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Outcome Assessment of Intradiscal Radiofrequency in Management of Discogenic Back Pain

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ABSTRACT
Background: Low back pain (LBP) is one of the most common causes of disability. Intradiscal RF appears to be a safe, minimally invasive treatment option for carefully selected patients with chronic discogenic LBP who have not responded to aggressive non-operative care. The aim of the present study was to investigate the efficacy and safety of percutaneous intradiscal radiofrequency (PRF) in patients with chronic disabling discogenic back pain.
Patients and methods: This a prospective Cohort studywas carried out at Neurosurgery Department, Faculty of Medicine, Zagazig University and included patients with chronic LBP without radiculopathy or neural compromise in MRI. Full history taking, complete clinical evaluation, laboratory and radiological examination were performed preoperative and post-operative.
Results: There is statistically significant decrease in mean CPK from 94.23 to 85.38 postoperatively.There is highly statistically significant decrease in OSI post-operatively. Median decreased from 35 to 15 four weeks postoperatively. There is highly statistically significant decrease in mean VAS from 6.31 to 4.38 postoperatively. There is highly statistically significant increase in time till sitting intolerance as median increased from 30 minutes to 75 minutes postoperatively. Final outcome showed improvement in both OSI and VAS and 10 patients had successful surgery.
Conclusion: Intradiscal radiofrequency maneuver exhibited more effective than other techniques that previously used. Intradiscal RF appears to be a safe, minimally invasive treatment option for carefully selected patients with chronic discogenic LBP who have not responded to aggressive non-operative care.
Keywords: Discogenic Back Pain;Intradiscal Radiofrequency; Outcome

INTRODUCTION

Back pain can be categorized by the origin of the pain: discogenic low back pain (LBP), radicular back pain, facet joint osteoarthritis back pain, muscle and fascia-induced back pain, and spontaneous occurring LBP. Although there are a variety of etiologies, it has been estimated that discogenic LBP occurs in approximately 28-40% of all patients with LBP **(1)**. Discogenic pain is attributed to degenerative changes in the intervertebral disc due to aging or to traumatic events. In degenerated discs, nerves, containing nociceptive neurotransmitters and introdicing cytokines, have been found to penetrate into deeper intradiscal structures as far as the inner third of the annulus and the nucleus pulposus, creating nociceptive information from within the disc **(2)**. The production of pro-inflammatory mediators within the nucleus pulposus is assumed to be a major factor in the genesis of a painful lumbar disc **(3).**

The modality to diagnose discogenic pain in all these criteria includes provocative discography or CT discography.As a result, the clinical use of discography should be limited to select patients who are planning a surgical procedure in the near future as a confirmatory step rather than as an early diagnostic procedure. Therefore, diagnostic methods other than discography are needed; currently there are no standard diagnostic methods **(4).**

In recent years, there has been a general trend in interventional treatment away from radiofrequency thermocoagulation toward PRFas a less invasive treatment. The use of PRF in the disc relies on the electric field generated, and the electric field is assumed to induce changes in the tissue that may explain changes in pain conduction and possibly induce a healing process **(5).**Intradiscal PRF, achieved by means of an electrode placed in the center of the nucleus pulposus, in patients with discogenic LBP produced excellent to good outcomes in 8 cases. Recently, minimally invasive intradiscal Diskit II® needles (NeuroTherm; USA), which are able to provide PRF to the disc with the 20mm active tip, have been developed **(6)**. In the application of PRF, the length of the active tip has been shown to be an important element and the magnitude of the electric field parallel to the uninsulated part of the needle has been shown to be largest area **(7)**. Therefore, this study aimed to investigate the efficacy and safety of PRF in patients with chronic disabling discogenic back pain.

PATIENTS AND METHODS

This a prospective Cohort studywas carried out at Neurosurgery Department, Faculty of Medicine, Zagazig University and included patients with chronic LBP without radiculopathy or neural compromise in MRI .

Inclusion criteria:

Chronic low back pain of at least 6 months continuous duration. Clinically the patients complain of chronic LBP often radiating into the buttock and the leg, bilaterally but without significant radicular pain. The pain is often provoked by cumulative loading. Patients also experience sitting intolerance. Lack of satisfactory improvement with a comprehensively applied non-operative care program including the following: epidural corticosteroid injection, a trial of physical therapy, and oral antiinflammatory medication. Normal neurologic examination findings with negative SLR results.

