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Research Article

The Effect of Intradiscal Electrothermal Therapy on Quality of Life and Satisfaction of Patients with Discogenic Low Back Pain

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Abstract

Objectives: Intradiscal electrothermal therapy (IDET) is an intervention option for discogenic low back pain treatment. The aim of this study was to research the pain level, quality of life, and satisfaction of patients who underwent IDET.
Methods: This study was performed retrospectively with 50 patients treated with IDET for low back pain between April 1, 2014 and November 20, 2014. Age, weight, sex, body mass index, pain spread, location of intervention, 36-Item Short Form Survey (SF-36) score, visual analogue score (VAS), and satisfaction level of the patients were recorded from data in the files. The satisfaction level of the patients was 70% (40% "benefitted" and 30% "fully recovered").
Results: Of the 50 patients included in the analysis, the male/female ratio was 31/19, the mean age was 43.2±2 years, and the mean weight was 72.2±9 kg. There was a statistically significant difference in SF-36 physical function result, pain score, and VAS between mean pretreatment results and 3 months after treatment ($p<0.05$).
Conclusion: There was a significant difference in VAS, the SF-36 subscale of physical function, and pain points before treatment and after treatment with IDET, and the post-treatment satisfaction level of the patients was high.
Keywords: Intradiscal electrothermal therapy, low back pain, quality of life, satisfaction level
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Currently the majority of people complain of low back pain at least once during any period of their lives. Low back pain occurs linked to rheumatological, neoplastic, infectious, mechanical, vascular or endocrine factors. There are many treatment choices, both non-invasive and invasive.

Intradiscal electrothermal therapy (IDET) is an intervention for discogenic low back pain treatment. It was first applied by Saal et al. in 1997.[1] With this method, a specially-designed catheter system is inserted into the disc interval with a posterolateral percutaneous approach and the posterior section of the disc interval is heated to nearly 75°C tissue temperature to ensure contractions of the collagen fibers in the posterior annulus fibrosis.[2]

IDET is an appropriate treatment for patients who are physiologically stable and with functional limitation due to chronic low back pain, who do not experience improvement with aggressive exercise-based rehabilitation program and have documented discogenic sourced pain.[2]

The research published by Saal et al. stated that IDET significantly reduced visual analog scale (VAS) scores during 16 months of follow-up.[1] However, Spruit et al. in a study of 20 patients concluded that IDET did not reduce discogenic low

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back pain and did not improve functional performance.[3]

In this study, we aimed to research the pain levels, quality of life and satisfaction of patients at our clinic who underwent IDET.

Materials and Methods

The study retrospective investigated the files of patients after receiving permission from Uludağ University Faculty of Medicine ethics committee. The files of patients with IDET applied for low back pain at our algology clinic from 01/04/2014 – 20/11/2014 were included in the study review.

Inclusion criteria for patients were:

1- Mechanical low back pain lasting more than 3 months
2- Investigation with MR imaging technique with degenerative disc disease findings
3- No response to at least 4 weeks of conservative treatment
4- Loss of more than 25% disc height determined

Exclusion criteria for the study were:

1- Previous lumbar surgical intervention history
2- Extruded and sequestered disc hernia requiring surgery on lumbar MR
3- Identification of neurological deficit
4- Structural deformity of vertebrae, spondylolisthesis, scoliosis and spinal stenosis,
5- Local skin infection or systemic infection
6- Disc level below 75% determined on MR imaging.

Pretreatment Assessment

Low back pain patients applying to the algology clinic were questioned about the spread of the pain, and severity of pain before treatment (VAS score). All patients had at least one MRI investigation to confirm the presence of lumbar disc pathology. The quality of life of patients was assessed with the Short Form-36 (SF-36 score) quality of life scale. The subscales are assessed health from 0 to 100 with 100 indicating good health. Patients with degenerative disc changes on clinical assessment and MR images had intradiscal radiofrequency thermal treatment planned with patients informed about the application. Three months after treatment, severity of pain (VAS score) and SF-36 quality of life scale were applied and patient satisfaction was assessed.

Treatment Application

Before intradiscal electrothermal treatment applied at our clinic, patients had a venous route opened. After filling the monitoring forms, they were assessed in terms of vital signs (blood pressure, pulse) and taken to the injection room. Patients lay on a C-arm fluoroscopy device table in supine position. The region was cleaned with povidone iodine and covered with a sterile cloth. The level of the intervention was determined with the aid of the fluoroscopy device and the scopy device was cranially or caudally rotated until the end-plat was flat. Fluoroscopy was set to nearly 45° on the pain-free side, in oblique position where the facet joint line came to the central point of the disc interval. Thus, the intervertebral disc interval was clearly observed. The point of intervention was marked at the point in accordance with the center of the disc superolateral to the superior articular protrusion. At this point 2 ml lidocaine was used for anesthesia of skin and subdermal tissue.

