Comparative Prospective Randomized Study Comparing Conservative Treatment and Percutaneous Disk Decompression for Treatment of Intervertebral Disk Herniation[1]

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Purpose: To compare short-, intermediate-, and long-term functional results concerning pain reduction and mobility improvement between conservative therapy and percutaneous disk decompression (PDD) in patients with intervertebral disk herniations.

Materials and Methods: The study received approval from both the university ethics panel and the institutional review board. Patients provided informed consent for the study. Over the past 4 years, two randomized groups of 31 patients with sciatica due to intervertebral disk herniation were prospectively studied and compared with the *t* test. The control group underwent conservative therapy (administration of analgesics, antiinflammatory drugs, muscle relaxants, and physiotherapy) for 6 weeks. The decompression group underwent fluoroscopically guided PDD. Pain reduction and mobility improvement were recorded at 3-, 12-, and 24-month follow-up on a numeric visual scale (NVS) (range, 0–10).

Results: The control group had a mean pain score of 6.9 NVS units ± 1.9 prior to conservative therapy. This was reduced to 0.9 NVS units ± 2.0 3 months after therapy; however, it increased to 4.0 NVS units ± 3.4 at 12-month follow-up and further increased to 4.0 NVS units ± 3.4 at 24-month follow-up. The decompression group had a mean pain score of 7.4 NVS units ± 1.4 prior to PDD. This was reduced to 3.0 NVS units ± 2.4 at 3-month follow-up and further reduced to 1.7 NVS units ± 2.4 at 12-month follow-up and 1.6 NVS units ± 2.5 at 24-month follow-up. No complications were noted.

Conclusion: When compared with conservative therapy, PDD shows improved amelioration of symptoms at 12- and 24-month follow-up.

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Herniation of intervertebral disks is an important and common cause of low back pain that reduces mobility, impairs physical function, decreases quality of life, and is associated with high costs to society (1,2).

Patients may present with acute symptoms or with symptoms that have gradually progressed over weeks or months (3). However, the natural history of spinal disk disease is often self limited (4). Patients with persistent pain due to intervertebral disk herniations initially undergo conservative treatment in the form of a 4–6-week course of analgesics, muscle relaxants, nonsteroidal antiinflammatory drugs, immobilization, bed rest, and physical therapy. This conservative treatment results in temporary or permanent pain reduction and mobility improvement in 80%–90% of these patients, with a complication rate of 1%–1.5% and a mortality risk for nonsteroidal antiinflammatory drug exposure as high as 12% and lasting more than 2 months (4–7).

In patients with low back pain in whom disk herniation is the causative agent and surgery is the treatment of choice, reported success rates vary from 80% to 95%, whereas complication rates vary from less than 1% to 10% (8). The complications and occasional suboptimal long-term results that accompany conservative therapy and open disk surgery in patients with intervertebral disk herniations have led to the development of other less invasive techniques.

Percutaneous disk decompression (PDD) is used in the therapy of painful contained intervertebral disk hernias to reduce the intradiskal pressure in the nucleus pulposus and to create space for the herniated fragment to implode inwards, thus reducing pain and improving mobility and quality of life (9–11).

The purpose of our study was to compare short-, intermediate-, and long-term pain reduction and mobility improvement between conservative therapy and PDD in the treatment of intervertebral disk herniation.

Advances in Knowledge

- The condition of patients with symptomatic disk herniations improved considerably with conservative therapy and percutaneous disk decompression (PDD).
- Patients who underwent PDD had significantly better self-reported outcomes at 12- and 24-month follow-up than did those who underwent conservative therapy.

Materials and Methods

All patients were informed about the study and technique, as well as possible benefits and complications associated with it, and they signed a written consent form. This study was approved by both the university ethics panel and the review board of our institution (University General Hospital Attikon). The principles of national legislation and the Declaration of Helsinki were followed. No industry support was received for this study. None of the authors received or receives commercial support or is financially involved with the device used in this study.

