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ORIGINAL ARTICLE

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Pain and function after intradiscal electrothermal treatment (IDET) for symptomatic lumbar disc degeneration

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Abstract The goal of this study was to evaluate the short-term effects of intradiscal electrothermal treatment (IDET) for chronic discogenic low back pain. Twenty consecutive patients with symptomatic degenerative discs were treated with IDET and evaluated preoperatively, and 3 and 6 months postoperatively. Pain was measured with a 100-mm visual analog scale (VAS) and function was evaluated with the Oswestry score and SF-36 questionnaire. The VAS scores improved by 14 mm on average (P=0.046), but the individual scores show great variation. The Oswestry scores did not improve significantly. The SF-36 showed improvement, but only for the subscales vitality (P=0.023) and bodily pain (P=0.047). Based on these results, we conclude that IDET is not effective in reducing pain and improving functional performance in a sample of 20 patients treated for chronic discogenic low back pain after 6 months follow-up.

Keywords Intervertebral disc · Low back pain · Electrothermal treatment · Recovery of function · Prospective studies

Introduction

Chronic low back pain due to symptomatic disc degeneration often fails to respond to comprehensive non-operative treatment programs. Surgical treatment consists of fusion of vertebral segments [6, 10]. This can be achieved with interbody fusion through an anterior [14, 21, 23] or posterior [2, 15, 25] approach, fusion of the posterior elements alone [3, 7], or with a combined approach [5, 12, 15]. The surgical treatment is aggressive and has obvious limitations such as the patient morbidity, increased odds of further surgery and risk of complications [1, 3, 22, 25]. Less invasive approaches to decrease low back pain and increase patient performance, and new technologies to achieve this, deserve attention.

In intradiscal electrothermal treatment (IDET, Oratec Interventions Inc., Menlo Park, Calif.), a catheter with a temperature-controlled heat resistive coil is percutaneously navigated into the disc and positioned at the posterior annular wall [17]. Heating of the catheter to 90°C would increase temperature in the annulus to 60–65°C. This is believed to damage nociceptors in the posterior annular wall [19] and contract the collagen type I fibers of the outer annulus [10]. Pain reduction and, in time, stiffening of the posterior annulus are possible effects of this treatment. Cadaver studies show that it is possible to navigate the catheter in the disc [4]. The effects of heating the disc were studied in cadavers [13, 24] and in an in vivo thermal mapping model in pigs [20]. In a water displacement model, 7% nuclear shrinkage was measured.

The IDET technique was developed by Saal and Saal, and their first clinical results have been presented [16] and published [9, 18, 19]. In the published study, the mean change in the visual analog scale (VAS) scores of 62 patients after mean follow-up of 16 months was 3.0 (P< 0.001).

When new treatments are introduced in clinical trials in other institutions, results usually are less successful. The purpose of the present study was to evaluate the short-term effects of this new treatment for chronic discogenic low back pain in a prospective case series.

Table 1 Selection criteria

Inclusion criteria	
Degenerative disc disease	
Affected level L1-S1	
Predominant low back pain	
Intolerance for sitting	
Neurological examination normal	
Conservative treatment applied for at least 6 months and failed.	
Patient has received information and signed informed consent.	
Expected to complete follow-up	
Exclusion criteria	
Spondylolysis or spondylolisthesis	
Infection	
Active malignancy	
Pregnancy	
Previous lumbar surgery	

Materials and methods

For this study, 20 consecutive patients with chronic discogenic low back pain were included after meeting the selection criteria (Table 1). All patients had provocative discography of the affected disc and experienced concordant pain. Eligibility for the study was assessed during outpatient visits. The current study is an explorative documentation study, and a sample size of 20 was considered sufficient to evaluate whether the technique provides confidence for application in a larger population, without exposing too many patients to unknown side effects or ineffective treatment. All selected patients signed an informed consent.

Demographic data and routine anteroposterior and lateral radiographs of the lumbar spine were obtained preoperatively. Low back pain was scored on a VAS (100 mm). Physical functioning was recorded with the Oswestry score and SF-36 questionnaire. Operation characteristics such as catheter position and complications were noted.

Thermal catheter protocol

Under local anesthesia with the patient in lateral decubitus position, a 17-gauge trocar containing needle was introduced into the center of the disc. The catheter was inserted through the needle and navigated along the annular wall as far posterior as possible. The temperature was then increased gradually to 90°C, and this temperature was maintained for 4 min. We did not leave prophylactic antibiotics or corticosteroids in the disc. The operative procedure has been described previously [8, 17].

