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Intradiscal electrothermal therapy for chronic discogenic low back pain: a comparison of two heating protocols

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ABSTRACT

Objectives. This study aims to evaluate the effect of intradiscal electrothermal therapy (IDET) applied in patients with chronic low back pain using two heating protocols. ***Methods.*** In this study, data of 50 patients who were exposed to percutaneous IDET using two heating protocols were retrospectively analyzed. The patients were divided into two groups: in Group 1 (n=25), maximum 750C catheter tipping was used, while in Group 2 (n=25), maximum 900C catheter tipping was performing. Pre-treatment (M0) and post-treatment results at 3 (M3), 6 (M6), 12 (M12), and 18 months (M18) were evaluated using the visual analogue acale (VAS), Oswestry disability index (ODI), and short form-36 (SF-36) scores. ***Results.*** There was no statistically significant difference in demografic characteristics and M0 VAS, ODI values and SF-36 dimensions of the patients between the groups ($p > 0.05$). It was found that there were statistically significant improvement than baseline values in the M3, M6, M12, and M18 VAS, ODI, and SF-36 scores in both treatment groups ($p < 0.05$). Between the group comparison; only the M18 VAS and SF-36 pain values were found statistically significant in the positive direction in Group 2 ($p < 0.05$). ***Conclusion.*** Similar successful results were obtained in our study involving two different heating procedures up to 12 months of administering IDET treatment. But at the 18th month the 900C IDET seems to be more effective in improving the pain scores.

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Keywords: chronic low back pain, intradiscal electrothermal therapy, intradiscal treatment

Introduction

A herniated disc is caused when the nucleus pulposus (NP) breaches the annulus fibrosus (AF). Low back and leg pain, and lumbar disc disease (LDD) develop as a result of degenerative disc herniation [1]. On the other hand, 40% of chronic low back pain has been reported to be due to discogenic pain [1, 2]. Many treatment methods have been reported in the treatment of LDD, including medical (i.e., non-steroidal anti-inflammatory drugs), physical medicine and rehabilitation (PMR), and, if indicated, surgery and minimal invasive interventions (i.e., epidural therapy, intradiscal interventions) can be

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applied [1]. Currently, percutaneous modalities including intradiscal electrothermal therapy (IDET), light amplification by stimulated emission of radiation (LASER), radiofrequency (RF), and pulsed RF techniques are frequently in use [3-5].

Intradiscal electrothermal therapy was first used by Sall&Sall [6] in 1997. The standard procedure is as follows: after inserting the intradiscal catheter with the flexible tip at the posterior annulus, the tip temperature is elevated from 65^{0}C to 90^{0}C over 12.5 minutes, and the procedure is maintained at this temperature for four minutes. The temperature of AF is elevated to 60^{0}C to 65^{0}C using this procedure. The possible mechanism for IDET involves thermocoagulation of unmyelinated nerve fibers and stabilization of collagens in the annular fracture through shrinking of nociceptors [7]. Several studies have reported the short-term (12-month) and long-term (24-month) success of this treatment modality, while some others have shown no efficacy of this procedure [8-10]. On the other hand, literature reviews and meta-analyses of meticulously selected studies among patients with positive discography and magnetic resonance imaging (MRI) findings have demonstrated that the procedure can be effective and safe [10, 11]. Although rare, certain permanent or temporal neural injuries due to heat effect have been also reported following IDET as a minimal invasive procedure [12, 13].

We could not find a study comparing different catheter tip temperatures in patients who applied IDET in the literature. In this study, we aimed to evaluate the effect of IDET applied at targeted catheter tip temperatures of 75^{0}C and 90^{0}C in patients with chronic low back pain (CLBP) associated with LDD.