Patient Selection and Evaluation

During the past 4 years (from November 2006 until March 2010), we prospectively studied and compared two groups, each of which consisted of 31 patients with sciatica due to intervertebral disk herniation with no neurologic deficit. Inclusion criteria were as follows: adult patients who were capable of providing consent with a small- to medium-sized intervertebral disk herniation (occupying less than one-third of the canal diameter at magnetic resonance [MR] imaging) that was symptomatic (leg pain with or without back pain; leg pain greater than back pain when these two coexisted; lancinating, burning, stabbing, or electrical sensation of pain; straight leg raise limited to less than 30°), with the symptoms consistent with the segmental level where herniation was seen at MR imaging (an L4-5 right foraminal herniation is expected to produce right L4 root neuralgia). The primary inclusion criterion was the presence of pain of the appropriate quality with neurologic signs of radiculopathy. The diagnosis was made by an interventional radiologist with 10 years of experience (A.Kelekis) and an orthopedic surgeon with 11 years of experience (D.E.) who identified the potential participants and verified their eligibility. Patients in both groups had undergone different conservative therapies without success. In our study, preenrolment conservative therapy was not prespecified in the protocol but potentially included the following: use of nonsteroidal antiinflammatory drugs and opioid analgesics and chiropractic care.

For the randomization process, we used the following procedure: When a patient met the inclusion criteria, he or she was assigned a number (the first patient referred to our department was assigned number 1; the second patient, number 2; the third patient, number 3; etc). Patients who were assigned odd numbers were assigned to the control group, and patients who were assigned even numbers were assigned to the decompression group.

The control group (17 men; mean age, 33 years ± 4.3 [standard deviation];

Implication for Patient Care

- PDD yields significant and long-lasting results concerning pain reduction in symptomatic patients with disk herniation.

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Abbreviations:
NVS = numeric visual scale
PDD = percutaneous disk decompression

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Guarantors of integrity of entire study, D.E., D.K.F., A. Kostakos, N.L.K., A. Kelekis; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; manuscript final version approval, all authors; literature research, D.E., D.K.F., A.M., A. Kostakos, E.B., N.L.K.; clinical studies, D.E., D.K.F., A. Kostakos, N.L.K., A. Kelekis; statistical analysis, D.E., D.K.F., A. Kostakos, N.L.K.; and manuscript editing, all authors

Potential conflicts of interest are listed at the end of this article.

14 women; mean age, 39 years ± 8.3; overall mean age, 36 years ± 5.8) underwent a 6-week course of monitored and registered conservative therapy (during which they received analgesics, antiinflammatory drugs, muscle relaxants, and physiotherapy) and experienced pain reduction and mobility improvement. Detailed medical records were kept for each patient. The recommended protocol of conservative therapy included education and counseling of the patient, physical therapy, and use of nonsteroidal antiinflammatory drugs, muscle relaxants, and analgesics. Patients who underwent conservative therapy were tracked prospectively by means of personal communication once every week between the prescribing physician (D.E.) and the patient. The mean duration of conservative treatment was 22 days (range, 7–35 days) and depended on symptom regression. Our initial study design was set up to provide supervised conservative therapy for 6 weeks. However, when symptoms cleared and patients were free of pain for 3 consecutive days, conservative therapy was interrupted.

Patients in the decompression group (19 men; mean age, 36 years ± 4.3; 12 women; mean age, 40 years ± 8.4; overall mean age, 38 years ± 4.2), underwent fluoroscopically guided PDD. Each patient underwent physical examination and coagulation laboratory tests at least 24 hours prior to PDD. Before each procedure, each patient underwent a thorough clinical examination, review of his or her medical records, and evaluation of prior imaging studies. Preprocedure imaging included radiography (according to the national care system in our country, this is the standard examination when a patient is admitted to a hospital for low back pain and sciatica) and multiplanar MR imaging (T1-weighted, T2-weighted, and short inversion time inversion-recovery sequences at 1.5-T field strength). Exclusion criteria for the procedure included response to a 6-week course of rigorous conservative treatment; untreatable coagulopathy; active, systemic, or local infections; herniation occupying more than one-third of the spinal canal diameter; and noncorrelating pain. The presence of significant degenerative disease of the intervertebral disk with a disk height reduction of more than 50%–60% was considered a relative contraindication (10,12). No patient was excluded from our study because of successful conservative treatment prior to the study protocol, but 11 patients were excluded due to disk height reduction of more than 50%–60%,

Just prior to PDD, percutaneous provocative diskography was performed to verify that the disk was symptomatic. Provocative diskography yielded positive results in all patients in the decompression group. In the control group, provocative diskography was not performed, since the authors believed that it would be unethical to perform this test if minimally invasive or open surgery would not follow.