A magnetic resonance scan that did not demonstrate a neural compression lesion .Concordant pain at low pressurization (low volume ≤1.25 mL contrast medium) during discography of the concerned disc. Intradiscal administration of 1 mL of lidocaine 2% diminished pain more than 70%.

Exclusion criteria:

Disc extrusion or a sequestered fragment ; degenerative spinal canal narrowing; segmental instability or psychological issues; systemic infection or localized infection at the anticipated needle entry sites; previous lumbar surgery; chronic lower extremity radiculopathy and history of opioid abuse were excluded.

Ethical consideration:

The study was approved by the Local Ethical Committee of Zagazig University. Written consent was obtained from every patient prior to the procedures. This study has been carried out in accordance with the code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

II. Operational Design:

All patients were enrolled for full history taking including symptoms suggesting evidence of spinal tumors, systemic infections, CKD, muscle diseases, recent fractures in the lumbar spine region or history of proven osteoarthritis of the hip joint to be excluded; history of clinical symptoms suggesting pain related to radiculopathy or facet joint origins to be excluded; or history of allergies to injected medications; and history symptoms suggesting evidence of sacroiliitis.

Complete clinical examination was performed. Radiological Diagnosis included the outcome of degeneration include annular fissures, disc herniation, endplate damage, collapse of the annulus, and disc narrowing will produce lumbar related symptoms. Radiological tests such as X ray done for all patients to exclude vertebral instability , fracture, facet arthropathy, birth bone defects ,osteoarthritis , osteoporosis , malignancy or hx of previous lumbar surgery.CT scan to confirm radiological findings in patients suspicious of underlying pathology not detected in plain x ray.

Oswestry Scale Index:

The Oswestry Disability Index (aka the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability and considered the 'gold standard' of low back pain functional outcome tool**.**

VAS score:

A VAS is a straight line, the end anchors of which are labeled as the extreme boundaries of the sensation, feeling, or response to be measured. On the more frequently used unipolar scales, ratings of the intensity of a phenomenon such as pain are made between the extremes of absence of the phenomenon (no pain) to a maximum intensity of the phenomenon (worst pain 1 can imagine or pain as bad as it could possibly be). Normal mood is assumed to lie somewhere around the midpoint between these two extremes **(8)**.

Intradiscal PRF Technique:

Intradiscal radiofrequency was performed on an outpatient basis.Patients were informed about the procedure and the way discogenic pain could be provoked by discography. All patients received intravenous injections of antibiotics before the procedure and consciously sedated with alfentanyl 0.5 mg and 1 to 2 mg midazolam without muscle relaxant using local anasethia .Lying prone with a pillow under the abdomen. The end position was controlled by means of fluoroscopy in at least 2 directions Lateral view and anteroposterior (AP).

The skin was aseptically draped, the needle pathways were locally anesthetized, and without hitting the segmental nerve, the needle was placed into the middle of the nucleus of each disc.The discs treated were selected on clinical grounds according to the level of provocative discography. Under

fluoroscopic guidance and via a posterior oblique approach, the Diskit II® needle (20 G, 15-cm length, 20-mm active tip, with radiopaque marker active tip; NeuroTherm) was percutaneously advanced and placed centrally the disc which was responsible for the symptoms. Proper placement of the introducer needle was confirmed with anteroposterior, oblique, and lateral fluoroscopic projections. The proximal end of the tip was equipped with a radiopaque marker, and the active tip was advanced to a position where it was completely within the disc.

After performing electro-stimulation at 2 V at 2 and 50 Hz to confirm that the needle position was far enough away from the segmental nerve, we applied higher voltages for longer exposure times. We applied intradiscal RF at a frequency of 5 Hz, pulse width of 5 ms, amplitude of 60 V, and a maximum temperature of 60o C, for a duration of 2 minutes, with the NT1100 generator (NeuroTherm) then needle was withdrawn without removing it from the disc, another electro-stimulation is done at 2 V at 2 and 50 Hz to confirm that the needle position far away from the nerve and repeat the current thermal heat again and so on for 3 or 4 times. After an hour of bed rest, patients were allowed to leave the outpatient clinic.