After-treatment protocol

Patients were requested to limit physical activities such as standing for more than 1 h and heavy lifting for the first 6 weeks. We encouraged patients to walk and do exercises. After 6 weeks they were advised to resume their normal activities.

Follow-up visits were scheduled after 3 and 6 months. VAS score for low back pain, Oswestry score and SF-36 were repeated at each visit. Follow-up was limited to 6 months to evaluate the short-term effectiveness of IDET.

Table 2 Demographics and disease-related data

Demographics: mean (SD; range)	
Age at operation (years)	37.6 (8.0; 26.1–56.2)
Duration of symptoms (months)	44.2 (32.9; 15–120)
Disease-related data (*n*)	
Back pain	20
Leg pain	11
Gender: M/F	10/10
Level	
L3-4	3
L4-5	10
L5-S1	3
L3-4/L4-5	2
L4-5/L5-S1	2

Table 3 Average visual analog scale and Oswestry scores preoperatively and at 3 and 6 months

	VAS			Oswestry		
	Mean	SD	Range	Mean	SD	Range
Preoperative (*n*=20)	65.40	14.89	42–96	43.10	7.35	26–52
3 Months (*n*=19)	56.31	25.34	10–95	39.00	16.15	6–68
6 Months (*n*=19)	50.63	26.52	2–100	36.68	21.07	0–64

Statistical analysis

Primary outcome was analyzed with a repeated measurements method. Average values of the VAS, Oswestry scores and SF-36 subscales were determined for each follow-up visit, with standard deviations.

Results

The 20 patients who entered the study were the first patients to receive IDET at our hospital. Table 2 shows patients' demographics and disease-related data. Sixteen patients were treated in daycare at one disc level and four patients received treatment at two levels. Patients with two-level treatment received one-level IDET followed by the second level 1 week later. One patient was lost to follow-up after 3 months (case 4). This patient did not respond to two additional autoreply envelopes and could not be reached by phone. This was a 32-year-old woman. Her VAS and Oswestry scores were respectively 70 and 46 at the 3 months visit. None of the other patients withdrew from the study. There were no device-related complications. Ten patients received additional physiotherapy after 3 months.

Average VAS and Oswestry scores are presented in Table 3. The mean VAS pain score at 6 months had significantly improved by 14 mm (P=0.046), compared to the preoperative score. Individual VAS and Oswestry scores are graphically displayed in Fig. 1 and Fig. 2.

