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A factor analysis of lumbar intradiscal electrothermal annuloplasty outcomes

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Abstract

BACKGROUND CONTEXT: Intradiscal electrothermal annuloplasty (IDET) is a minimally invasive procedure for managing chronic discogenic low back pain (LBP). Although there have been numerous reports of IDET outcome rates, few have dissected the detailed factors affecting those outcomes.

PURPOSE: To evaluate how heating variables and the number of catheters used affect the outcomes and pain flare-up in LBP patients treated with IDET.

STUDY DESIGN/SETTING: Retrospective analysis.

PATIENT SAMPLE: Data were gathered on the basis of chart records from January 6, 1999 to January 6, 2000. Twenty-five cases treated at a single level with disc protrusion ≤2 mm, nonfocal neurological abnormalities, and positive discogram with annular tear were studied. Six patients were unavailable for follow-up at 16 months.

OUTCOME MEASURES: All assessments were incorporated into our own evaluation sheet, completed before the procedure and at follow-up. Assessments included the following: 1) Visual Analog Scale (VAS) and 2) Back Pain Improvement Scales (BPI) preoperatively and at 8 and 16 months post-procedure. Post-procedure flare-up of the pain was defined as the pain aggravation after the IDET procedure from the pre-procedure baseline pain. It was evaluated by a 10-point numeric rating scale, ranging from no aggravated pain "0" to the worst aggravated pain "10".

METHODS: Patients were partitioned into a single-catheter group and a double-catheter group. In these two groups, statistical analyses were done to compare the outcomes and flare-up duration and intensity. In each catheter group, the correlation coefficients were analyzed between heating variables such as heating duration/temperature and two outcome scales. Then, two outcome scales relative to intensity and duration of post-IDET flare-up were analyzed with Pearson's correlation. Also the combined effect of the heating duration and temperature was evaluated as a thermal dosage, which is the total amount of heat developed during the procedure. It was calculated by multiplying the temperature and its heating duration above a starting temperature of 65°C.

RESULTS: Comparing the single- and double-catheter groups, patients placed in the single-catheter group showed significantly shorter flare-up duration (11.00±19.17 vs. 24.89±20.84 days, $p<.05$). In the single-catheter group, the flare-up duration manifested moderate linear correlation with heating variables (0.580 with temperature, 0.519 with thermal dosage, $p<.05$). Also, the improvements of pain with VAS displayed moderate reverse correlation with heating variables at 8 months (−.436 with temperature, −0.439 with thermal dosage, $p<.1$). In the double-catheter group, the Back Pain Improvement% had strong reverse correlations with temperature and thermal dosage at 8 months (−.735 and −.729, $p<.05$). The correlation between the improvement of VAS and temperature yielded a moderate reverse relationship (−.619, $p<0.1$). These correlations were not, however, observed at 16 months in either the single- or double-catheter groups.

FDA device/drug status: approved for this indication (intradiscal electrothermal annuloplasty [IDET]).

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CONCLUSIONS: Higher temperatures and larger total heating doses during IDET procedures with catheters placed in the outer annulus may increase the duration of post-procedure pain flare-ups and lead to less favorable outcomes at 8 months follow-up. The long-term outcomes at 16 months may, however, not be affected by these heating variables.

Keywords: IDET; Outcome; Low back pain; Temperature; Catheter position; Flare-up

Introduction

Intradiscal electrothermal annuloplasty (IDET) is a minimally invasive procedure for managing chronic discogenic low back pain (LBP) in patients failing conservative treatment [1,2]. Initial outcome studies have reported positive response rates of 62–80% [3,4]. In a double-blind, placebo-controlled trial, Pauza et al. [5] showed that IDET may provide worthwhile relief (Visual Analog Scale [VAS] 2.4 in IDET vs. 1.1 in control) in a small proportion of strictly defined patients undergoing this treatment for intractable LBP. However, Freeman et al. [6] also showed that no subject met the criteria for successful outcome.

