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Risk Factors for Failure and Complications of Intradiscal Electrothermal Therapy: A Pilot Study

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Study Design. A bi-institutional, retrospective clinical data analysis.

Objectives. To determine risk factors for failure and complications of intradiscal electrothermal therapy, a treatment for discogenic back pain.

Summary of the Background Data. Intradiscal electrothermal therapy is a relatively new treatment for discogenic back pain. Though previous studies have shown it to be an effective treatment, there are few published studies examining complications and none examining risk factors for failure.

Methods. The authors treated 79 patients with discogenic back pain using intradiscal electrothermal therapy. Complications were assessed by patient report and, when indicated, further diagnostic testing. Success or failure was determined by visual analogue pain scores at 6-month follow-up. Variables examined for their relationship to failure and complications were age, sex, duration of pain, number of levels heated, smoking history, diabetes, obesity, leg pain, and previous back surgery.

Results. Forty-eight percent of patients reported more than 50% pain relief at their 6-month follow-up. There were eight complications (10%), most of which were self-limited and transient. The only risk factor associated with intradiscal electrothermal therapy failure was obesity ($P = 0.01$). Whereas 54% of nonobese patients reported good pain relief at 6 months, only one out of 10 obese patients had successful intradiscal electrothermal therapy. The obese patients in our study were more likely to have a complication from intradiscal electrothermal therapy than they were to obtain pain relief.

Conclusion. The only risk factor found to be associated with IDET outcome was obesity, which was a strong predictor of failure. Obesity should be considered a relative contraindication to performing IDET. [Key Words: back pain, discogenic pain, discography, internal disc disruption, intradiscal electrothermal therapy] **Spine 2003;28: 1142–1147**

Low back pain is one of the most frequently encountered problems physicians face. Among the various sources of low back pain, pain arising from the intervertebral discs has been estimated to be involved in approximately 39% of cases.[1] Over the past few years, the management of discogenic pain using intradiscal electrothermal therapy (IDET) has been reported to be a valuable addition to the therapeutic armamentarium of back specialists.[2,3,4,5] The mechanism by which IDET is postulated to work is by altering the collagen architecture of the discs and coagulating nociceptors.[6] Early reports of treating internal disc disruption with a spinal catheter consisting of a thermal-resistive heating coil have been extremely promising, with success rates consistently above 60%.[2,3,4,5] However, these studies have generally involved small numbers of patients, used flawed designs, and included minimal discussion of complications. In addition, the validity of claims about alterations in the collagen structure has recently been challenged.[7]

Risk factors for failed back surgery include smoking, diabetes, and obesity, and for spinal fusion, leg pain greater than back pain.[8,9,10,11] Yet because it is so new, the risk factors for failed IDET have not been identified. The purpose of this multicenter study is twofold: 1) to identify risk factors for failed IDET, and 2) to describe complications with this procedure based on patient self-report.

Materials and Methods

After obtaining permission to conduct this study from the Internal Review Boards at Walter Reed Army Medical Center (WRAMC) and Massachusetts General Hospital (MGH), the charts of 80 consecutive patients who underwent 109 IDETs between 1999 and 2002 were retrospectively reviewed. One patient in whom the catheter could not be threaded to cover the posterior anulus adequately was excluded from the study, leaving 79 study patients and 108 IDETs. Sixty-five of these patients were from WRAMC; 14 were from MGH. The diagnostic criteria used to establish a diagnosis of discogenic pain were based on the discographic categories outlined by Derby.[12] All patients classified as having discogenic pain had one or more discs with a grossly abnormal radiologic appearance on MRI and discography, and at least 6/10 concordant pain at less than 50 psi above opening pressure when contrast was injected at the abnormal discs. Patients also had to have at least one adjacent control disc.

Inclusion criteria for performing IDET were as follows: back pain duration of longer than 6 months; lack of response to previous conservative treatment, including nerve blocks; nonfocal neurologic examination; absence of prominent radicular signs and symptoms; and positive provocative discography. Exclusion criteria included age greater than 60 years, severe spinal stenosis, loss of more than 50% of disc height, significant

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spondylolisthesis, inflammatory arthritis, and unstable medical conditions that would preclude participation and follow-up, such as cardiac patients taking anticoagulants.