Follow up:

All included patients was followed clinically 1 and 4 weeks then radiologically 3, 6 months post operatively

Statistical analysis:

Data analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean±SD. Differences between quantitative independent multiple by ANOVA or Kruskal Wallis.Wilcoxon signed-rank test was applied to evaluate the improvement in NRS and RMDQ scores before and after the procedure. P value was set at <0.05 for significant results &<0.001 for high significant result.

RESULTS

The present study included 26 patients with age ranged from 16 to 58 years with mean 36.38 years. Male represented 53.8%. Body mass index ranged from 17 to 35 kg/m^2 with mean 24.19 kg/m^2**(Table 1)**.

There is statistically significant decrease in mean CPK from 94.23 to 85.38 postoperatively. Among the studied patients, 73.1% had decrease in mean CPK postoperatively while 15.4% had no change and 11.5% had CPK levels increased postoperatively **(Table 2)**.

There is highly statistically significant decrease in OSI postoperatively. Median decreased from 35 to 15 four weeks postoperatively. Among the studied patients, 76.9 % had decrease in OSI postoperatively while 15.4 % had no change and 7.7% had OSI increased postoperatively. According to disability assessed by OSI, 26.9% of patients with mild disability increased to 84.6% postoperatively. While 42.3% and 30.8% had moderate and severe disability preoperatively, 11.6% and 3.8% reported moderate and crippled disability postoperatively **(Table 3)**.

There is highly statistically significant decrease in mean VAS from 6.31 to 4.38 postoperatively. Among the studied patients, 76.9% had decrease in mean VAS postoperatively while 15.4 % had no change and 7.7% had VAS increased postoperatively**(Table 4)**.

There is highly statistically significant increase in time till sitting intolerance as median increased from 30 minutes to 75 minutes postoperatively. Among the studied patients, 73.1% had increase time postoperatively while 19.2% had no change and 7.7% had time decreased postoperatively **(Table 5)**.

Regarding final outcome (improvement in both OSI and VAS), 10 patients had successful surgery **(Table 6)**.

A case of male patient 24 years free medical history, single, manual worker, smoker complaining of LBP and leg pain of 2 years duration of gradual onset and intermittent course slightly improved on medical treatment but last 8 mns pain become worse increase with setting. By Examination of Pt is vitally stable with BMI 2. Full motor power with no sensory or sphincteric deficits. Negative SLR test, negative Femoral steretch test, free SIJ bilateral. Dynamic plane x ray showing no fractures , no vertebral instability, no osteoporosis. MRI show black disc L5-S1. Preoperative assessment showed setting intolerance approximately 15 mns, VAS 7, OSI 45. To confirm the pressurized disc ,we injected of contrast media into different discs guided with Fluoroscopy and record pain response , it was positive at level L5-S1 so Radiofrequency of black disc L5-S1 was done at maximum temperature 60 for 8 mins. Postoperative evaluation showed back pain improved with increasing duration of setting tolerability for 3 hrs, VAS 3, OSI 20 **(Figure 1)**.

Table (1): Distribution of the studied patients according to demographic data:

	N=26	**%**

Age (year): Mean ± SD **Range**	36.38 ± 10.22 16 – 58	
Gender: Male **Female**	14 12	53.8% 46.2%
BMI (kg/m^2): Mean ± SD **Range**	24.19 ± 4.9 17 – 35	

Table (2) Change in CPK pre and postoperatively among the studied patients:

CPK	**Time**		**Test**	
	Preoperatively	**Postoperatively**	**t**	**P**
	N=26 (%)	**N=26 (%)**		
Mean ± SD **Range**	94.23 ± 18.8 50 – 125	85.38 ± 17.43 50 – 120	4.687	<0.001**
Decrease **No change** **Increase**	19 4 3	73.1% 15.4% 11.5%		

t paired sample t test **p≤0.001 is statistically highly significant

Table (3) Change in OSI findings pre and 4 weeks postoperatively among the studied patients:

OSI	**Time**		**Test**	
	Preoperatively	**Postoperatively**	**Wx**	**p**
	N=26 (%)	**N=26 (%)**		
Mean ± SD **Range**	33.85 ±14.09 35 (10 – 60)	17.88 ± 6.68 15 (10 – 65)	-3.8309	0.0001 2*
Change OSI: **Decrease** **No change** **increase**	 20 4 2	 76.9% 15.4% 7.7%		
Disability **Minimal** **Moderate** **Severe** **Crippled**	 7 (26.9%) 11 (42.3%) 8 (30.8%) 0 (0%)	 22 (84.6%) 3 (11.6%) 0 (0%) 1 (3.8%)	 -3.615	 0.0000 1*

*p<0.05 is statistically significant Wx Wilcoxon signed rank test

Table (4) Change in VAS pre and 4 weeks postoperatively among the studied patients:

VAS	**Time**		**Test**	
	Preoperatively	**Postoperatively**	**t**	**p**
	N=26 (%)	**N=26 (%)**		
Mean ± SD **Range**	6.31 ±1.78 3 – 10	4.38 ± 1.9 1 – 10	3.7638	0.0004**
Decrease **No change** **Increase**	20 4 2	76.9% 15.4% 7.7%		

t paired sample t test **p≤0.001 is statistically highly significant

Table (5): Change in sitting intolerance pre and 4 weeks postoperatively among the studied patients:

Sitting intolerance (minute)	**Time**		**Test**	
	Preoperatively	**Postoperatively**	**T**	**p**
	N=26 (%)	**N=26 (%)**		
Mean ± SD **Median (Range)**	26.35 ±13.08 30 (10 – 60)	115.38 ± 92.61 75 (10 – 300)	-4.979	<0.0001**
Increase **No change** **Decrease**	19 5 2	73.1% 19.2% 7.7%		

t paired sample t test **p≤0.001 is statistically highly significant

Table (6) Distribution of the studied patients according to surgical outcome:

	N=26	**%**
Outcome		
Success	10	38.5%
Failure	16	61.5%

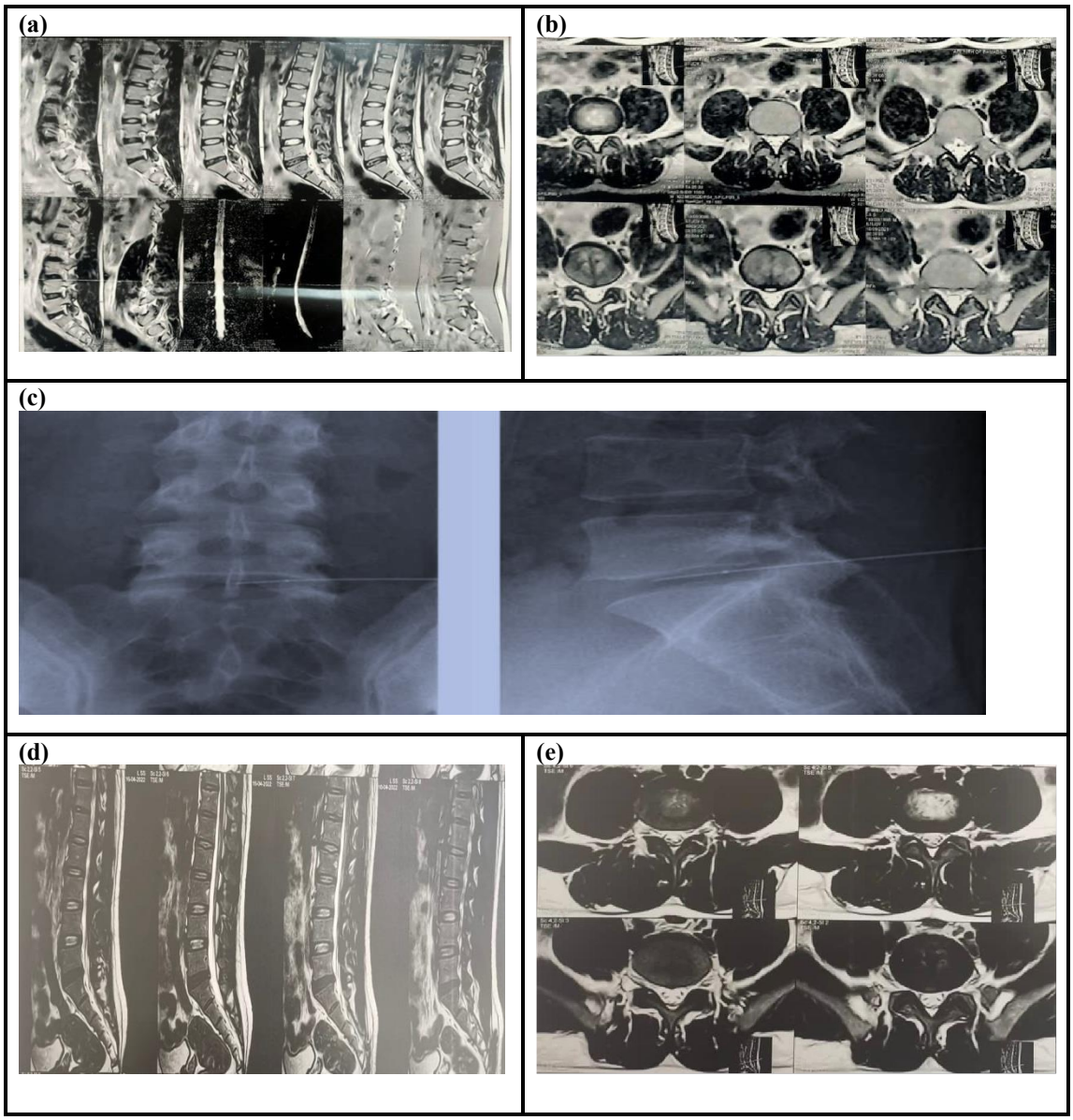

Figure (1):A case of male patient 24 years complaining of LBP and pain become worse increase with setting.Preoperative**(a)**MRI L.S.S sagittal&**(b)** MRI L.S.S axial showing degenerative L5-S1 disc with bulge without neural compromise;**(c)**Intraoperative imaging showing Lat view and AP view inserted intradiscal L5-S1; postoperative **(d)**Sagittal Film MRI LSS &**(e)** Axial Film MRI LSS showing black disc with no post operative changes or complications

DISCUSSION

Low back pain (LBP) is one of the major clinical and socioeconomic global health burdens. The prevalence of LBP is reported to be 31%, and lifetime prevalence is reported to be 60% to 80%. LBP is a multifactorial condition that includes physiological and psychological factors, as well as brain changes. Intervertebral disc (IVD) degeneration is a significant cause of pain in LBP patients **(9).**Discogenic back pain and axial back pain are terms commonly used to describe back pain associated with IVD degeneration without herniation, anatomical deformity, or other alternate clear causes of pain and disability **(10).**

LBP has been categorized in many ways. First, LBP can be divided into specific LBP and nonspecific LBP. Nonspecific LBP has been reported to account for 80% to 90% of overall LBP despite the recent progress in diagnostic tools such as radiography. In addition, treatment choices for chronic nonspecific LBP lack clarity; outcomes are often mixed because of the difficulty identifying the pain generator and multifactorial characteristics. Specific pain includes nociceptive and neuropathic pain associated with muscle and fascia injury, spinal osteoarthritis, osteoporosis, and radicular back pain **(11).**

The present study included patients with chronic LBP to investigate the efficacy and safety of percutaneous intradiscal RF in patients with chronic disabling discogenic back pain.

The results of our study indicate that, the study included 26 patients with age ranged from 16 to 58 years with mean 36.38 years. This was not consistent with what **Waterman et al. (12)**reported that there were bimodal age peaks for low back pain from 25-29 years and 95-99 years. This difference could be attributed to the difference in demographic criteria among populations of the two studies regarding general life style, life expectancy, occupation and socioeconomic levels. However, our results were close to **Singh et al. (13)** reported that age of patients with discogenic low back pain ranged from 20-50 years.

On the other hand, **Ganesan et al.(14)** agreed with our study that discogenic backpain was more in males.