Although there have been many retrospective and prospective outcome studies, few have evaluated the influence of technical factors on outcome. Derby et al. [7] reported that discogram findings, catheter position, and previous surgery may affect IDET outcome. Kleinstueck et al. [8] studied temperature and thermal dose distributions during IDET in vitro. The fact that temperatures sufficient to ablate nerves were developed in some areas, but were not reliably produced in clinically relevant regions (eg, the posterior annulus), suggested that beneficial clinical outcomes may be critically dependent on probe placement or unknown factors. The original heating protocols recommended by Oretec were designed to modify collagen by reaching temperatures in access of 65° Celsius in the tissue adjacent to the catheter. Although the protocol was empiric, it was based on cadaver studies and on measuring outer annular and epidural tissue temperatures in the original patient series. Most clinicians continue to follow the recommended heating protocols and use catheters from both sides to achieve full coverage of the posterior and lateral annulus in case of bilateral back pain. However, no studies have specifically looked at the influence of heating doses or the number of catheters on outcome and morbidity.

The purpose of this study is to evaluate how heating variables and the number of catheters used affect both outcome and pain flare-up in LBP patients treated with intradiscal electrothermal annuloplasty. Because the outcome of IDET may be influenced by the number of treated levels [9], and heating variables and catheter positions may vary, to maximize the consistency and reliability of our analysis we included only single-level procedures.

Methods

We retrospectively analyzed a case series of single-level IDET procedures. All data used for this study were collected prospectively from January 6, 1999 to January 6, 2000. During this time a total of 129 patients underwent an IDET procedure. Thirty-five of these underwent the procedure at a single level. Twenty-five patients were available for interview at the 8-month follow-up. Of 25 patients, 19 patients completed follow-up at 16 months. Subjects were required to have discogenic LBP, a recent magnetic resonance imaging scan, and lumbar spine discography within the last 6 months.

Inclusion criteria

Participation required either back pain with or without referred leg/buttock pain of >6 months duration, lack of response to previous conservative treatment including nerve blocks, nonfocal neurological abnormalities, disc protrusion ≤2 mm, single-level pathology, and positive discogram with annular tear which was scored if the pain response was 3 (bad) or greater and if two or more pain behaviors were documented on the videotape record of the injection [10,11].

Exclusion criteria

Subjects with allergy to any contrast media, iodine, or cephalosporin antibiotics and inability to undergo magnetic resonance imaging scanning due to ferromagnetic implants, claustrophobia, or inability to tolerate positioning for magnetic resonance imaging or discography were excluded. We also excluded patients who had unstable medical conditions, previous spinal surgery, instability and spondylolisthesis, spinal stenosis, and reduced disc height >50%. Patients unable to speak English were also excluded to ensure accuracy of outcome.

IDET procedure

The IDET procedure used a navigable intradiscal catheter with a thermal resistive coil. The procedure was performed under conscious sedation that typically included between 50 and 100 mg of Demerol or an equivalent dose of Fentanyl and 2 to 4 mg of Versed. Using a standard posterior-lateral discogram technique, an Oratec Interventions 30-cm SpineCATH catheter (Oratec Interventions, Inc., Menlo Park, CA) with a 6-cm active electrothermal tip was inserted

through a 17-gauge introducer needle and advanced circuitously to the posterior annulus. Catheter positions and locations were assessed by fluoroscopy (Fig. 1), and in all cases the operative report described and/or images showed that the active heating element crossed the annular tear as demonstrated on the preoperative computed tomography–discogram. In nine patients with bilateral pain, we were unable to pass a single catheter across the midline, and in these cases catheters were inserted from both the left and right sides. In all cases, the catheter tips were within 5 mm of the posterior vertebral margin upon review of saved fluoroscopic films. In the first nine cases, a standard protocol was used in which heating began at 65°C and was increased incrementally by 1°C every 30 seconds to achieve a final temperature of 80–90°C. The final temperature was maintained for 5 minutes, giving a total treatment time of 13.5–16.5 minutes [7,8]. In subsequent cases, the temperature was incrementally increased to 80°C but the final temperature and duration was determined by the patient's pain response from baseline, which was defined as zero before applying heat. When the patient reported greater than 6/10 pain, no further increments in temperature were performed and the temperature was then maintained for up to 4 minutes as long as the patient's back pain remained below 8/10 intensity.