All treatments were performed in an ambulatory care setting using conscious sedation and superficial local anesthesia. The IDET procedure was performed in either one disc (n = 50) or two (n = 29), depending on the number of positive discograms. Using standard discographic practices, a 17-gauge introducer was placed into the center of the disc, with its position confirmed using fluoroscopy in oblique, anteroposterior, and lateral views. A navigable intradiscal catheter with a 6-cm active electrothermal tip (SpineCATH, Oratec Interventions, Menlo Park, CA) was then advanced through this trocar to pass diametrically across the nucleus pulposus until it contacted the inner, anterolateral annulus. With continued insertion, the electrode deflected circumferentially back toward the insertion side, with its circuitous route encompassing the inner perimeter of the annulus. In 11 cases in which envelopment of most of the posterior annulus could not be achieved, following coagulation the procedure was repeated from the contralateral side so that a majority of the posterior annulus was traversed by catheter and coagulated. As such, in all study patients, more than 70% of the posterior annular wall was heated.

After catheter placement was deemed satisfactory, it was attached to an Oratec radiofrequency generator and gradually heated to a temperature of 90°C over 16.5 minutes. In 10 patients who could not tolerate the full heating period, the coagulation session was terminated early. However, in all these patients, the duration of heating exceeded 12 minutes. Once coagulation was completed, cefazolin antibiotic and bupivacaine 0.5% were administered intradiscally for antimicrobial prophylaxis and postprocedure analgesia, respectively.

Following the procedure, all patients were given a lumbar support brace in order to deter movements that might elevate intradiscal pressure (*i.e.*, forward bending) and were instructed to forego intense physical training for 6 months. In the first month, permitted activities included walking and gentle leg stretches. Over the next 5 months, the intensity of exercise was gradually increased until all patients were engaged in normal activities by 6 months. In addition, all participated in a 6-week lumbar stabilization program beginning in their second month.

Since this study was undertaken with no external funding (at WRAMC there was no reimbursement for the procedure) and a large percentage of our patients were referred from great distances, our outcome measure was pragmatic. There were no patients on disability and less than 20% on opioids, so that return to work and tapering of medications were not viable indicators of success. Instead, our primary outcome measure was pain relief, with more than 50% reduction in pain 6 months postprocedure defined as success, and less than 50% relief indicating failure. Instruments used to measure pain were visual analogue scales performed at 2-month, 4-month, and 6-month follow-up visits, along with telephone and e-mail follow-ups for those patients residing outside the United States.

Patients were instructed to notify the pain center should they experience any complications or unusual symptoms. In addition, a nurse contacted all patients within 2 weeks of their procedure specifically to inquire about this. If a complication was thought to have occurred, the patient received a full neurologic examination, with referral for an MRI on a case by case basis. Variables analyzed for their association with complications and failure were as follows: age, sex, duration of pain, presence of nonradicular leg pain, smoking history, diabetes, obesity (body weight more than 20% above ideal body weight), number of levels (one or two), and previous back surgery. Categorical data were analyzed by χ^2 tests, and continuous data by *t* tests. If the *P* values associated with these tests were statistically significant, the odds ratios and confidence intervals (CIs) were reported. For those variables found to be associated with outcome or complications, logistic regression was used to obtain a multivariate analysis.

Table 1. Demographic and Clinical Characteristics of Study Patients as Determined by Outcome

Demographic and Clinical Features of IDET Patients	Positive Outcome n=38	Negative Outcome n=41
Age (mean)	37.3 (SD 11.0)	37.9 (SD 10.1)
Sex	30 M, 8 F	33 M, 8 F
Mean Duration of Low Back Pain (years)	6.0 (SD 5.5)	5.5 (SD 4.3)
Pre-IDET VAS Pain Score (mean)	5.9 (SD 1.8)	6.2 (SD 1.9)
6-Month Post-IDET VAS Pain Score (mean)	2.1 (SD 1.3)	5.1 (SD 1.8)
Number of Levels* (1 or 2)	1 level (n=27) 2 levels (n=11)	1 level (n=23) 2 levels (n=18)
Smokers (n=15)	6 (40%)	9 (60%)
Diabetics (n=3)	2 (67%)	1 (33%)
Obese Patients** (n=10)	1 (10%)	9 (90%)
Prior Back Surgery (n=13)	7 (54%)	6 (46%)
Leg Pain (n=32)	14 (44%)	18 (56%)

