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Intradiscal Thermal Annuloplasty Versus Intradiscal Radiofrequency Ablation for the Treatment of Discogenic Pain: A Prospective Matched Control Trial

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ABSTRACT

Objective. Two minimally invasive techniques have been used more recently as a possible treatment for painful internal disk disruption (IDD). Intradiscal thermal annuloplasty (IDTA), known as IDET, has already shown promising results in pain reduction and functional restoration. The second technique, radiofrequency posterior annuloplasty (RFA), is used in many interventional pain practices, although studies on the technique's efficacy are lacking. This study compares the effectiveness of those two methods.

Design and Patients. We matched 42 patients (21 had IDTA and 21 radiofrequency annuloplasty) for age, sex, weight, smoking history, manual labor, and number of intervertebral disks treated. Enrolled patients completed pain disability index (PDI) questionnaires before receiving either IDTA or RFA; at 2 weeks; and 2, 3, 6, 9, and 12 months following either treatment.

Results. From the third to the twelfth month after the procedure, the IDTA group had significantly lower mean pain scores than the RFA group. Visual analog scale (VAS) pain scores decreased from 6.6 ± 2.0 before to 4.4 ± 2.4 at 1 year after radiofrequency annuloplasty ($P = 0.001$), while in the IDTA group the average VAS pain score decreased from 7.4 ± 1.9 before IDTA to 1.4 ± 1.9 at 1 year follow-up. Similarly, PDI scores in the IDTA group had a significantly larger improvement than those for patients who received radiofrequency annuloplasty.

Conclusions. This study shows significant improvement in pain scores and patients' PDI following IDTA but not after RFA of the intervertebral disks. IDTA appears to be more efficacious than RFA based on PDI and VAS scores measured at 1 year following procedure.

Key Words. Radiofrequency Ablation; Intradiscal Thermal Annuloplasty; Intradiscal Electrothermal Therapy; IDET; Intervertebral Disk; Degenerative Disk Disease; Internal Disk Disruption

Introduction

A common cause of chronic low back pain is internal disk disruption (IDD) [1]. This condition is characterized by degradation of the nucleus pulposus of the affected disk and disruption of the inner lamella of the annulus fibrosus by radial fissures [2,3]. Radial fissures correlate strongly with reproduction of the patient's pain by discography, and are independent of age and degenerative changes [4]. There are no clinical tests by which IDD can be distinguished from other causes of low back pain [1]. Provocation

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discography is the only means of establishing the diagnosis [1].

Until recently, the only specific treatment for IDD has been total disk excision and arthrodesis. However, two minimally invasive procedures have been developed and promoted as alternatives to major surgical intervention. Both involve the introduction of a flexible electrode into the painful disk, with aim of coagulating the posterior annulus.

The first technique was named intradiscal electrothermal therapy (IDET); however, as originally described, the procedure did not require placement of the electrode explicitly in the annulus fibrosus [5]. The name, intradiscal thermal annuloplasty (IDTA), is used to distinguish variants of the procedure in which the posterior annulus is specifically targeted. The electrode is a flexible, thermal resistive coil which coagulates adjacent tissue with radiant heat. The mechanism of action has not been established, but it has been proposed that heating the annulus may serve to strengthen collagen fibers, seal fissures, denature inflammatory exudates, or coagulate nociceptors [6]. IDTA has been evaluated in descriptive [7–12] and comparative [13,14] studies, as well as in a placebo-controlled trial [15]. Although IDTA is not universally effective, it achieves significant reductions in pain, improvements in function, and return to work, in a substantial proportion of patients [8,13,14]. Its efficacy cannot be wholly attributed to a placebo effect [15].

The second technique, radiofrequency posterior annuloplasty (RFA) is also commonly known by the name of the device used to place the lesion (DiscTRODE™; Radionics, Burlington, MA). The electrode is a semirigid, radiofrequency probe which does not, by itself, generate heat. Instead, the electrode focuses an alternating, radiofrequency current onto surrounding tissues, whose component molecules are oscillated and, thereby, heated. The electrode also serves to monitor the temperature generated in those tissues. There is far less literature on this procedure than there is for IDTA. It is limited to one comparative study [16] which found that RFA was more effective than conservative therapy, but that like IDTA only a proportion of patients significantly benefited.

