Percutaneous lumbar discectomy using the Dekompressor®-system under CT-control

Original article

Short title: Percutaneous discectomy under CT-control

Key words: Percutaneous; lumbar; discectomy; Dekompressor; CT-control;

Abstract

Background:

During the last years, the introduction of new minimally-invasive therapies for the treatment of radicular pain associated with contained disc herniation has changed the field of interventional pain management. In a prospective, non-randomized case study we treated patients using the Dekompressor® system. For the first time, these procedures were performed under the use of computed tomography instead of fluoroscopy.

Methods:

In a prospective, non-randomized case study we treated patients using the Dekompressor® system. For the first time, these procedures were performed under the use of computed tomography instead of fluoroscopy. Pain scores, analgesic usage and deficits in activities of daily life were reassessed by a study nurse in structured telephone interviews 6 and 12 months after the procedure.

Results:

64 patients were treated at 76 lumbar levels. Follow-up data after 12 months are available for all patients. The average reported pain level was VAS 7.3 before the procedure and 2.1 after 12 months. Before the procedure, 61 patients (95 %) used opioid or non-opioid analgesics regularly, after 1 year a reduction in analgesic use was seen in 51 patients (80 %). None of the patients reported procedure-related complications.

Conclusions:

If standardized patient selection criteria are used, treatment of patients with radicular pain associated with contained disc herniation using the Dekompressor® is a safe and efficient procedure.

Indroduction

Compressive or non-compressive radiculopathy due to herniation of the intervertebral disc is a frequent cause of discogenic leg pain. When a progressive motor, sensory, or reflex change is noted on serial neurological examination, decompression of the spinal nerve has to be considered. Surgical disc decompression produces clinical improvement by reducing the pressure within the intervertebral disc and on the adjacent nerve root (Smith et al., 1995, Alo 2003). The efficacy of that approach may be limited however, by re-herniation and/or scar tissue-related complications. Open surgical disc decompression is associated with complications resulting from infections, prolonged immobilization and wound healing disorders; furthermore, it shows to be ineffective in some patients (Lee et al., 1995, Coppes et al., 1997, Alo 2003).

In the larger group of patients with non-compressive disc herniation, open surgical disc decompression plays only a limited role. These patients typically present with pain, but non-progressive neurological changes. They are usually treated with rest, physical therapy and nonsteroidal anti-inflammatory medications, but also these non-operative strategies commonly fail. Thus, over the last 30 years a variety of percutaneous intradiscal therapies have been developed. During the last years, the introduction of new minimally-invasive therapies has changed the field of interventional pain management.

The Stryker Dekompressor® (Stryker, Kalamazoo, MI, USA) is a single-use probe intended for percutaneous discectomies under fluoroscopic imaging. The device removes a predetermined amount of disc material from the herniated disc, reducing pressure in the disc and the surrounding area. Using a cannula placement similar to that used for a standard discography, less perineural scarring and less postoperative fibrosis may be expected. After various studies showed promising results of the use of the Dekompressor®, we started using this therapy in a series of carefully

selected patients with lumbar disc herniations. The standard imaging method for spinal injections is fluoroscopy, but this method doesn't enable to visualize soft tissue (Lierz et al., 2005). To improve post-interventional results and to minimize the rate of complications, we therefore assessed the alternative use of computed tomography for this procedure in a prospective, non-randomized case study with a one year follow-up.

Methods

Between January 1, 2005 and December 31, 2007 we included all patients undergoing percutaneous discectomy at our hospital in this prospective non-randomized trial.
We obtained institutional review board approval and informed patient consent to perform this study.

Inclusion Criteria:

- Radicular pain associated with contained disc herniation less than or equal to 6mm.
- Clinical history and physical examination findings consistent with radiographic findings of a disc herniation < 6mm.
- Duration of radicular pain greater than 6 months.
- Failure of conservative therapy including: physical therapy, therapeutic injections, oral analgesics and anti-inflammatory medications.
- Good to excellent short-term (< 2 weeks) response to fluoroscopically guided transforaminal injection of local anesthetic and corticosteroid at symptomatic level(s).
- Confirmatory selective segmental spinal nerve block with .5-1.5 cc of anesthetic providing >80% relief of radicular pain lasting at least the duration of local anesthetic.
- Preservation of disc height (less than 50% loss).

Exclusion Criteria:

- Progressive neurological deficit.
- More than 2 symptomatic levels.
- Previous open surgery at proposed treatment level.
- Spinal instability.
- Spinal fracture or tumor.

- Pain drawing inconsistent with clinical diagnosis.
- Significant co-existing medical or psychological condition.