* P=0.17
** P=0.01

■ Results

The average age of the 79 patients was 37.6 years (range 15–60, SD 10.5), with the mean duration of low back pain 5.7 years (range 1–22, SD 4.9). There were 63 males and 16 females, with the preponderance of males due to the large percentage of military members at Walter Reed (n = 54). Fifty patients had one level treated; 29 had two discs. There were 15 smokers (19%), three patients with diabetes (4%), and 10 patients (13%) classified as obese. Thirty-two patients (40%) had symptoms of nonradicular leg pain, and 13 patients (17%) had undergone previous back surgery.

After treatment, 48% (n = 38) of patients reported more than 50% pain relief persisting at their 6-month follow-up, with eight of these patients (10%) obtaining over 90% relief. There was no difference in outcomes between active duty (26 successful IDETs out of 54) and civilian patients (12 successful IDETs out of 25). The average pre-IDET and post-IDET visual analogue scale pain scores in those with successful procedures were 5.9 (SD 1.8) and 2.1 (SD 1.3), respectively. In those with unsuccessful outcomes, the scores were 6.2 (SD 1.9) and 5.1 (SD 1.8). The breakdown of demographic and clinical data by outcome and complications can be seen in Tables 1 and 2.

Complications

Eight patients reported complications, a 10% complication rate. One patient noted a new burning sensation in one of his legs; this sensation disappeared after 2 weeks.

Table 2. Demographic and Clinical Characteristics of Study Patients as Determined by Complications

Demographic and Clinical Features of IDET Patients	Complications n=8	No Complications n=71
Age (mean)	36.5 (SD 9.3)	37.7 (10.6)
Sex	7M, 1F	56M, 15F
Mean Duration of Low Back Pain (years)	5.3 (SD 3.2)	5.8 (5.0)
Number of Levels (1 or 2)	1 level (n=5) 2 levels (n=3)	1 level (n=45) 2 levels (n=26)
Smokers (n=15)	3 (20%)	12 (80%)
Diabetics (n=3)	0	3 (100%)
Obese Patients (n=10)	2 (20%)	8 (80%)
Prior Back Surgery (n=13)	2 (15%)	11 (85%)
Leg Pain (n=32)	4 (13%)	28 (87%)

His MRI was unchanged. Two patients reported new nondermatomal paresthesias and numbness in their thighs; these symptoms resolved within a month. Only one of these had an MRI, which was unchanged. This patient went on to obtain 70% pain relief. One patient noted weakness in the L4 distribution ipsilateral to the trocar insertion site, manifested as foot drop. This resolved by 6 weeks. His MRI was unchanged. One patient reported a considerable increase in his back and thigh pain immediately following the IDET, along with new paresthesias. This patient was noted to have an increase in the size of his disc protrusion at the level heated, as well as a new disc bulge one level above. However, more than 10 months had elapsed between his pre-IDET and post-IDET MRIs. He ended up doing well with surgery. One patient who noted infrequent radicular symptoms before his IDET reported a significant increase in his lower leg pain. This patient missed two separate MRI appointments and informed us that he was following up with a physician closer to his home. One patient with a history of migraine headaches reported a severe, nonpositional headache different than her usual migraines that required hospitalization for 5 days. This patient's workup, including a CT scan of her head and lumbar puncture, was negative. Her headache resolved on its own, and she went on to obtain 100% relief from the procedure. Finally, one patient with a small, contained L5–S1 herniated disc whose symptoms included thigh pain without signs of radiculitis developed radicular symptoms and was noted on a follow-up MRI to have a very large herniation at the L5–S1 disc. However, the time interval between his pre-IDET and post-IDET MRI scans was 17 months. This patient had a two-level IDET, L4–L5 and L5–S1, proceeded by a follow-up discogram 4 months later to determine the success of the procedure and the need for surgery at the level above his herniated disc (L4–L5). The follow-up discogram was negative, indicating a successful IDET at the L4–L5 level. This patient proceeded to undergo surgery, which was successful at alleviating most of his symptoms. Only two patients with complications went on to a successful outcome. Table 3 displays a complete list of complications.