To date, the choice between these two procedures has been a matter of operator preference. Some operators prefer RFA because they believe that the electrode is easier to place within the disk and produces a more controlled lesion in a more restricted region. However, there have been no head-to-head comparative studies of the efficacy of these two techniques.

The specific aim of the present study was to test the hypothesis that there is no difference in outcome with respect to pain and functional capacity following RFA compared with the IDTA. A prospective matched control trial study design was elected, whereby matching patients were assigned to either treatment modality based on five clinical criteria associated with low back pain. These include history of smoking, weight, manual labor, age, and sex, which have been reported as determinants of IDTA outcome [17,18]. Furthermore, we excluded from the study patients who had more than two degenerated intervertebral disks, as seen on magnetic resonance imaging (MRI), because in our experience, such patients fare significantly worse 1 year following IDTA than patients with one- or two-level symptomatic IDD [9].

Methods

The study was approved by Institutional Review Board of The Cleveland Clinic Foundation. All patients were referred by spine surgeons at our institution who requested diagnostic discography anticipating future fusion surgery or annuloplasty if indicated. The mean duration of low back pain in these patients was 3.2 years. All had failed different conservative approaches and maintained high pain scores.

The inclusion criteria were: history of chronic low back pain unresponsive to nonoperative care for longer than 6 months; no evidence clinically of compressive radiculopathy; reproduction of pain on provocation discography in the target disks but not in control disks; no prior surgery at the symptomatic level(s); disk height at least 50% of adjacent nondegenerated control disks; no symptoms or signs of the lumbar canal stenosis; and no psychological issues evident on history or during clinical examination. Formal psychological testing was not undertaken and was not used as a criterion for selection into this study. As well, on MRI, patients had to have evidence of single-level or two-level disk disease, but with no evidence of disk herniation. Excluded were patients with pending workers compensation claims or litigation, because some investigators have found that such patients respond less favorably when treated with IDTA [10].

All patients who satisfied the inclusion criteria and provided written informed consent were enrolled in the study. Twenty-one patients each

were allocated to treatment with IDTA or RFA. There was no overlap between the IDTA patients in the present study and those in our previous studies [9,10].

Upon enrollment, baseline scores for pain and disability were obtained using a visual analog scale (VAS) for pain, and a pain disability index (PDI). The PDI is composed of eight subscales: pain, sexual disability, family and home duties, recreation, occupation, self-care, social, and basic life functions disability [19]. Each of those individual scales ranges from 0 to 10, with 10 indicating the highest level of disability. To obtain the PDI, the responses to the eight subscales are added. A score of 80 would indicate the maximum level of disability.

Discography was performed as recommended previously [20], although manometry was not used to determine intradiscal pressures. Provocation discography was positive at one (N = 20) or two levels (N = 22) in matched patients receiving either therapeutic intervention.

IDTA was performed as described elsewhere [5,7,8,15]. In brief, the procedure was performed under sterile conditions using local anesthesia. Under fluoroscopic guidance, a 17-gauge introducer needle was first inserted into the targeted disk. Through that needle the electrode was introduced and navigated circumferentially through the disk until positioned appropriately, with the heating segment covering the posterior annulus. According to the distributor's protocol (Smith and Nephew, London, UK), the electrode generates a rising temperature inside the disk from 65°C to 90°C at increments of 2°C per minute. The temperature is then maintained at 90°C for 4 minutes.

The procedure for RFA required first placing an introducer needle superficially into the posterolateral corner of the annulus. The electrode was inserted through the introducer needle and navigated so as to pass medially across the posterior annulus. Once the electrode was placed, the annulus was heated so that the electrode registered temperatures of 55°C for 4 minutes, then 60°C 5 minutes, and finally at 65°C for 5 minutes.