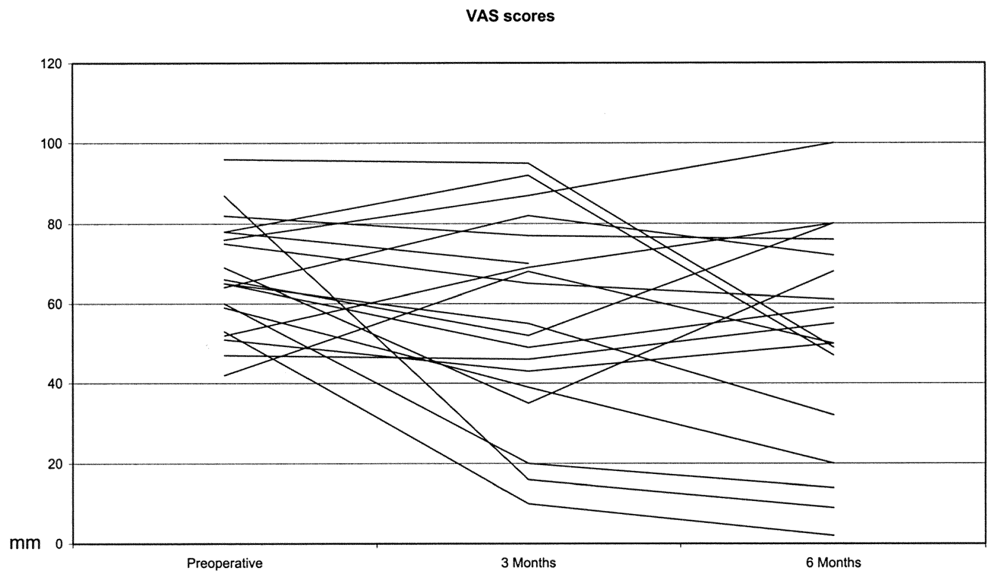

Fig. 1 Graphical display of individual visual analog scale (VAS) scores

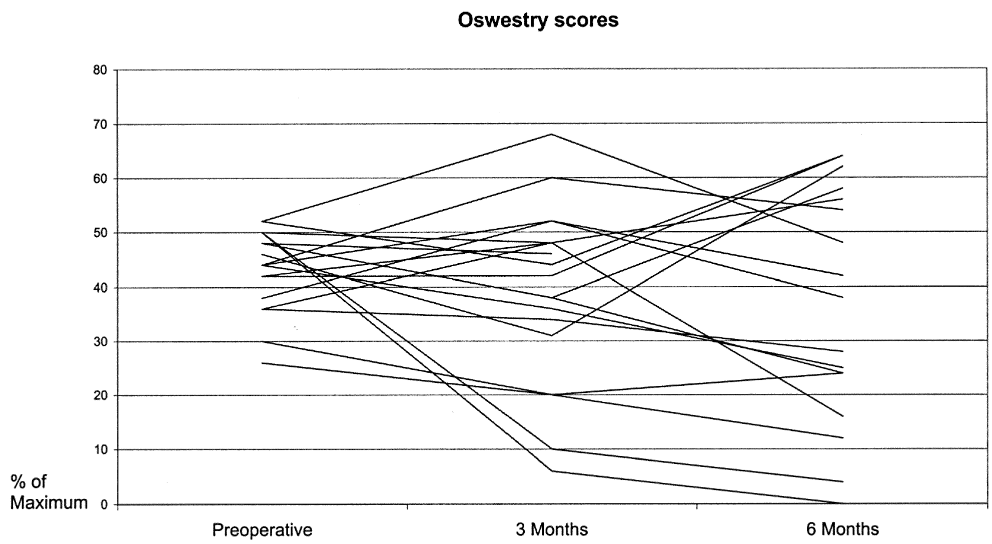

Fig. 2 Graphical display of individual Oswestry scores

The average subscale scores on the SF-36 are shown in Fig. 3. The mean subscale scores for vitality and bodily pain improved significantly after 6 months, by 10% (P=0.023) and 11.8% (P=0.047) respectively. The other SF-36 subscale scores did not improve significantly.

Post-hoc analysis of variance could not detect differences for sex, leg pain, duration of symptoms or additional physiotherapy after 3 months. Appropriate catheter position along the posterior annular wall was observed in 16 patients. There was no correlation between catheter position and improvement in VAS, Oswestry, or SF-36. Patients treated at two levels had an 8-point increase in Oswestry score and patients treated at one level had a 10.8-point decrease.

Discussion

The current study is an explorative documentation study to demonstrate the efficacy of a novel minimal invasive treatment for chronic discogenic low back pain in a sample of 20 patients. The follow-up was limited to 6 months, because we feel that IDET should show improvement in pain scores and functional performance after this follow-up period to allow for further application of this treatment in a larger population. If an explorative documentation study were to show efficacy of IDET, the next logical step would be a randomized controlled trial. We observed a mean VAS low back pain score reduction of 14 mm after 6 months, which is a significant difference compared to the mean preoperative score. The individual scores, however, show great variation. The Oswestry score did not