Age, Sex, and Duration of Pain

Age, sex, and duration of pain were not related to patient-reported outcomes. The mean age of the 38 patients with positive outcomes was 37.3 years (SD 11.0), with the average age of the 41 patients with less than 50% pain relief 37.9 years (SD 10.1). In the eight patients with complications, the average age was 36.5 (SD 9.3); in those without complications, it was 37.7 (SD 10.6). Thirty of the 66 males in the study (48%) reported good relief at their 6-month follow-up. Among the 16 females, half (n = 8) reported good relief. Seven of the eight complications were in men, with only the headache occurring in a woman. The average duration of pain in those obtaining good relief with IDET was 6.0 years (SD 5.5), with the mean duration in those obtaining poor relief 5.5 years (SD 4.3). The eight patients with complications had a mean duration of back pain of 5.3 years (SD 3.2). In the other 71 patients, the average duration of back pain was 5.8 years (SD 5.0). These results were not statistically significant.

Obesity and Diabetes

Of the 69 nonobese patients, 37 (54%) had a good outcome with IDET. In contrast, in the 10 obese patients, only one had a positive outcome ($P = 0.01$, odds ratio 0.096, 95% CI 0.012–0.800). Two of the 10 obese patients (20%) developed complications, which were the two worsening discs. In the normal body weight group, only six (9%) had complications. While there was a trend for obesity to be associated with complications, due to the low numbers involved, this did not reach statistical significance ($P = 0.27$). There were only three patients with diabetes in our study. Two of these obtained a good outcome, and none had complications.

Number of Levels and Back Surgery

Patients with one-level disc disease tended to have better outcomes than those with multilevel disease. Fifty-four percent (27/50) of patients who had a one-level IDET obtained more than 50% pain relief, *vs*. only 38% (11/29) of patients who had two-level IDET. Despite the trend, this difference did not reach statistical significance ($P = 0.17$, odds ratio 0.521, 95% CI 0.205–1.324). In both groups of patients, 10% experienced complications. The success rate in those patients without prior back surgery was 47% (31/66); in those with failed back surgery syndrome (FBSS), seven of 13 (54%) reported a positive outcome. These 13 FBSS patients included five who underwent laminectomy or diskectomy at the same level as their IDET (three positive outcomes), four who had laminectomy or diskectomy performed at different discs (two positive outcomes), and four who had fusions or instrumentation performed at other levels (two positive outcomes). Two of the 13 patients with FBSS developed complications (15%), *vs*. 9% (six of 66) in those

Table 3. IDET Complications

Case (patient #)	Age, Sex	Duration of Pain	No. of Levels	'Risk Factors'	Complication	Outcome
1	30, M	5 yrs	2	None	Burning sensation in leg ipsilateral to IDET; Resolved after 2 weeks	Minimal relief (VAS 9–7)
2	35, M	3 yrs	1	None	Worsening leg pain contralateral to catheter insertion site	No relief
3	29, M	1.5 yrs	2	Obesity, Leg pain	Small contained herniation converted to large, uncontained herniation at one of the discs IDETed. Patient developed new radicular symptoms post-procedure. Negative follow-up discogram at other level done.	No relief from IDET. Good pain relief reported after removal of 28 cc of disk material and single level lumbar interbody fusion.
4	40, M	7 yrs	1	Smoker, Leg pain, Prior back surgery	New paresthesias and numbness in ipsilateral thigh; Resolved after 3 weeks.	No relief
5	23, M	3 yrs	1	None	Nondermatomal parenthesias and numbness in ipsilateral leg. Resolved in 1 month. Neg MRI	70% pain relief (VAS 7 to 2)
6	37, M	8 yrs	2	Smoker, Obesity	Increased back and thigh pain. MRI showed increased size of disc protrusion at one of the levels heated, and new disc bulge at a disc not heated.	No relief with IDET. Moderate relief following single level spinal fusion.
7	49, F	4 yrs	1	Smoker, Leg pain	Severe, nonpositional headache that resolved within a week.	Complete pain relief
8	49, M	11 yrs	1	Prior surgery, Leg pain	Ipsilateral foot drop. Resolved by 6 weeks.	Mild relief (VAS 5 to 3)