The series of 21 consecutive RFA procedures was completed first. Then, 28 patients had IDTA procedures in order to achieve a complete match. Twenty-one of these patients were then matched for age, sex, weight, smoking history, manual labor, and number of intervertebral disks treated, with the 21 patients who were treated with RFA (Table 1). The investigator who completed the matching did not have access to patients' scores for pain and disability at the time of matching. Seven patients who received IDTA could not be matched because of differences in either number of disk levels treated, weight, sex, smoking, age, or manual labor. No sham control group was used in this comparative study. A single physician (NM)

Table 1 Tabulated matching criteria

Patient	Age	Sex	Weight (kg)	Smoking	ML	RFA	IDTA	ML	Smoking	Weight (kg)	Sex	Age	Patient
RFA1	30	M	85	–	–	1	1	–	–	92	M	26	IDTA1
RFA2	52	M	101	–	–	2	2	–	–	82	M	49	IDTA2
RFA3	44	F	76	–	–	1	1	–	–	81	F	43	IDTA3
RFA4	56	M	78	–	–	2	2	–	–	90	M	49	IDTA4
RFA5	45	F	66	–	–	2	2	–	–	79	F	44	IDTA5
RFA6	43	M	101	+	+	1	1	+	+	89	M	53	IDTA6
RFA7	38	M	92	+	–	2	2	–	+	81	M	40	IDTA7
RFA8	44	F	56	+	–	1	1	–	+	63	F	46	IDTA8
RFA9	27	M	85	–	+	2	2	+	–	91	M	36	IDTA9
RFA10	51	F	76	–	–	1	1	–	–	65	F	53	IDTA10
RFA11	30	F	62	–	–	1	1	–	–	56	F	32	IDTA11
RFA12	36	F	82	–	–	2	2	–	–	85	F	36	IDTA12
RFA13	66	F	81	–	–	1	1	–	–	72	F	57	IDTA13
RFA14	33	M	89	+	–	2	2	–	+	99	M	32	IDTA14
RFA15	44	F	70	+	–	1	1	–	+	60	F	46	IDTA15
RFA16	47	M	88	+	+	1	1	+	+	73	M	42	IDTA16
RFA17	27	M	72	+	–	2	2	–	+	81	M	36	IDTA17
RFA18	40	F	61	+	–	2	2	–	+	72	F	45	IDTA18
RFA19	54	M	93	–	–	2	2	–	–	110	M	62	IDTA19
RFA20	43	F	89	–	–	2	2	–	–	75	F	55	IDTA20
RFA21	24	F	56	–	–	1	1	–	–	60	F	20	IDTA21

Codes RFA 1–21 describe patients who underwent RF ablation and codes IDTA 1–21 describe those who had IDTA. The pairs of patients in both groups were matched by the number of intervertebral discs treated using RFA or IDTA (RFA, IDTA), age, sex, smoking habits, and manual labor. Their data are presented in the same row.
ML = manual labor; RFA = radiofrequency posterior annuloplasty; IDTA = intradiscal thermal annuloplasty.

performed all of the annuloplasties and was not blinded as he conducted either of those two techniques. He was experienced in using either technique at the time of the study and was enthusiastic about the RFA as a less expensive and simpler technique.

The patients were followed over a period of 12 months and completed PDI questionnaires before the procedure, at 2 weeks, 2, 3, 6, 9 months, and 1 year following either of the two procedures. The disability change at any given time was calculated as the baseline score minus the follow-up score. For the sexual, recreation, occupation, self-care, social, basic life, and family disability scales, the groups were compared using Wilcoxon rank-sum tests on the baseline scores, on the 1-year scores, and on the change scores (baseline—1 year). For the PDI and the pain scores, a mixed-effects model analysis was performed to compare groups over time [21].

Results

The patients treated by RFA were aged 41.6 + 10.8 years and weighed 79 + 13.6 kg. In these respects, they did not differ significantly from the patients treated by IDTA, who were aged 42.9 + 10.5 years and weighed 78.8 + 13.8 kg. Fifty-two percent of the patients were female, 38% were smokers, 14% were manual laborers, and 52% had to have a two-disk-level IDTA.