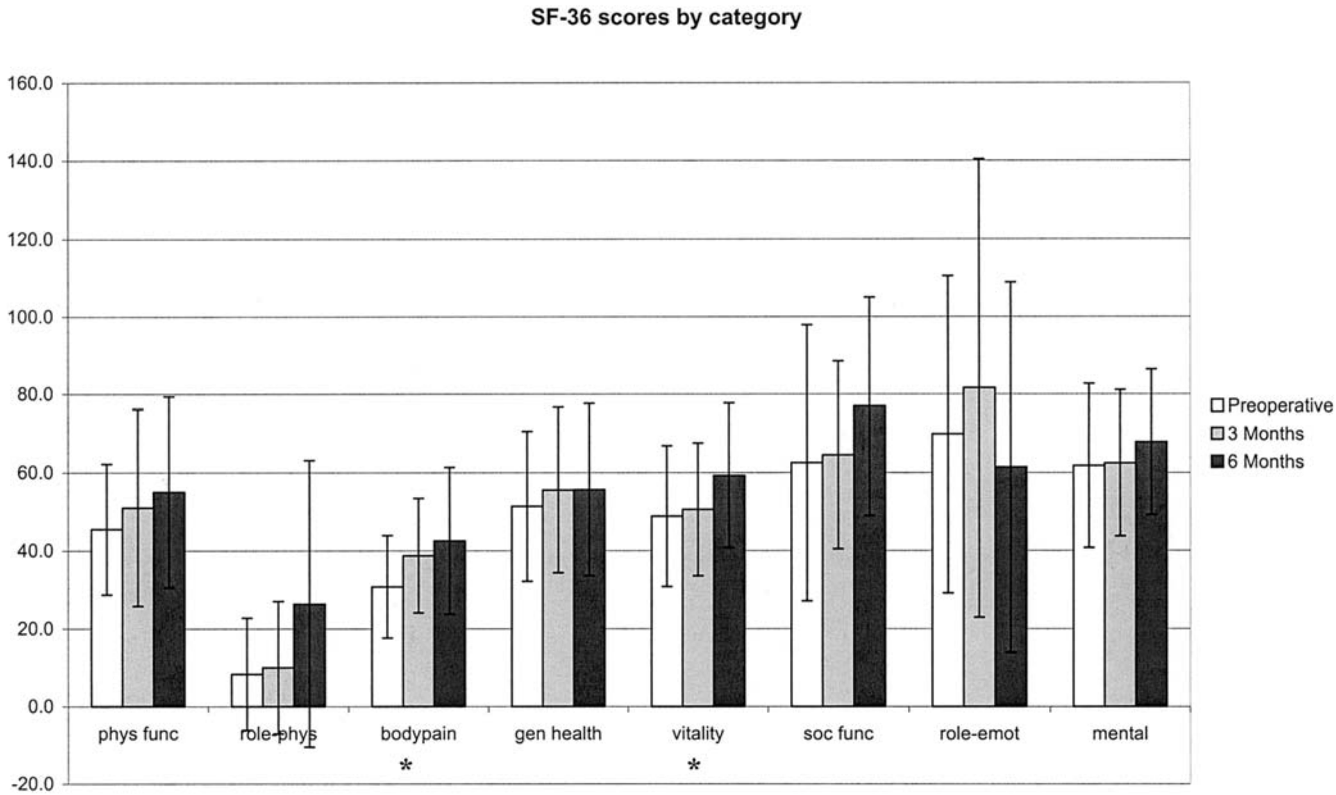

Fig. 3 SF-36 results by category. Subscales vitality and bodypain improved significantly (P=0.023 and P=0.047, respectively) and are marked with an *asterisk*

improve significantly after the IDET procedure. The SF-36 showed improvement, but only for subscales vitality and bodily pain, and not for the remaining subscales. Our results do not match results from previous prospective case series [18, 19]. The current study results do not meet previously published [10] criteria for improvement, and therefore we conclude that IDET is not an effective method to treat chronic discogenic low back pain and cannot be offered as a treatment option in a larger population.

As we could not demonstrate a correlation between appropriate catheter position and clinical improvement, we feel that the actual temperature rise and thermal damage in the posterior annulus are limited and probably insufficient to damage nociceptors and induce collagen shrinkage. Evidence in favor of the working mechanism of the temperature-controlled heat resistive catheter is weak and comes from studies with methodological limitations [20]. Kleinstueck et al. [11] did not observe the necessary temperature in the disc to induce collagen shrinkage in a human lumbar disc model. Temperatures sufficient to damage nerves were, in fact, reached, but not in areas of clinical relevance such as the posterior annulus.

The indication for IDET is another critical issue. Saal and Saal [18, 19] include only "fusion candidates". Proper introduction of the catheter requires at least 50% intervertebral disc height preservation. In fact, for the catheter to curl along the inner annular border, the annulus has to lack advanced degeneration. In advanced degenerative discs it is difficult, if not almost impossible, to navigate the catheter to its desired position. We therefore feel that only relatively mild degenerative discs, such as black discs on magnetic resonance imaging, are technically suitable for IDET.

The final critical issue is the determination of efficacy. The definition of improvement by Saal and Saal [18] was a more than two points (20 mm) decrease on the VAS for low back pain. A two points decrease on VAS means the patient will still have low back pain. We feel in due time this will not be acceptable for the patient with chronic low back pain. We suggest that the definition for improvement should therefore be adjusted to at least five points reduction on the VAS.

Conclusion

In a prospective case series performed as an explorative documentation study with a sample size of 20 patients, we could not show efficacy of IDET for chronic discogenic low back pain after 6 months. Appropriate catheter position was not associated with favorable outcome. The mechanism of possible benefit for the patient remains unclear.

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