PDD Procedure

Intervertebral disk decompression (17-gauge Dekompressor; Stryker, Kalamazoo, Mich) was performed by the aforementioned interventional musculoskeletal radiologist (A.Kelekis). This procedure was performed with fluoroscopic guidance and use of a sterile technique (including prophylactic antibiotics) in accordance with the Cardiovascular and Interventional Radiological Society of Europe Standards of Practice for percutaneous treatment of intervertebral disks (Figs 1, 2) (10).

In the decompression group, we removed approximately 1–3 g of disk material. According to the guidelines provided by the manufacturer in the operative technique guide, approximately 1 mL of tissue has been removed once the tissue becomes visible at the collection chamber entrance. In general, when the technique was interrupted, the material gathered at the collection chamber entrance was approximately three times greater than the material seen the first time. Decompression may also have been stopped when the substance removed was gray or black, either because it was charred or because it was substantially degenerated (Fig 3). We did not weigh the removed material.

The average duration of PDD and percutaneous provocative diskography performed prior to PDD was approximately 45–60 minutes and depended on the difficulty of trocar placement. Each patient was observed for 2 hours after the procedure and then discharged with a prescription for postprocedure nonsteroidal antiinflammatory drugs and muscle relaxants.

Outcome Measures

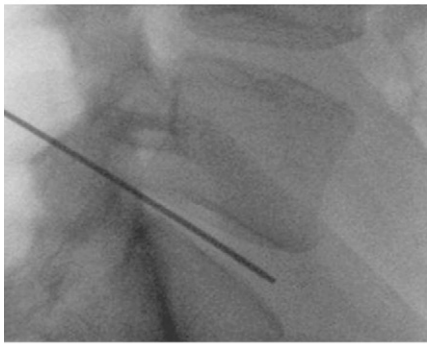
The primary outcome was defined as pain reduction, which was measured with numeric visual scale (NVS) questionnaires at 3-, 12-, and 24-month follow-up. The NVS is a 10-cm scale from 0 to 10 divided into 10 equal parts on which the patient subjectively assigns his or her pain on a scale of 0 (no pain) to 10 (worst pain patient can imagine). In addition, the inventory contains questions concerning the pain itself and its influence on the patient's activity (sleep, occupation and housework, walking) and mobility impairment. These data were obtained by an interventional radiologist with 2 years of experience who was blinded to the therapy used (D.K.F.).

Follow-up consisted of clinical visits with assessment of the *(a)* general, clinical, and neurologic condition; *(b)* pain reduction, and *(c)* mobility improvement with the NVS scale at 3-, 12-, and 24-month follow-up or whenever the patient experienced unusual discomfort or pain. At 6-month follow-up, spine MR imaging was performed in all patients (Fig 4). Patients with return of symptoms at 12- and 24-month follow-up underwent clinical evaluation and repeat MR imaging to exclude any other cause of increasing back pain, such as worsening of facet arthropathy. Questions asked during the follow-up period concerned pain reduction and mobility improvement and whether the symptoms decreased or were absent. Furthermore, on the NVS score sheet, patients answered questions concerning the effect of pain on their occupational history, as well as their daily dose of analgesics and whether there were any variations during the follow-up period.

Radiology

Figure 1

a.



b.

Figure 1: **(a)** Anteroposterior and **(b)** lateral views of the L5-S1 intervertebral disk during decompression. In **a**, the trocar is situated in the middle of the disk. In **b**, the trocar is situated in the anterior third of the disk.

Figure 2

Figure 2: The Dekompressor (Stryker) has a high rotation speed and two spiral formations that ensure aspiration of disk material during rotation.