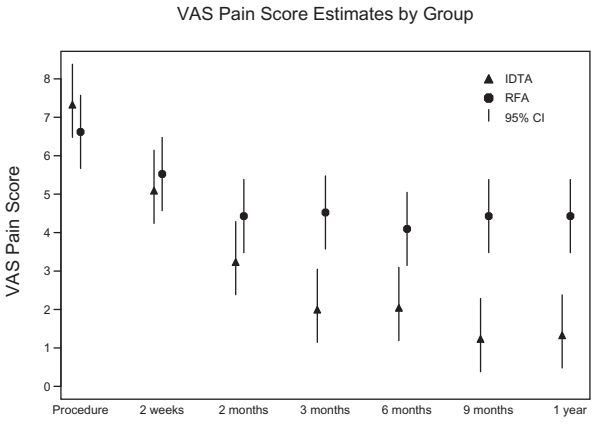

Figure 1 The mean pain scores by group at each time point following either intradiscal thermal annuloplasty (IDTA) or radiofrequency posterior annuloplasty (RFA) and 95% confidence intervals using mixed-effects model analysis. At baseline, the IDTA and RFA groups did not differ significantly in their pain scores. By 3 months, and at all subsequent time points, the IDTA group had significantly lower mean pain scores than the RFA group.

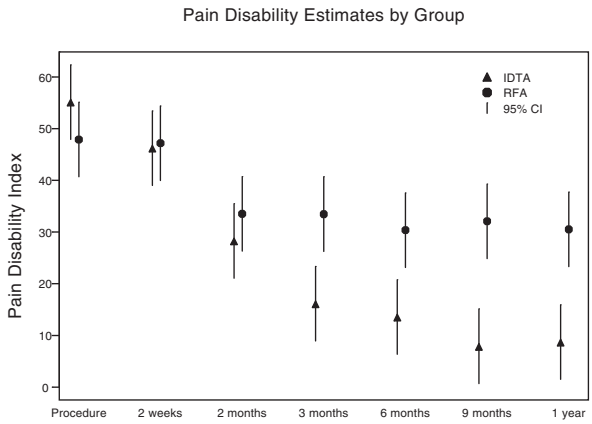

Figure 2 The mean pain disability index (PDI) scores and 95% confidence intervals by group at each time point following either intradiscal thermal annuloplasty (IDTA) or radiofrequency posterior annuloplasty (RFA) using mixed effects model analysis. The IDTA and RFA treatment groups did not differ significantly in their baseline PDI scores. While the mean decrease in PDI was significant for the RFA group at 2 months, the IDTA group experiences significant decreases again from 2 to 3 months, and from 6 to 9 months. By 3 months, and at all subsequent time points, the IDTA group had significantly lower mean PDI scores than the RFA group.

(Table 1). There were 10 patients in each group who underwent annuloplasty at one level, while 11 patients were treated at two levels. Before treatment, the two groups did not differ significantly in the pain scores ($P = 0.24$) (Figure 1) or PDI ($P = 0.16$) (Figure 2).The IDTA group had a significantly higher score on the recreation disability subscale of the PDI (Table 2). The seven unmatched patients did not significantly differ from matched patients in baseline VAS pain scores or PDI scores (7.4 ± 2.5; 58 ± 21). Their mean weight was 72.7 ± 12 kg. There were four females, no smokers, no manual laborers, and two underwent annuloplasty at two levels.

By 3 months following the procedure and at all subsequent time points, the IDTA group had a significantly lower mean pain scores than the RFA group. In the RFA group, VAS pain scores dropped significantly until the second month of follow-up and remained stable afterwards (Figure 1). In that group, VAS pain scores decreased from 6.6 ± 2.0 before to 4.4 ± 2.4 at 1 year after annuloplasty ($P = 0.001$). In the IDTA group, a precipitous drop in VAS pain scores continued until the third month after procedure and remained stable afterwards. The average VAS pain score decreased from 7.4 ± 1.9 before IDTA to 1.4 ± 1.9 at 1 year follow-up (Figure 1).