Body mass index ranged from 17 to 35 kg/m2 with mean 24.19 kg/m2 with majority of patients classified to be overweight with BMI (19- 25) 38.4% which is consistent with **Asadi et al. (15)**. On the other hand **Edwards et al. (16)**reported that patients with morbid obesity (BMI>25) represented the majority. This difference could be explained by the fact that our sample siza is smaller and our study was more exclusive with more exclusion criteria unlike this study which included all types of backpain.

Among the studied patients, 73.1% had decrease in mean CPK postoperatively while 15.4% had no change and 11.5% had CPK levels increased postoperatively. We found that there is statistically significant decrease in mean CPK from 94.23 to 85.38 postoperatively which is the opposite of what **Tao et al. (14)**proved that there was no statistically significant decrease in CPK levels after intraoperative radiofrequency ablation which could be attributed to the fact that the authors selected patients with long standing lumbar disc prolapse with neural compromise and they targeted the roots unlike our study in which we targeted the disc matter and our patients showed only black disc or disc bulge grade 1 with no neural compromise.

According to disability assessed by OSI after 4 weeks, 26.9% of patients with mild disability increased to 84.6%. While 42.3% and 30.8% had moderate and severe disability preoperatively, 11.6% and 3.8% reported moderate and crippled disability postoperatively.Those results are consistent with what **park et al.(18)**proved that ID-PRF was shown to be effective for the treatment of discogenic LBP where there was reduction in OSI from mean 58.1 to 23.6 and 23.7 after 2 weeks and 6 months respectively taking into consideration that it was performed at 7 minutes interval. Also, there was reduction from mean 55.3 to 22.5 and 23.5 after 2 weeks and 6 months respectively taking into consideration that it was performed at 15 minutes interval. This agrees with our study that radiofrequency is effective in reduction of disability due to discogenic back pain measured by OSI however the differences between us could be attributed to the fact that they included a larger sample size, with application of monopolar ID-RF with a frequency of 5 Hz, a pulse width of 5 muscle, amplitude of 60V, and a maximum temperature of 42°C, for either 7 or 15 minutes using the NT1100 generator (Neuro-Therm) and follow up clinically was performed at larger time intervals of 2 weeks and 6 months compared to 1 and 4 weeks in our study.

Our results including OSI, VAS and setting intolerance are consistent with what **Jung et al.(19)**proved that that the application of intradiscal monopolar PRF might be relatively effective where the mean VAS for low back pain reduced significantly from 6.4±1.1 at pre-treatment to 4.4±1.9 at 12 months ($p<0.05$). The mean ODI score was 47.3±15.4 points at pre-treatment and 36.7±19.5 at 12 months ($p<0.001$). The ST was 27.8±20.4 minutes at pre-treatment and 71.5±42.2 at 12 months ($p<0.001$).

The difference between us could be attributed to the difference in techniques where **Jung et al. (19)**used an RF generator RFG-1A (COSMAN Medical Inc., Burlington, USA) with the following parametres frequency 2, 20 milliseconds pulse width, and 60 V for 20 minutes.

Regarding final outcome after one week (improvement in both OSI and VAS), 10 patients had successful surgery. However, this successful outcome increased to 17 patients compared to 9 with failure 4 weeks postoperatively.

Our results also consistent with what **Rohof, (20)**proved that PRF in the nucleus may be considered for patients with proven discogenic pain where Pulsed radiofrequency in the nucleus was

studied in 76 patients with discogenic pain confirmed by magnetic resonance imaging and provocative discography. At 3-month follow-up, 38% of the patients had > 50% pain reduction at 12 month the effect is maintained in 29%. The difference between us is attributed to the difference in technique, larger sample size and patients selected with multiple affected discs.

CONCLUSION

Intradiscal radiofrequency maneuver exhibited more effective than other techniques that previously used. Patients who underwent intradiscal RF for chronic discogenic LBP showed significant improvements in terms of pain relief and reduction of disability. Intradiscal RF appears to be a safe, minimally invasive treatment option for carefully selected patients with chronic discogenic LBP who have not responded to aggressive non-operative care.

No Conflict of interest.

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