Figure 3

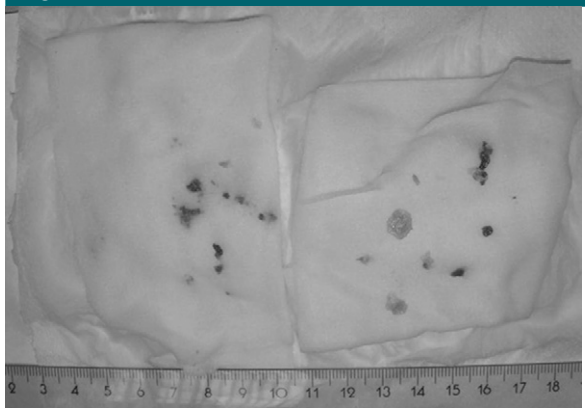


Figure 3: Intervertebral disk fragments that have just been removed with the Dekompressor (Stryker).

Statistical Analysis

All patients included in the study met the inclusion criteria and were randomly assigned to a group, as stated previously. If we had made a comparative study in two groups according to age, sex, or any combination of these, the samples would have been very small. In our study, the groups had approximately the same age and male-female ratio. To ensure impartiality, there is stratification in the two samples as a reference to age and sex. The *t* test is used for small independent groups (treatment arms). According to Masala et al (13), we considered a decrease of at least four NVS units to represent a significant improvement in numeric pain scores. Pain-free patients were those with an NVS score of 0. Since the baseline pain score was different between the groups (6.87 NVS units in the control group, 7.4 NVS units in the decompression group), we performed one-sided *t* tests to determine whether pain levels were lower at each follow-up time point than at baseline. To compare the mean value of pain reduction among the two groups, the Welch *t* test with Sattherwaite information ($P < .01$) was performed. We compared arms in terms of both the observed pain levels at follow-up and the change in pain from baseline to follow-up, adjusting for the level of pain at baseline as a covariate.

The threshold for statistical significance was $P < .01$.

For statistical computations, we used MiniTab 14 software (MiniTab Statistical Software; Pennsylvania State University, University Park, Pa).

Results

In the control group, the age of men was not significantly different from that of women. These patients had a mean pain score of 6.9 NVS units ± 1.9 (range, 4–10 NVS units) prior to conservative therapy. This was reduced to 0.9 NVS units ± 2.0 (range, 0–2 NVS units) 3 months after therapy; however, it increased to 4.0 NVS units ± 3.4 (range, 0–10 NVS units) at 12-month follow-up and further increased to 4.1 NVS units ± 3.4 (range, 0–10 NVS units) at 24-month follow-up (Table). On a percentage basis, mean pain reduction in the control group was 36% within a 24-month follow-up period.

For the patients in the control group, six (19%) experienced 100% pain relief; one (3%), 60% pain relief; two (6%), 50% pain relief; one (3%), 40% pain relief; five (16%), 30% pain relief; eight (26%), 20% pain relief; three (10%), 10% pain relief; three (10%), no relief; and two (6%), 10% aggravation of pain.

In the decompression group, the age of men was not significantly different from that of women. These patients had a mean pain score of 7.4 NVS units ± 1.4 (range, 4–9 NVS units) prior to decompression. At 2-year follow-up, they had a mean pain score of 1.6 NVS units ± 2.5) (range, 0–9 NVS units); therefore, patients included in our study had a mean decrease in pain score of 5.8 NVS units ± 2.4 ($P \leq .01$) during the 2-year follow-up. We compared pain scores obtained prior to decompression and those obtained at 3-month follow-up (mean, 3.0 NVS units ± 2.4; range, 0–9 NVS units) and discovered a mean decrease of 4.4 NVS units ± 2.1 ($P \leq .01$), which is further expanded at 12-month follow-up (mean, 1.7 NVS units ± 2.4)

Figure 4

a. b.

Figure 4: Sagittal reconstructed T2-weighted MR images of a female patient (not included in our study) who presented with back pain and sciatica. **(a)** Note the presence of L4-5 disk herniation and disk height reduction. Images were acquired at first presentation to our department, approximately 6 months after surgery. Left and right images are successive images of the same sagittal reconstruction of this MR image. **(b)** This image was acquired 6 months after treatment and shows substantial regression of herniation. Note that the disk space height has decreased further.

for a mean decrease of 5.7 NVS units ± 2.4 ($P \leq .01$) (Table).

