Microendoscopic discectomy; APLD – Automated percutaneous lumbar discectomy; RMDQ – Roland–Morris disability questionnaire

is low. In properly selected patients with internal disc disruption who underwent IDET, the need for surgical intervention may be obviated or delayed for an extended period. The American Society of Interventional Pain Physicians concluded in their 2007 evidence-based practice guidelines in the management of CLBP that the evidence for IDET was moderate for short-term and long-term pain relief.^[108] In addition, the North American Spine Society suggests that for less disabled patients with annular tears or protrusions <3 mm–4 mm and relatively well-preserved disc heights, IDET would seem to be a reasonable primary option treatment.^[44]

In contrast to IDET, there is far less literature on RFA and IDB procedures. There are little data on the effectiveness of RFA and IDB, and according to Helm *et al.*,^[6] the evidence is limited for both procedures regarding whether they are effective in relieving discogenic CLBP. One prospective survey^[58] compared IDET to RFA and concluded that IDET should be the preferable treatment option for discogenic CLBP. Further high-quality surveys are needed to assess the effectiveness of RFA and IDB and to provide efficient evidence for their use in the management of CLBP.

According to the results of many studies, nucleoplasty is regarded as a potentially effective treatment approach

in patients with discogenic LBP. Increased success rates have been reported and average pain reduction is significant, while the procedure is safe and well tolerated from the patients. Prospective RCTs with higher quality of evidence are necessary to confirm the efficacy of the procedure. Similarly, increased success rates have been found in observational studies and systemic reviews for PLDD. These findings have been validated by Brouwer *et al.*'s RCT.^[99] The authors mentioned the efficacy of the procedure and the need for surgical intervention if the symptoms persist. APLD has been approved by the American Academy of Orthopedic Surgeons as a treatment option for patients with herniated lumbar discs.^[109] Prospective studies have reported favorable clinical outcomes and the importance of strict patient selection is acknowledged.

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Conflicts of interest

There are no conflicts of interest.

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