A 17 G guide needle was used to direct to this point under "tunnel vision" and when the edge of the disc was reached, the needle was halted and fluoroscopy was brought to lateral position. While fluoroscopy was in lateral position, resistance was felt passing the annulus. The needle remained in the transition between the annulus and nucleus. Before inserting the catheter the impedance of the disc was measured and impedance was set to 120-200 Ohm. The Spine-CATH catheter system was passed through the needle until the tip of the needle was reached. Under continuous fluoroscopy with lateral imaging, the catheter was advanced until it was observed to curl along the inner wall of the annulus giving sensorial and motor electrical control warnings. The patients were questioned and observed for pain, burning or motor action in the leg. In this way, the location of the thermal probe was reliably determined. After inserting the catheter, 65-90ºC temperatures were applied for 15 minutes then the catheter was retracted through the needle. Before removing the needle 1 ml physiologic serum containing 50 mg cefalozine was injected into the disc, then the guide needle was removed.

After the procedure patients were taken for bed rest in supine position for 4 hours. Six hours after the procedure after ensuring there were no abnormalities, systemic symptoms were checked and neurological examination performed again. After being sure the patient's general state was good, precautions to be taken after the operation were explained and discharged patients were given a check-up appointment for three months later.

Statistical Analysis

Data obtained in the research were analyzed with SPSS (Statistical Package for Social Sciences) for Windows 21.0 program. When assessing the data, descriptive statistical methods were used (number, percentage, mean, standard deviation). Comparison of quantitative data used the t-test for two groups and one way ANOVA test to compare pa-

Table 1. Demographic data

	n	Mean	SD
Age (years)	50	43.2	8
Weight (kg)	50	72.2	9
		n	%
Sex			
Female		19	38
Male		31	62
Total		50	100
Body mass index (kg m^{-2})			
<18.5		–	–
18.5–24.9		45	90
>25		5	10

SD: Standard deviation.

Table 2. Pain spread, MR results and entry points

	n	%
Pain spread		
None	27	55
Posterior thigh	14	28
Anterior thigh	3	6
Calf	6	11
MR Results		
Bulging	10	20
Protrusion	40	80
Localization of intervention		
L_{3-4}	10	20
L_{4-5}	30	60
$L_{5-}S_1$	10	20

rameters in more than two groups. The Scheffe test was used to identify the group causing difference. Continuous variables in the research were tested with correlation analysis. The obtained results were assessed at the 95% confidence interval with 5% significance level.

Results

The research included a total of 50 patients. These were 31 males (62%) and 19 females (38%). Mean age was 43.2±2 years with mean weight of 72.2±9 kg (Table 1). While 23 patients (45%) had spread of low back pain, 27 (55%) did not have spread of pain. When assessed in terms of region of pain spread, 14 cases (28%) had pain in the posterior of the thigh, 6 (11%) had pain in the calf and 3 (6%) had pain in the anterior of the thigh (Table 2).

Paired group analysis to determine whether there was a significant difference between the means of the SF-36 subtests for social function, role limitations linked to physical problems, role limitations linked to emotional problems, mental health, vitality and general health before treatment and 3 months after treatment found no statistically significant difference between the means ($p>0.05$).

Table 3. Comparison of before treatment and 3 months after treatment

Measurements	BT Mean±SD	AT Mean±SD	p
SF-36 Physical function score	34.3±5.9	62.7±24.2	0.0
SF-36 Pain score	49.0±11.6	72.6±16.0	0.0
VAS	7.7±1.2	3.9±2.2	0.0

BT: Before treatment; AT: After treatment; SD: Standard deviation.

Table 4. Levels of patient satisfaction

Satisfaction	Total	
	n	%
I did not see any benefit	7	14
I saw partial benefit	8	16
I benefitted	20	40
I am fully recovered	15	30

Paired group analysis to determine whether there was a difference between the mean pretreatment SF-36 physical function and mean SF-36 physical function score 3 months after treatment found a statistically significant difference between the means ($p<0.05$). Paired group analysis to determine whether there was a difference between the means of SF-36 pain before treatment and 3 months after treatment found a statistically significant difference between the means ($p<0.05$). The difference between mean VAS before treatment and mean VAS 3 months after treatment was statistically significant ($p<0.05$). The comparisons of SF-36 physical function, pain scores and VAS values before treatment and 3 months after treatment are summarized in Table 3.

When patients were questioned about satisfaction level, the rate who stated they "saw no benefit" was 14%, with 16% saying they "saw partial benefit, 40% saying they "benefitted" and 30% saying they were "fully recovered" (Table 4).