Methods

This study was planned as retrospective and controlled. The study protocol was approved by the local Ethics Committee (The decision number: 2011-KAEK-25 2016/08-02). A public hospital records of a total of 260 patients who were admitted to neurosurgery, algology, and PMR outpatient clinics between January 2012 and January 2015, and who underwent percutaneous intradiscal intervention were retrospectively analyzed. Inclusion criteria were as follows: the presence of low back pain unresponsive to medical or PMR therapies for more than six months, presence of a negative straight-leg raise test, normal neurological examination findings, positive discography as assessed by higher visual analogue scale (VAS) scores (> 50% with discography), absence of nerve root compression on lumbar MRI, less than 50% decrease in the disc height, and ≤ 3 mm disc protrusion with a VAS score of >5.

Exclusion criterias were as follows: extruded or sequestrated discs, two or more pathological discs, moderate or severe spinal stenosis, systemic infection, history of or current disc infection, surgical site infection, lower extremity radiculopathy, and systemic opioid use.

Fifty patients who met the inclusion criteria during follow-up were examined into two groups: Group 1 included the patients who underwent 75^{0}C IDET (n=25), and Group 2 included the patients who underwent 90^{0}C IDET (n= 25).

The level where the procedure was to be performed in the prone position was identified with C-arm fluoroscopy. After site preparation, local anesthesia was given. The needle in an appropriate length was, then, inserted 8 to 12 cm laterally in the midline at the appropriate disc level using the tunnel-vision technique. The needle site was confirmed in the anteroposterior and lateral positions. The intradiscal catheter directed with 17G (SpineCATH® NeuroTherm, Wilmington, MA, USA) was placed in the posterior annulus of the symptomatic disc. After initiating the 65^{0}C heating protocol, an increase of 1^{0}C was made within 30 seconds. Approximately five minutes after the beginning of the procedure, a stable temperature of 75^{0}C was achieved and the procedure was terminated at this temperature at 16 minutes. In Group 2, a temperature of 90^{0}C was achieved over 12.5 minutes with a standard procedure. The procedure was terminated at this temperature at 16 minutes.1 mL physiological saline + antibiotic (cefazolin) mixture was injected into the disc following the procedure. Both heating protocols were applied by the same expert investigator. The patients did not know which heating procedure they were treated. The routine controls of the patients were performed in physical therapy outpatient clinics. Before treatment (M0) and after treatment results at three (M3), six (M6), 12 (M12), and 18 months (M18) were evaluated using the VAS, Oswestry disability Index (ODI), and short form-36 (SF-36) scores by an another blind investigator who did not attempt the intradiscal electrothermal therapy in routine controls. Pain intensity was measured using 0-10 cm VAS (0 = no pain, 10 = intolerable pain) [14]. ODI is used to assess the level of functional disability. It is a self-

administered questionnaire and is consisting of 10 questions about activities of daily living scored between 0 and 5. Final result is calculated as patient's score/ maximum score X 100. The total score is between 0 and 50 [15].

The SF-36 is also a self-administered questionnaire which gives information on positive or negative health status of the individual. This scale evaluates the eight dimensions for the past four weeks [16].

The patients were asked whether they had received any other treatment when they came for control visit and were allowed to use paracetamol for pain.

Statistical Analysis

All statistical calculations were performed by using the SPSS 22.0 program. When the study data were evaluated, the Fisher Exact test was used to compare gender and the Pearson chi square ($\chi 2$) test was used in the comparison of the qualitative variables, in addition to descriptive statistical methods (frequency, percentage, mean and standard deviation). Shapiro-Wilk test were used to assess for conformity to normal distribution. When normally distribution was found, student's t test was used for comparisons between groups. When variables were found non-normally distributed, Mann Whitney U test was used for comparisons between groups and Wilcoxon test was used for intragroup analysis. Friedman's test was used for multiple time point comparisons. Where significant differences have been detected, LSD and Tukey's HSD tests were used to identify the time point/s responsible for such differences. Significance level was set at p=0.05.