Evaluation of the heating variables

The patient's charts contained a detailed record of the heating protocol, and from these records the data of the incremental increases in temperature and duration were used to calculate a thermal dosage. We defined the thermal dosage as the temperature times the heating duration and represented the area under the incremental heating curve (Fig. 2). All discs were incrementally heated beginning at 65°C and incrementing the temperature 1 degree every 30 seconds until a final temperature between 70 and 90°C was reached. The temperature was then maintained at the final highest temperature from 1 to 4 minutes. Each increment in temperature times duration was added to obtain a total thermal dosage. When two catheters were required to cover the affected posterior annulus (9 cases), the heating data of both the right and left catheters were added together.

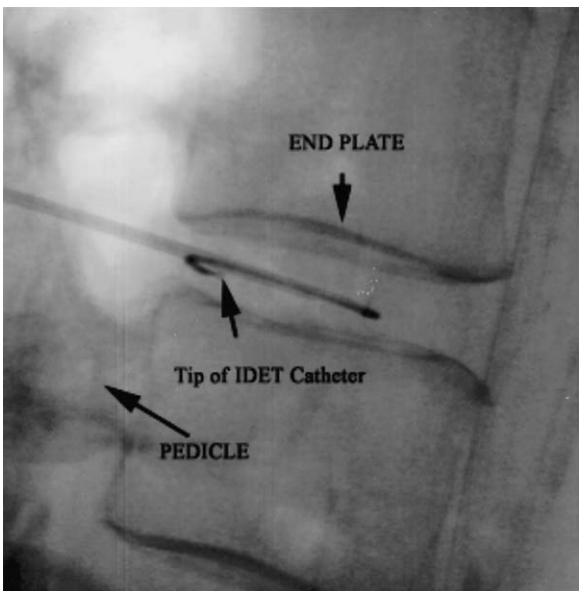

Fig. 1. Fluoroscopic image of the IDET procedure. The electrothermal wires are placed within 5 mm of the outer annulus.

Evaluation of outcome

Patients were interviewed preoperatively and at 8 and 16 months post-procedure. All assessments were incorporated into our own evaluation sheet, completed before the procedure and at follow-up. Assessments included the following: 1) VAS, and 2) Back Pain Improvement (BPI), evaluating the percentage of improvement patients reported post-procedure, which is a 200 numeric rating scale from −100%, the worst outcome, to 100%, the best outcome [7].

Grouping according to the number of catheters

We partitioned patients into single- and double-catheters groups. At 8 months there were 16 patients in the single-catheter group and 9 patients in the double-catheter group. At 16 months follow-up there were 12 patients in the single-catheter group and 7 patients in the double-catheter group. The outcomes and post-procedure pain flare-up, duration, and intensity were compared between two groups. The correlation coefficient between flare-up and outcome with heating variables was analyzed in each group, because there was no reliable method to compare the thermal dosages between two groups.

Evaluation of the post-procedure flare-up

Post-procedure flare-up of the pain was defined as the pain aggravation after the IDET procedure from the pre-procedure baseline pain. It was evaluated using a 10-point numeric rating scale, from no aggravated pain "0" to the worst aggravated pain "10". The intensity and duration of the flare-up were used to analyze the effect of thermal dosage on the patients.

Data analysis

All statistical analyses were executed with SPSS/PC+ software (SPSS, Inc., Chicago, IL) using the Mann-Whitney *U* test and Pearson's correlation.