Discussion

In this study there was no significant difference observed for the social function, role limitations linked to physical and emotional problems, mental health and general health tests SF-36 scores before treatment and after treatment. However, significant improvements were observed

in terms of VAS and SF-36 pain scores. Different to other research in the literature patient satisfaction was at 70%.

Saal et al. completed the first non-randomized prospective research including a 7 month follow-up period on a total of 25 patients with chronic low back pain.[4] Of patients who underwent IDET improvement was found for 80% in VAS scores, 72% in sitting tolerance and 72% in SF-36 test scores. However, there was no control group included in this research.

Three research articles including case series are Freedman et al.[5] with 31 patients, Endres et al.[6] with 54 patients and Cohen et al.[7] with a total of 79 patients. Freedman et al.[5] in a study of soldiers with chronic discogenic low back pain included 31 cases with 2 year follow-up from a total of 41 patients who underwent IDET.[6] After 6 months follow-up, the success rate was 47% (17/36) which fell to 16% (5/31) at two year follow-up. Though the two-year follow-up success rate had fallen, 20 of the 31 patients had a permanent reduction in terms of VAS scores. At the end of two years, only 7 of the 31 patients (23%) required surgical treatment due to insufficient improvement.

Cohen et al.[7] in a research including 79 patients assessed IDET complications and success. While 41 of the 79 patients obtained negative results, the IDET technique was positive for 38 patients. Of the patients with positive results, the mean VAS score fell from 5.9 to 2.1; a 64% change.

In two randomized controlled studies, researchers compared IDET with placebo treatment.[8, 9] These two studies included 64 and 57 patients, respectively. Pauza et al.[8] determine results according to three variables (pain severity, SF-36 points and Oswestry points) and stated that only the pain severity points had a significantly reduced percentage variation compared to placebo. The reductions in other points were similar to placebo.

Freeman et al.[9] in a 2005 study of 54 patients used SF points and Oswestry scale to measure results. With no complications observed, this randomized placebo controlled research, did not observe any significant difference between the two result measurements between the results (SF p=0.8 and Oswestry points p=0.5).

In two non-randomized controlled studies, researchers compared IDET with conservative treatment.[10, 11] With no side effects observed, the two studies included a total of 53 patients each. The result measurement parameter used was pain severity. In both studies pain severity fell from an initial value of 8 to 3 ($p<0.001$). In other words, there was a 63% reduction in pain severity. Additionally Karasek et al.[10] found that with conservative treatment pain severity fell from an initial value of 8 to 7 ($p>0.001$). Bogduk et al.[11] observed a fall in pain severity from an initial value of 8 to 7.5 ($p>0.001$).

The third group of studies related to IDET compared pretreatment values with values after treatment. At the same time, these types of studies comprise the majority of studies related to IDET. This research design complies with our study.

In research with pain severity as a result measurement parameter, Singh et al.[12] observed only a 37% reduction (6.2 to 3.9) while Kapural et al.[13] identified a 66% (7.4 to 2.5) reduction and Mekhail et al.[14] found a 71% (8 to 2.3) reduction. The reduction in VAS scores became significant after the third month in the studies by Mekhail et al.[14] and Kapural et al.[13] In terms of the reduction in pain severity, the results obtained by Mekhail et al.[14] and Kapural et al.[13] are significantly higher than other studies. Similar success rates were obtained by Karasek et al.[10] and Bogduk et al.[11] in their studies comparing IDET with conservative management (63% and 63%, respectively). Though the research by Singh et al.[12] only obtained a reduction of 37%, the fall in pain complaints of 67% of patients was above 50%. Additionally, in terms of daily functions (sitting, standing and walking) there was clinically significant improvement in walking for 71% of patients with improvements in sitting and standing for 62% of patients.[12]

In our study when we compared the pretreatment VAS values with VAS values after treatment, the mean VAS before treatment was 7.6 while the mean VAS after treatment was 3.9 with a nearly 49% reduction occurring. These results are similar to the results obtained by Saal et al.[15]

Saal et al.[1] in a study comprising 62 patients with the SF-36 survey, they observed a significant improvement in physical function in 74%, with improvement in quality of life for 51% of patients after IDET ($p<0.001$). However, in spite or observing an improvement in terms of pain severity in 75% of IDET patients with chronic low back pain in a study by Gerszten et al.[16] they stated that this result did not cause a significant difference in terms of SF-36 follow-up results. As a result, they concluded that IDET may be more successful in certain carefully selected patients. In our study, we observed a significant difference in terms of mean points for the subscale of SF-36 physical function before treatment and after treatment.

Limitations

There are two important limitations to our study. The first is that it has retrospective design and the second is that there is no control group.

In conclusion, there were significant differences in VAS and SF-36 subscales of physical function and pain points before treatment and after treatment with IDET and also satisfac-

tion levels patients were high.

Disclosures

Ethics Committee Approval: The study was approved by the Local Ethics Committee.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

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