Results

Of 50 patients, 20 were males and 30 were females. The median age for group 1 was 58 (range: 48 to 70) years and for group 2 was 59 (range: 36 to 70) years. When the demographic characteristics of the patients are examined, there was no statistically significant difference in terms of age, gender, body mass index (BMI), duration of disease and level of the disc between the groups (p>0.05) (Table 1). Additionally, there was also no statistically significant difference between groups in M0 VAS, ODI values and SF-36 dimensions of the patients (p>0.05) (Tables 2 and 3).

When the values of M3, M6, M12 and M18 VAS and ODI subcomponents are compared with M0 values, statistically significant improvement was found in all groups according to M0 values in both groups (p<0.05) (Table 2).

Between the groups, there was no statistically significant difference in the M3, M6 and M12 VAS and SF-36 subcomponent values (p>0.05), while the M18 VAS and SF-36 pain values were found statistically significant in the positive direction in Group 2 (p<0.05). When the values of M3, M6, M12 and M18 in ODI and SF-36 values other than pain subcomponent were compared, no statistically significant difference was found between the two groups (p>0.05) (Table 3).

Three patients in Group 2 reported pain-related discomfort during the procedure, however, pain was

Table 1. Comparison of the demographic characteristics of the patients.

	Group 1 (n = 25)	**Group 2 (n = 25)**	***p****
Age (year)	58 (48-70)	59 (36-70)	0.800
Gender			
Female	14 (56%)	16 (64%)	
Male	11 (44%)	9 (36%)	0.773
Body Mass Index (kg/m^2)	29.59 ± 4.48	29.83 ± 3.63	0.691
Duration of pain (month)	13.4 ± 4.07	14.84 ± 4.96	0.335
Level of disc			
L4-L5	19 (76%)	20 (75%)	
L5-S1	6 (24%)	5 (25%)	0.735

Data are shown as mean±standard deviation, or median (min–max) or number (percent). Group 1 = 75^0C IDET (intradiscal electrothermal therapy), Group 2 = 90^0C IDET, * Comparison between groups

Table 2. Comparison of the M0 and M3, M6, M12, M18 VAS and ODI values of study and control groups.

		M0	M3	M6	M12	M18	*p***
VAS	Group 1	6 (3-9)	2 (0-6)	2 (0-5)	2 (0-3)	3 (0-7)	***< 0.001***
	Group 2	6 (5-8)	3 (0-5)	3 (0-4)	2 (0-5)	2 (0-6)	***< 0.001***
	*p**	0.563	0.402	0.128	0.439	***0.018***	
ODI	Group 1	38 (26-50)	24 (8-48)	18 (6-36)	12 (6-20)	12 (0-28)	***< 0.001***
	Group 2	40 (32-45)	24 (20-38)	19 (12-36)	10 (6-24)	10 (6-24)	***< 0.001***
	*p**	0.334	0.408	0.328	0.067	0.321	

Data are shown as median (min–max). Group 1 = 75^{0}C IDET (intradiscal electrothermal therapy), Group 2 = 90^{0}C IDET, VAS = visual analog scale, ODI = Oswestry disability index, M0 = month 0, M3 = month 3, M6 = month 6, M12 = month 12, M18 = month 18, * Comparison between groups, ** Comparison within groups (M0 between others)

not enough to warrant the termination of the procedure. None of the patients had permanent or temporal complications. No additional analgesics, PMR, or any other intervention was given to the patients during follow-up.

Discussion

In the present study, to reduce the risk of thermal injury, we applied IDET by using 2 different catheter tips (75^{0}C and 90^{0}C) and compared the results of M0, M3, M6, M12, and M18 using the VAS, ODI, and SF-36. We reported a statistically significant improvement in both groups at the end of the M12. However, we demonstrated a statistically significant improvement in the VAS and SF-36 pain scores at M18 in patients

Table 3. Comparison of the M0 and M3, M6, M12, M18 SF-36 values of study and control groups.