Results

General outcome

The average age of the 25 patients was 39.00±9.59 years old. Average follow-up times were 8.04±2.49 and

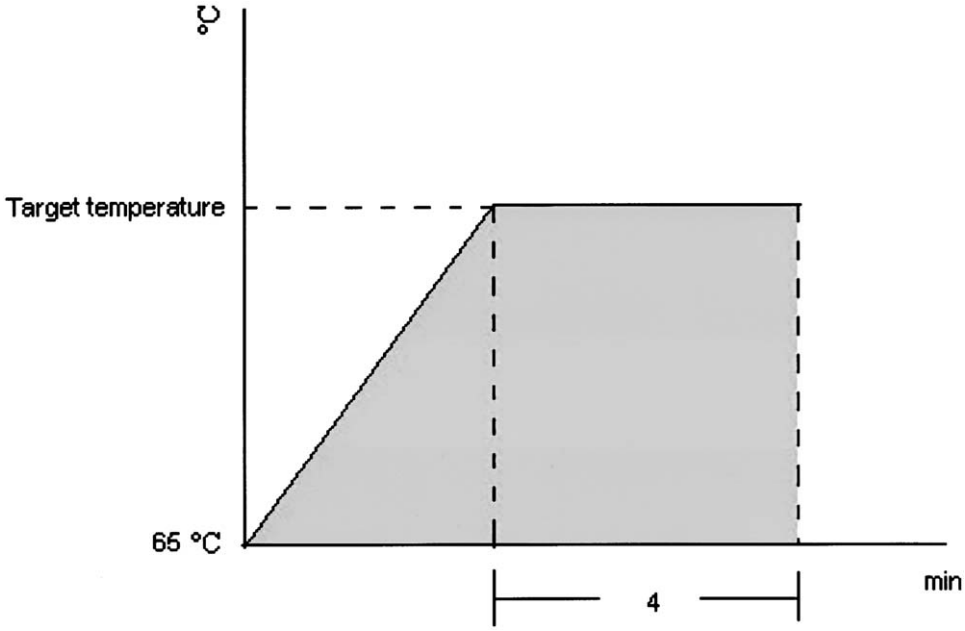

Fig. 2. Thermal dosage (TD). The TD was calculated as an area (gray shading). Target temperature was adjusted with patient's tolerance between 80°C and 90°C.

16.74±3.26 months. During the procedure, the average total heating duration was 14.81±2.89 minutes and the average temperature was 83.08±6.29°C. At 8 months post-procedure, the mean improvement of pain using the VAS score was 2.92±2.12 in 25 cases and 2.74±2.45 in 19 cases at 16 months. The mean Back Pain Improvement values were 36.80±41.68% at 8 months and 32.37±39.14% at 16 months. Back Pain Improvement was positive in 15 patients at 8 months and in 10 patients at 16 months. Seventeen patients (70.8%) had a flare-up after IDET. The average flare-up duration was 16.67±20.67 days. Data for all 25 patients are given in Table 1.

Single vs. double catheter

The mean subjective percent improvement in LBP was Back Pain Improvement of the single-catheter group 45.31±41.73% at 8 months and 40.83±37.59% at 16 months,

Table 1
Demography of IDET patients

Patient	Age	Catheter	Heating duration (min)	Temp (°C)	TD (°C min)	BPI1 (%)	BPI2 (%)	Baseline VAS	VAS at 8 mo	VAS at 16 mo
#1	38	Double	15	85	200	85	80	9	3	3
#2	29	Single	16.5	85	230	50	0	8	4	7
#3	42	Single	11	70	47.5	100		8	0	
#4	32	Double	10	75	75	55	0	10	5	9
#5	31	Single	11	80	112.5	−10	0	8	7	8
#6	30	Double	20	80	243.75	40	70	8	3	4
#7	40	Double	15	85	200	0	0	4	4	4
#8	38	Single	17	90	268.75	75	25	7	5	3
#9	37	Single	15	85	200	60	80	8	4	1
#10	36	Double	19	90	318.75	−30		8	8	
#11	39	Double	17	90	268.75	−15	0	7	6	7
#12	32	Single	16.5	90	256.25	80	60	7	3	5
#13	47	Single	15	75	125	50		8	8	
#14	17	Single	10	70	43.75	100	100	8	0	0
#15	56	Single	14.5	85	190	0	20	8	6	5
#16	30	Single	17	87	253	−30	80	10	10	7
#17	51	Single	15	85	200	60	50	6	2	3
#18	43	Double	17	90	268.75	0	−25	7	6	7
#19	52	Single	10	80	105	30	0	9	6	5