without previous surgery. These differences were not significant.

Smoking

There were 15 smokers in our study, nine (60%) of whom failed IDET. Of the 64 nonsmokers, half experienced good outcomes ($P = 0.485$). Because previous studies have shown smokers to have worse outcomes with back surgery, and because there was a slight trend toward statistical significance, a multivariate analysis was performed to determine whether this difference could be explained by other factors. One third (n = 5) of the smokers were also obese, and these five patients had poor outcomes. Among the 10 smokers who were not obese, 60% (n = 6) obtained good outcomes with IDET. Therefore, after controlling for obesity, a greater percentage of smokers actually had a successful procedure than those who did not smoke, although this difference was not significant. Twenty percent (three of 15) of the smokers experienced complications with their IDET, as opposed to 8% (five of 64) of nonsmokers ($P = 0.159$). Since only one of these three patients was obese, even after controlling for obesity, the complication rate remained 20%.

Leg Pain

Fourteen of the 32 (44%) patients with nonradicular leg pain had a successful IDET procedure, compared with 51% (n = 24) of the 47 patients whose only symptom was low back pain. This difference was not significant. The eight complications were equally divided between patients with leg pain and those without, a difference that did not reach statistical significance.

■ Discussion

The introduction of IDET for the treatment of discogenic back pain has been met with intense interest over the past 5 years. During this time, there have been several uncontrolled studies published on the procedure, the large majority of which have shown excellent outcomes and few if

any complications. This study attempts to identify risk factors for failed IDET and address the complications that may occur. It is unique in that patient-reported, rather than physician-reported complications were recorded.

Our success rate of 48% is lower than that of most previous studies[2,3,4,5] but better than a more recent one.[13] Two factors may have contributed to this: our stricter criteria for success and less stringent inclusion criteria. When we first started performing IDETs in 1999, the recommended selection criteria were more liberal than today. Specifically, when the original guidelines for IDET were set forth, patients with markedly decreased disc height, prior surgery at the levels treated, and even large anular tears were deemed by some to be eligible candidates. As a result, some of the earlier patients in our study might have been excluded today. Interestingly, previous back surgery (even at the same level as the IDET), the presence of leg pain (which can indicate discogenic or radicular symptomatology), and the presence of an anular leak on discography (noted on 86% of failures *vs*. 78% of successful IDETs) were not associated with a higher failure rate.

A large percentage of patients in this study were active duty military. While this may appear to be an ideal population given the lack of workman's compensation and litigation issues, it turns out that the military has confounding psychosocial factors of its own. The medical board system in the military and workman's compensation in the civilian sector work similarly. Consequently, some soldiers may see a medical problem as an ideal means of escaping an undesirable work situation (*i.e.*, a transfer overseas or deployment to a combat arena).

The lone risk factor for IDET failure that emerged from our study was that of obesity. Obese patients in our study were far more likely to fail their treatment than nonobese patients. As a result of this finding, we no longer offer IDET to obese patients; instead, we offer to enroll them in weight reduction and exercise programs first. The other factors studied all failed to achieve statistical significance. This was due to either the relatively small sample size (as was probably the case for the number of levels) or a true lack of effect. Perhaps the ability of age, smoking, and diabetes to interfere with healing processes is less important after IDET than it is following surgery.