SF-36	M0	M3	M6	M12	M18	*p***
Physical Function						
Group 1	45 (35-55)	65 (50-80)	70 (50-80)	65 (45-80)	60 (40-75)	***< 0.001***
Group 2	45 (35-60)	60 (45-75)	60 (45-75)	60 (45-75)	60 (45-80)	***< 0.001***
*p**	0.334	0.150	0.063	0.145	0.353	
Physical Role						
Group 1	25 (10-50)	40 (25-55)	50 (25-75)	37.5 (12.5-55)	37.5 (12.5-60)	***< 0.001***
Group 2	25 (12.5-37.5)	50 (25-75)	50 (25-75)	37.5 (12.5-60)	37.5 (12.5-60)	***< 0.001***
*p**	0.975	0.068	0.322	0.387	0.730	
Pain						
Group 1	35 (22.5-55)	62 (50-70)	55 (35-81)	45(35-81)	67(22.5-70)	***< 0.001***
Group 2	22.5 (16.30-70)	55 (22.5-70)	67 (22.5-70)	35 (22.5-70)	45 (22-70)	***< 0.001***
*p**	0.175	0.421	0.155	0.095	***0.003***	
General Health						
Group 1	35 (20-55)	65 (50-70)	60 (40-70)	60 (40-70)	50 (35-70)	***< 0.001***
Group 2	22.5 (16.30-70)	60 (35-70)	65 (40-70)	60 (35-70)	60 (35-70)	***< 0.001***
*p**	0.175	0.155	0.441	0.858	0.353	
Vitality						
Group 1	35 (25-55)	60 (25-80)	60 (50-80)	65 (25-80)	55 (50-75)	***< 0.001***
Group 2	35 (25-60)	60 (50-75)	60 (50-75)	65 (50-80)	55 (25-70)	***< 0.001***
*p**	0.690	0.192	0.138	0.707	0.920	
Social Function						
Group 1	37.5 (25-62.5)	62.5 (25-75)	62.5 (25-75)	62.5 (25-75)	62.5 (25-75)	***< 0.001***
Group 2	37.5 (25-50)	50 (25-75)	62.5 (25-75)	50 (25-75)	50 (25-75)	***< 0.001***
*p**	0.908	0.309	0.992	0.385	0.056	
Emotional Role						
Group 1	33 (16.3-50)	50 (16.3-75)	50 (16.3-75)	50 (16,3-50)	50 (16.3-50)	***< 0.001***
Group 2	33 (16.3-50)	33 (16.3-50)	33 (16.3-50)	50 (16.3-75)	50 (16.3-50)	***< 0.001***
*p**	0.418	0.567	0.406	0.791	0.837	
Mental Health						
Group 1	44 (25-55)	62 (52-71)	62 (52-71)	62 (52-71)	55 (52-80)	***< 0.001***
Group2	35 (25-52)	60 (35-80)	60 (40-80)	55 (35-80)	60 (52-75)	***< 0.001***
*p**	0.141	0.487	0.852	0.531	0.611	

Data are shown as median (min–max). Group 1 = 75^{0}C IDET (intradiscal electrothermal therapy), Group 2 = 90^{0}C IDET, SF-36 = short form 36, M0 = month 0, M3 = month 3, M6 = month 6, M12 = month 12, M18 = month 18, * Comparison between groups, ** Comparison within groups (M0 between others)

who were exposed to 90^{0}C, compared to those who were exposed to heat temperature of 75^{0}C.