BPI=Back Pain Improvement Scale (BPI1=BPI at 8 months; BPI2=BPI at 16 months); TD=thermal dosage (initial heating from 65°C until final temperature was obtained); VAS=Visual Analog Scale.

relatively larger than the double-catheter group, which showed a mean Back Pain Improvement of 21.67±39.29% at 8 months and 17.86±40.19% ($p>.05$, Table 2). The mean changes of VAS at 8 and 16 months post-procedure showed more improvement in the single-catheter group than in the double-catheter group ($p>.05$).

The mean flare-up duration was 24.89±20.84 days in the double-catheter group, significantly longer than the single-catheter group ($p<.05$, Table 2). However, only the duration of post-procedure flare-up was significantly different between the two groups.

Correlation between flare-up and heating variables

Correlations between flare-up duration and heating variables (eg, heating duration, temperature, and thermal dosage) in the single-catheter group were significant (see Table 3). The correlation coefficient between flare-up duration and thermal dosage was .519 ($p<.05$). The correlation coefficient between flare-up intensity and peak temperature was .508 ($p<.05$). There were no significant correlations between flare-up duration and heating variables in the double-catheter group.

Correlation between outcomes and heating variables

In the single-catheter group at 8 months there was a moderate negative correlation ($p<.01$) between improvement in the VAS and both the peak heating temperature (−.436) and total thermal dosage (−.439); however, there was no significant correlation between heating variables and percent improvement in back pain (Table 4). At 16 months there was no correlation in either VAS or percent back pain improvement and heating variables.

In the double-catheter group there also was a moderate (−.619) negative correlation between peak temperature and improvement in back pain and a strong negative correlation between the percent improvement in back pain and both peak temperature (−.735) and thermal dosage (−.729, Table 5) At 16 months follow-up, however, there was no significant correlation between heating variables and outcome.

Table 2
Mean outcome and flare-up with the number of catheters

	Catheter	
	Single	Double
Back Pain Improvement %		
8 months (n=25)	45.31±41.73	21.67±39.29
16 months (n=19)	40.83±37.59	17.86±40.19
Improvement of VAS		
8 months (n=25)	3.44±2.34	2.56±2.30
16 months (n=19)	3.25±2.45	1.86±2.34
Flare-up		
Duration (days, n=25)	11.00±19.17	24.89±20.84*
Intensity (n=25)	5.38±4.91	8.44±3.21

VAS=Visual Analog Scale.
* p value <.05.

Table 3
Correlation (r) between flare-up and heating variables in single-catheter group at 8 months follow-up

	Heating duration	Peak temperature	Thermal dosage
Flare-up duration (n=16)	−.099	.580*	.519*
Flare-up intensity (n=16)	−.021	.508*	.425

Pearson's r correlation: .90–1, very strong; .70–0.89, strong; .40–0.69, moderate; .20–.39, weak; .01–0.19, negligible relationship.
* $p<.05$.

Discussion

Intradiscal electrothermal heating treatment (IDET) is a minimally invasive procedure used to treat patients with low back and referred leg pain, but how or why heating decreases discogenic pain is unclear [12,13]. Proposed mechanisms include alteration of spinal segment mechanics via collagen modification, thermal nociceptive fiber destruction, biochemical mediation of inflammation, stimulation of an outer annular healing response, induced healing of annular fissures, and cauterization of vascular ingrowth [9,13]. None of these proposed mechanisms has been proven. In fact, the most commonly sited benefit of reducing the number or outer annular nociocepters was not substantiated in a sheep animal model [6]. In addition, the original concept that annular heating would cause beneficial collagen modification remains unproven and animal studies suggest that instead there may be a decrease in motion stability [12].