Table 2 Tabulated are the values for all of the pain disability index (PDI) subscales at baseline, 1 year, and change (baseline—1-year score) by group

PDI Subscale and Time Interval	RFA Median (Q1, Q3)	IDTA Median (Q1, Q3)	Wilcoxon Rank-Sum *P* Value
Sexual disability			
Baseline	6.0 (4.0, 9.0)	8.0 (6.0, 9.0)	0.33
1 year follow-up	3.0 (0.0, 5.0)	0.0 (0.0, 0.0)	0.013
Change: baseline—1 year	4.0 (1.0, 6.0)	7.0 (5.0, 9.0)	0.002
Family and home duties disability			
Baseline	6.0 (5.0, 7.0)	7.0 (5.0, 8.0)	0.42
1 year follow-up	4.0 (2.0, 6.0)	0.0 (0.0, 1.0)	0.006
Change: baseline—1 year	1.0 (0.0, 5.0)	5.0 (4.0, 8.0)	0.003
Recreation disability			
Baseline	8.0 (5.0, 8.0)	9.0 (8.0, 10.0)	0.004
1 year follow-up	5.0 (4.0, 8.0)	1.0 (0.0, 4.0)	0.004
Change: baseline—1 year	0.0 (0.0, 5.0)	7.0 (4.0, 9.0)	<0.001
Occupation disability			
Baseline	8.0 (5.0, 10.0)	8.0 (5.0, 9.0)	0.62
1 year follow-up	5.0 (3.0, 5.0)	0.0 (0.0, 2.0)	0.004
Change: baseline—1 year	4.0 (1.0, 4.0)	5.0 (3.0, 8.0)	0.055
Self-care disability			
Baseline	4.0 (2.0, 5.0)	6.0 (5.0, 7.0)	0.064
1 year follow-up	4.0 (0.0, 5.0)	0.0 (0.0, 0.0)	0.002
Change: baseline—1 year	1.0 (0.0, 3.0)	5.0 (4.0, 7.0)	<0.001
Social functions disability			
Baseline	5.0 (4.0, 7.0)	7.0 (5.0, 8.0)	0.066
1 year follow-up	4.0 (0.0, 5.0)	0.0 (0.0, 0.0)	0.001
Change: baseline—1 year	1.0 (0.0, 4.0)	7.0 (4.0, 8.0)	<0.001
Life-supporting functions disability			
Baseline	4.0 (2.0, 5.0)	5.0 (3.0, 8.0)	0.21
1 year follow-up	2.0 (1.0, 4.0)	0.0 (0.0, 1.0)	<0.001
Change: baseline—1 year	0.0 (0.0, 3.0)	5.0 (1.0, 7.0)	0.002

At baseline, there are no significant differences between the two groups on sex, family, occupation, self, social, or life scales. The IDTA group had significantly higher baseline recreation disability scores. At the 1-year time point, there is a significantly larger decrease in all subscale scores except occupation in the IDTA group compared with the RFA group.
RFA = radiofrequency posterior annuloplasty; IDTA = intradiscal thermal annuloplasty.

The PDI improved significantly in both groups by 2 months following annuloplasty (Figure 2). The larger average improvement in VAS pain scores in the IDTA group (Figure 1) coincided with better improvement in PDI within the same time period (Figure 2; Table 3). Detailed analysis of PDI scores showed that the IDTA group had a significantly larger improvement in all subscales (family and home activities, recreation, occupation, sexual activities, self-care, social activities, and life-support activities) (Table 2).

When patients were grouped according to percentage improvement in PDI, six RFA patients (29%) had more than 60% improvement, while 17 IDTA patients (81%) had that level of improvement (Figure 3). Reciprocally, three IDTA patients (14%) had less than 30% improvement in disability scores as opposed to 13 RFA patients (62%) with little or no improvement.