With the increased use of IDET in patients with CLBP, increased complication rates have been reported in the literature. Manchikanti *et al.* [17] evaluated complications of 3,500 patients and reported that complications were often associated with technical problems and with heat. Complications associated with heat are cauda equina syndrome due to nerve injury, temporary or permanent long-term low back and leg pain, and vertebral osteonecrosis [17]. The results of this study showed that, unlike seen with the spinal cord, nerve roots and dorsal ganglion were not found in the cerebrospinal fluid (CSF); hence, they were not protected from heat temperatures of more than 45^{0}C. A meta-analysis analyzing 17 IDET studies demonstrated that this treatment modality was relatively effective and safe with a complication rate of 0.8% (0.2 to 1.4%) [11]. The insertion of a catheter is also critical in terms of the risk of complications. Konno *et al.* [18] demonstrated that 70^{0}C exposure for five minutes was sufficient to create nerve damage and that there was a possibility of injury, when the catheter was wrongly inserted. In our study, we did not encounter any complications in both groups. This may be due to the fact that our patient count was low or we did not displace the catheter wrongly.

Furthermore, human cadaver studies have investigated the mechanism of the effect of IDET and evaluated its effect on the disc and surrounding tissues [19-21]. In the studies conducted by Wegener *et al.* [19] in 10 human L4-L5 cadaver vertebral discs, discs with bulging and fissure were excluded. During the measurements of IDET treatment administered to the discs which were considered healthy, the annulus temperature was measured to be 45^{0}C, although the posterior annulus acted as a heat barrier, and a possibility of thermal injury was considered. However, one of the two risks of the study was the inability of proper insertion of the catheter; the second was the possibility of different heat distributions and variability on damaged discs involved in the study [19]. In another study, heat temperature surrounding the catheter was evaluated and a temperature of 60^{0}C to 650C was obtained, when the catheter was localized at a distance of 2 mm, whereas a temperature of 45^{0}C was reported for a distance of 9 to 14 mm [20]. Kleinstueck *et al.* [21] including 12 human cadaver specimens demonstrated that a catheter placed at a distance of 1 to 2 mm could yield collagenous denaturation and reported that the success of treatment could be attributed to other causes. On the other hand, the main limitations of cadaver studies include the lack of the effect of CSF flow and surrounding tissue structures of the platform used for the procedure [19-21].

In a study conducted by Derby *et al.* [22] different procedures of administering IDET were investigated to identify the duration of heating catheter tips at different temperatures during the administration of IDET. A total of 35 patients were evaluated in a treatment procedure involving one or two catheters. Although good results were reported at high temperatures in this retrospective study including 25 patients at eight months, its 16-month follow-up results revealed that the treatment was not effective at high temperatures [22]. The interesting results of our study was, however, the fact that, although the degree of benefit for VAS and SF-36 pain subgroup scores at a catheter tip temperature of 75^{0}C which decreased 12 months after treatment, we did not observe any statistically significant difference in the other measurable variables between the two groups.

Furthermore, although favorable conditions prevailed in the group which received a maximum heat temperature of 90^{0}C, the decline in benefit after 12 months of 75^{0}C heating can be attributed to the inability of adequately or permanently maintaining the posterior annulus nerve damage. The affinity of centrifugal growth of the annular nerve fibers was suggested to be due to pain, which also supports our findings [23]. In a study investigating the effect of heat on the nerve tissue, short-term exposure at heat temperatures of 40^{0}C to 45^{0}C were reported to induce certain damages; however, the damage was reported to be manageable and non-fatal [24]. The physiological effects of the exposures at these temperatures include an increased cellular metabolism, inactivation of enzymes, increased permeability, and increased blood flow [24]. Another factor during recovery was the degree of collagenous shrinking [25]. The catheter tip temperatures used in both groups of our study seem to have attained a degree of providing collagenous shrinking at the nucleus. For this reason, we think that there is no statistically significant difference between the groups in functional recovery in both groups.

The Limitations of the Study

There are some limitations to this study. Small sample size and retrospective design of the study can be regarded as the limitations.

Conclusions

Similar successful results were obtained in our study involving two different heating procedures up to 12 months of administering IDET treatment. But at the 18th month the 900C IDET seems to be more effective in improving the pain scores.

Authorship declaration

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors, and all authors are in agreement with the manuscript.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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