Our spine center prospectively collected treatment outcome variables and saved the detailed heating record and the fluoroscopic images of the IDET procedure. In earlier cases, the standard IDET heating protocols were followed. When prolonged pain flare-up was observed with 90°C protocols, temperature and heating duration were decreased using the patient's response as a guide. In some cases of bilateral back pain, catheters were inserted from both sides to achieve full coverage of the posterior and lateral annulus. These data permitted analysis of various factors influencing IDET outcome.

Our retrospective evaluation did not find any significant benefit in using higher heating temperatures and either 8 months or 16 months post-procedure. At 8 months post-procedure, higher maximal temperatures and higher total

Table 4
Correlation (r) between outcomes and heating variables in single-catheter group at 8 months follow-up

	Heating duration	Peak temperature	Thermal dosage
Improvement of VAS (n=16)	.039	−.436*	−.439*
Back Pain Improvement % (n=16)	.394	−.268	−.237

Pearson's r correlation: 0.90–1, very strong; 0.70–0.89, strong; 0.40–0.69, moderate; 0.20–0.39, weak; 0.01–0.19, negligible relationship.
* $p<.1$.

Table 5
Correlation (r) between outcomes and heating variables in double-catheter Group at 8 months follow-up

	Heating duration	Peak temperature	Thermal dosage
Improvement of VAS (n=16)	−.215	−.619*	−.481
Back Pain Improvement % (n=16)	−.509	−.735†	−.729†

Pearson's r correlation: 0.90–1, very strong; 0.70–0.89, strong; 0.40–0.69, moderate; 0.20–0.39, weak; 0.01–0.19, negligible relationship.
* $p<.1$.
† $p<.05$.

thermal dosages actually showed a moderate negative correlation to improvement in VAS scores and percent improvement in LBP. Furthermore, not only did increased thermal dosage fail to improve outcome measures, higher thermal dosage was associated with longer flare-up durations post-procedure. In addition, when we placed two catheters on opposite sides to cover the posterior annulus, these patients showed the worst outcome and longer duration of flare-ups, with a strong negative correlation between thermal dosage and outcome at 8 months. Because the 6-cm catheter may heat both normal and abnormal annulus, the increased flare-up might be explained by the increased tissue thermal necrosis caused by larger thermal doses [11]. These poorer outcomes could be a either a result of damage to normal annulus causing increased motion and decreased stiffness of the intervertebral disc [13], or the fact that patients requiring two catheters usually had more extensive annular disruption and may inherently have been less than ideal candidates for the IDET procedure.

Using a shorter heating element confined to the specific area of nocioception would seem more appropriate and supports the anecdotal observations of fewer and shorter duration flare-ups when using the recently introduced SpineCATH Intradiscal Catheter that has a 1.5-cm active heating element. Using the standard IDET protocols to 90°C, one can achieve temperatures over 46°C within a 6- to 10-mm radius of the catheter [11]. Catheters placed 1–2 mm within the outer annulus should reach temperatures sufficient to coagulate nociocepters at temperatures lower than the maximal protocol temperatures.

Because we are unsure of why intradiscal heating may relieve pain in any one particular case, determining ideal catheter placements and ideal heating protocols may be impossible. Our results do, however, suggest that we may achieve as good or better results with less flare-up if we modify the heating protocol downward depending on the amount of pain experienced by the patient during the incremental increases in temperature. The amount of pain is likely the combination of the temperature, time, and the length of innervated annulus exposed to the heat. When the catheters are in the outer annulus, more may not necessarily be better.

Conclusion

When a 6-cm electrothermal heating catheter is placed in the outer annulus, higher temperatures and longer heating times correlate with longer flare-ups and a slightly poorer outcome at 8 months post-procedure. Patients requiring two catheters to cover the posterior annulus had significantly longer flare-ups and poorer 8-month outcomes compared with those patients requiring only one catheter.

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