We observed no complications during the procedure or up to 24 months thereafter.

In terms of percentage, mean pain reduction was 86%. In the decompression group, 17 patients (55%) experienced 100% pain relief; two patients (6%), 90% pain relief; two patients (6%), 80% pain relief; one patient (3%), 70% pain relief; one patient (3%), 60% pain relief; four patients (13%), 50% pain relief; one patient (3%), 40% pain relief (this patient underwent surgery 21 days later); one patient (3%), 30% pain relief; and two patients, no pain relief (6%, one of these patients underwent surgery within 1 year). Six of the eight patients with minimal improvement had reduced disk height (more than 50%–60% of the original disk height).

At 3-month follow-up, four of 31 patients in the decompression group and three of 31 patients in the control group recorded on the NVS questionnaires that pain affected their occupational status.

Comparison of Pain Reduction Achieved in Decompression and Control Groups during Follow-up Period

Time	Decompression Group (NVS units)	Control Group (NVS units)	*P* Value
Baseline	7.4 ± 1.4	6.9 ± 1.9	...
3-month follow-up	3.0 ± 2.4	0.9 ± 2.0	>.005
12-month follow-up	1.7 ± 2.4	4.0 ± 3.4	.005
24-month follow-up	1.6 ± 2.5	4.0 ± 3.4	.004

Note.—Unless otherwise indicated, data are mean ± standard deviation. No complications were reported.

At 12- and 24-month follow-up, 22 of 31 patients in the control group reported an effect of pain on their occupational status due to the return of symptoms, while the number of patients in the decompression group who reported an effect of pain on their occupational status remained unchanged (n = 4). Detailed examination of the medical records revealed that the patients with return of symptoms at 12- and 24-month follow-up reported that they had started taking analgesics again at the same daily dose as before.

In all patients with return of symptoms at 12- and 24-month follow-up who were examined clinically and with MR imaging, the noticed symptoms were attributed to intervertebral disk herniation (diagnosis was made by both A.Kelekis and D.E.). In one patient who underwent conservative therapy and was reexamined, MR imaging revealed a complete disappearance of the L5-SI intervertebral disk herniation; however, it also revealed a new L1-2 disk herniation.

Figure 5

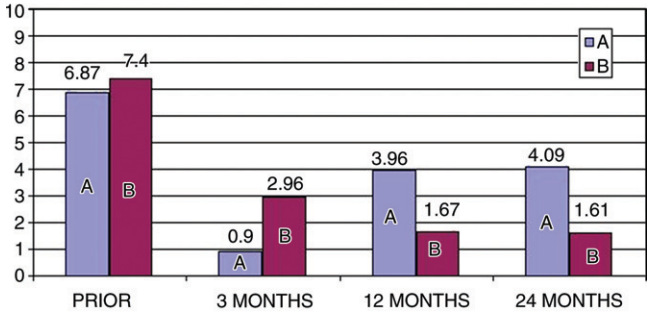


Figure 5: Graph shows that the pain reduction achieved with conservative treatment (group *A*) or PDD (group *B*) was significant at 12- and 24-month follow-up. Numbers on the vertical axis are NVS units.

Figure 6

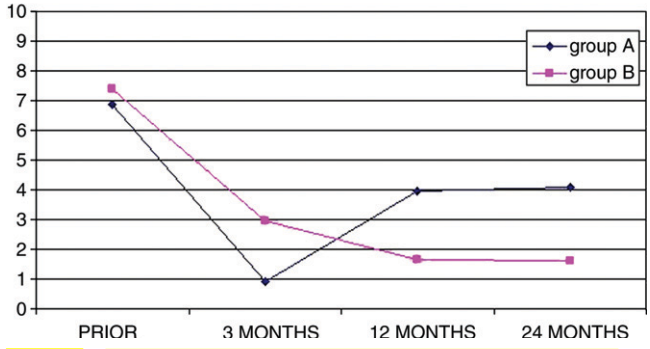


Figure 6: Graph shows results of the two methods were similar during the first 3 months; however, follow-up showed that conservative treatment *(group A)* failed in the long run, whereas results achieved with PDD *(group B)* were sustainable. This difference was significant at 12- and 24-month follow-up. Numbers on the vertical axis are NVS units.