Discussion

To some operators, RFA has been attractive for a variety of reasons. The device used allows impedance to be monitored as the electrode is advanced into the annulus, and that is believed to be helpful

Table 3 Differences in mean pain disability index (PDI) between the two groups

Time	Estimated Mean Difference in PDI (IDTA–RFA)	Lower Level 95% CI	Upper Level 95% CI	*P* Value
Preprocedure	7.2	–3.0	17.4	0.16
2 weeks	–0.95	–11.2	9.2	0.85
2 months	–5.2	–15.4	5.0	0.31
3 months	–17.3	–27.5	–7.1	<0.001
6 months	–16.8	–27.0	–6.6	0.001
9 months	–24.2	–34.4	–14.0	<0.001
1 year	–21.8	–32.0	–11.6	<0.001

The *P* values were calculated from a mixed effects model analysis. There was a significant difference in PDI after the third month. Thereafter the IDTA group maintained significantly lower PDI scores than the RFA group.
IDTA = intradiscal thermal annuloplasty; RFA = radiofrequency posterior annuloplasty.

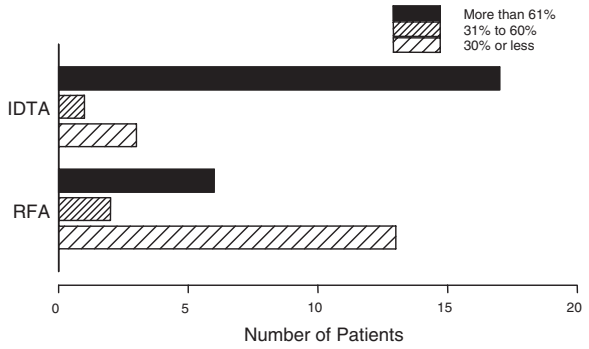

Figure 3 Comparison of percentage improvement in pain disability index (PDI) following intradiscal thermal annuloplasty (IDTA) and radiofrequency posterior annuloplasty (RFA). Percent improvement was calculated as [(Baseline score – 12-month score) / Preprocedure score] × 100. Patients were grouped according to whether they experience 0–30%, 31–60%, or more than 61% improvement. The majority of the patients in the IDTA group experienced 60–100% of PDI improvement, while in the RFA group the majority experienced 0–30% improvement.

in determining the required depth of insertion. Some feel that the direct insertion across the posterior annulus is less demanding than the circuitous, circumferential insertion required by IDTA. The ability to monitor temperature at the outer annulus is perceived as a safety feature.

Perhaps most significantly, the device for RFA is less expensive.

Notwithstanding these perceptions, there are few data on the effectiveness of RFA. The evidence is limited to only one study [16]. That study obtained outcomes that were not better than those reported for IDTA, and in some respects were inferior. A smaller proportion of patients obtained complete relief, and return to work was not reported. Consequently, there is no clinical evidence to match or justify what amounts to operator preference between two similar procedures.

It was in that context that the present study was undertaken. It was not intended as an explanatory trial. The mechanism of effect was not the objective. For that reason, placebo or other controls were not adopted. The study was explicitly a head-to-head comparison of two techniques, by an operator experienced with both. The hypothesis was simply that outcomes would be no different.

The results refuted this hypothesis. Patients treated with IDTA achieved significant improvements in pain scores and PDI, while those treated with RFA did not. A majority of patients treated with IDTA improved in almost every single activity of daily living, while the majority of patients treated with RFA did not. It appears therefore that IDTA was effective, at 1 year following treatment, whereas RFA was not.

There may be various reasons why RFA was not effective. Patient selection is not among them, because in the present study, both groups of patients satisfied the same selection criteria. Possible explanations include where the electrode was placed, the temperature generated, and the size of the lesion generated. The present study does not provide data upon which these possibilities can be judged, but it does raise them for consideration by proponents of RFA.

Meanwhile, the clinical results of the present study warn proponents of RFA that operator preference may not beget better outcomes. Even in the hands of an enthusiast, RFA was not effective, yet IDTA was. Until contrary data are forthcoming, it appears that IDTA should be the more preferable of the two competing minimally invasive interventions for discogenic pain.

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