To date, there has been only one study that specifically addresses complications with IDET.[14] In that series, the reported rate of complications was 0.7% (12/1675). These complications were equally divided between disc herniations and nerve root injuries. In contrast, the complication rate in this study was 10%. This discrepancy is probably due to the fact that the complications listed in the IDET database were reported by physicians who were sent a questionnaire. Thus, the only complications likely to be included were significant ones that led to patients returning to their physician for additional treatment. In contrast, our complication data were derived from patient self-report. We included not only the three cases with objective findings but also subjective complaints. When viewed in this light, our complication rate actually reflects well on IDET.

Even disregarding subjective complaints, we still had an objective complication rate of close to 4%. Our two disc herniations among 79 patients is higher than that cited in other studies. In each of these cases, the patient had a pre-existing contained protrusion/herniation that seemed to have expanded after IDET. However, since many months had elapsed between their pre-IDET and post-IDET MRIs, these changes could not be definitively attributed to IDET. In addition to the IDET itself, other possible reasons for these herniations include the pre-IDET discography, post-IDET disc vulnerability (which in some patients may have been even more pronounced because of noncompliance with their post-IDET activity guidelines), and a natural occurrence in patients at high risk for disc disease. Both of the patients with disc herniations were obese, which, when considered in conjunction with our data showing poor outcomes in this population, has led us to conclude that IDET is not a good treatment for overweight people. As a result of these complications, we now require patients to have an MRI within 9 months of performing IDET. These two disc herniations, coupled with the patient with worsening leg pain who missed two MRI appointments and the patient who developed a temporary foot drop, should serve as reminders that IDET is not a risk-free procedure.

The mechanism by which IDET works is the subject of intense debate. While some experts feel pain relief is secondary to both collagen denaturation and denervation of nociceptors, others believe that nociceptor denervation alone is responsible. Ironically, both sides cite temperature studies as part of their evidence.[7,15,16] Our complication data lend credence to the theory of collagen reformation as the primary factor in successful IDETs. The fact that disc herniations can occur with IDET supports the concept that there is a critical period after coagulation and before reparative processes occur in which collagen fibers are weaker and more prone to breakage. This forms the rationale for limiting activities that result in the elevation of intradiscal pressure after IDET. If it were simply a matter of nociceptive denervation, one would not expect obese patients to have a lower success rate than nonobese individuals. We would also probably see a more rapid recovery after IDET instead of the slow, progressive improvement that typically follows a successful procedure. We postulate that obese patients are more likely to fail IDET for the following reasons:

1) Obesity itself may be a risk factor for back pain.[17] Obese patients are more likely than their nonobese counterparts to have factors besides disc disease contributing to their symptoms.

2) Following IDET, an obese patient may not be able to wear the protective lumbar brace properly secondary to enlarged abdominal girth.

3) Increased weight leads to elevated intradiscal pressure on the new, softer, vulnerable disc that may lead to either persistent microinjury (failed IDET) or macroinjury (complications).

4) Obesity may prevent patients from adequate participation in the rehabilitative process.

The major flaws of this study are its retrospective design and small cohort size. In the military, it is extremely difficult to get a placebo-controlled study approved. Since everyone is eligible for the same care without regard for compensation, the possibility of using a control group composed of patients not receiving the procedure for reimbursement reasons is eliminated. Instead, we are forced to evaluate the data in its current form. Even so, our success rate of 48% is better than expected from placebo, and the benefits in our patients held up for at least 6 months.

In conclusion, intradiscal electrothermal therapy appears to be a safe and relatively effective treatment for one-level or two-level discogenic back pain. While complications do occur, they are generally self-limited and treatable. Obesity should be considered a relative contraindication to performing IDET. Further studies are needed to ascertain the long-term effectiveness of IDET and to better identify outcome predictors.

■ Key Points

- Intradiscal electrothermal therapy was found to be a reasonably effective treatment for limited (one or two levels) discogenic pain, with 48% of patients obtaining 50% or greater relief at their 6-month follow-up.
- Including subjective patient complaints, we experienced a complication rate of 10%, with almost all complications being self-limited and treatable.
- Whereas more than 50% of nonobese patients experienced good pain relief with IDET, only 10% of obese patients had a favorable outcome.

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