Percutaneous intervertebral disk decompression led to a greater pain decrease when compared with conservative treatment at 12-month (P = .005) and 24-month (P = .004) follow-up (Figs 5, 6). In the control group (conservative treatment), the original pain decrease was 6.0 NVS units ± 3.2; however, the pain decrease was reduced to 2.9 NVS units ± 2.5 at 12-month follow-up and 2.8 NVS units ± 3.0 at 24-month follow-up. On the other hand, in the decompression group, the original pain decrease of 4.4 NVS units ± 2.1 is further expanded not only at 12-month follow-up (5.7 NVS units ± 2.4) but also at 24-month follow-up (5.9 NVS units ± 2.4).

Statistical analysis revealed that patients in either group who had a large (>4 NVS units) improvement at 1-month follow-up maintained these decreased symptoms ($P < .01$).

Discussion

Because of their position, role, and susceptible nature, intervertebral disks undergo injuries, as well as structural and degenerative changes, that trigger biochemical effects (inflammation and other neurobiologic processes) that can be accompanied by disabling pain (5).

PDD is a technique that uses the Archimede pump principle concerning the removal of small material volume that yields a large reduction in pressure. Compared with open surgery, PDD involves use of smaller instruments, requires no overnight hospitalization, and is performed without any epidural space violation or direct manipulation of the nerve root (14). The most common complication associated with PDD is diskitis (0.2% frequency) (8), although none of these patients had any complications.

Unfortunately, because of the small size of the apparatus and the minimally invasive approach, only small- to medium-sized disk herniations can be treated. This is because the most appropriate patients for PDD are those with less severe surgical disk disease, and with the high percentage of patients who respond to conservative treatment, at least a 6-week course of rigorous conservative treatment (use of analgesics, anti-inflammatory drugs, muscle relaxants, and physiotherapy) should precede PDD (8,14).

According to the results of our study, patients who undergo PDD have a similar response to those who undergo conservative therapy during the first 3 months after treatment. However, in the long run, we found that patients who undergo conservative treatment have significantly worse results than those who undergo PDD. Pain reduction after PDD occurred during the 1st month, was sustained for 2 years, and had a significantly better outcome than did conservative therapy. However, our study shows that the results of PDD in patients with disk herniation and disk height reduction of up to 40%–60% of the original height (as noted on the MR image prior to PDD) are not satisfactory.

Although our results support the relative long-term benefit of percutaneous disk decompression over conservative therapy, this does not mean that conservative therapy should no longer be the recommended initial therapy mode. The first step in the treatment of patients with symptomatic intervertebral disk herniation should be a 4–6-week course of conservative therapy. Interestingly, all patients in the group that underwent conservative treatment were pain free before the end of the 6-week course. However, it is unclear if there is a time window beyond which the relative benefit of conservative therapy diminishes or below which conservative therapy is deemed to fail.

One major limitation of our study was that the mode of the performed treatment could not be masked. Thus, since we measured subjective outcomes, there is a possibility that the patients might have been affected by knowledge of the treatment assignment. Recovery motivation differences, different expectations for therapy success, and the perception of a change in health status could have affected our results. Another drawback of this study is that since patients in the control group received some kind of conservative therapy, one might assume that those in whom conservative treatment had already failed would be predestined to have another form of therapy fail again.

In conclusion, in this prospective randomized study of patients with symptomatic intervertebral disk herniation, both groups improved considerably within the 24-month follow-up period. Nevertheless, patients who underwent percutaneous intervertebral disk decompression had significantly better self-reported outcomes than those who underwent conservative therapy.

Disclosures of Potential Conflicts of Interest: D.E. No potential conflicts of interest to disclose. **D.K.F.** No potential conflicts of interest to disclose. **A.M.** No potential conflicts of interest to disclose. **A.Kostakos** No potential conflicts of interest to disclose. **E.B.** No potential conflicts of interest to disclose. **N.L.K.** No potential conflicts of interest to disclose. **A.Kelekis** No potential conflicts of interest to disclose.

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