The procedure using the Dekompressor® was standardized prior to the initial patient evaluation.4 First, a detailed physical examination was performed to assess for lumbar radicular involvement. Any patient with an evolving neurological deficit (myelopathy, worsening sensory, paresis, reflex change, or bowel/bladder functional loss) was deemed to likely have a compressive herniation and was referred for spinal surgery evaluation and was not included in this cohort. Record review was then performed on included patients to confirm a lack of sustained response to medical management (physical therapy, oral analgesic/anti-inflammatory medication and/or corticosteroid at the root/epidural level). An imaging study (e.g. MRI) was then assessed specifically for a lumbosacral disc herniation or other structural explanation for the radicular findings. Pain was assessed using an 11 point visual analogue scale (VAS, 0-10 cm) at the day of the procedure and 2 days after the procedure. Type and daily dosage of the analgesics used by the patients were documented. Before the procedure, the patients self-assessed their activities of daily life. A standardized assessment of activities of daily life is routinely used by German medical review boards to examine patient care needs (Holdenrieder 2003). The patients requiring care are assigned to one of three defined care levels. Pain scores, analgesic usage and activities of daily life were reassessed by a study nurse in structured telephone interviews 6 and 12 months after the procedure. A reduction of the daily analgesic dosage of 50 % or more, termination of the use of opioid analgesics or complete termination of chronic analgesic use after the procedure were considered to be a reduction in analgesic usage. Change of the care level to a less intensive care level or to a situation requiring no care after the procedure was considered a functional improvement. All patients were also asked whether they were satisfied with the effects of the procedure.

Prior to percutaneous decompression, informed consent was obtained with full disclosure. Monitored anesthesia care was used with the patient remaining awake and interactive throughout the procedure. Patients were placed on the CT-table in a prone position, native imaging was performed and the injection (angle and depth) was simulated on the screen. Patients in which the disc appeared not to be reached with the needle without conflict with blood vessels or nerves were excluded. Disc access was gained with a posterolateral, extrapedicular approach on the symptomatic side using the straight 1.5 mm (17G) Dekompressor® cannula with stylet (Fig. 1-2). This approach is similar to that used for standard lumbar discography.

Once the cannula was placed under CT-control, a depth stop was then positioned on the cannula to mark the ventral annular/nuclear boundary. The probe (titanium auger) was then introduced through the cannula. This auger is connected to a disposable rotational motor, which mechanically aspirates nucleus along this element toward the proximal chamber (Figure 3). Each herniation was decompressed for an average of 3 minutes. The duration of the procedure was measured from the beginning of the first CT-imaging to the removal of the cannula. The time of duration was averaged over the first and the last 10 procedures in patients where only 1 level was treated.

Results are expressed as mean, minimum and maximum. The relationship between two variables was tested using Pearson's product-moment coefficient. Patients treated at one level were compared with patients treated at two levels. The patients treated on one level were divided into two groups: patients with removed disc volumes lower or higher than the calculated average. For comparison of the groups, the chi-square test was used. Differences were considered statistically significant for $p < 0.05$.

Results

In the period between January 1, 2005 and December 31, 2007 percutaneous lumbar discectomies were planned in 66 patients at our hospital. 2 patients were excluded because we saw in the CT simulation before performing the procedure a spinal root nerve in the way of the needle. This both patients did not receive a discectomy or a puncture with the needle.
Demographic data from the 64 patients are listed in Table 1. Before the procedure, 61 patients (95 %) used opioid or non-opioid analgesics regularly. The average reported pain level was VAS 7.3 (minimum 4, maximum 9), all patients (100 %) suffered from disabilities in their activities of daily live.

Percutaneous decompression/discectomy was completed in all 64 patients at 76 levels. Over the observation period, duration of the CT-controlled percutaneous discectomy decreased from 33 minutes to less then 15 minutes. The distribution of levels is also listed in Table 1. The average pain score was at VAS 3.5 (minimum 0, maximum 7) two days after the procedure, at VAS 2.4 (minimum 0, maximum 6) after 6 months and after 12 months at 2.1(minimum 0, maximum 6) after 12 months. The improvement in pain levels was statistically significant 2 days ($p<0.001$), 6 months ($p<0.001$) and 12 months ($p<0.001$) after the procedure. Patient satisfaction was 73 % after 6 months and 77 % after 12 months. A reduction in analgesic use was seen both after 6 months in 49 patients (77 %) and after one year in 51 patients (80 %). Improved activities of daily life were seen in 44 patients (69 %) after 6 months and in 49 patients (77 %) after 12 months. None of the patients reported procedure-related complications.

The average volume of removed disc tissue was 1.26 mL (minimum 0.3 mL, maximum 2.25 mL). Between the two groups of patients in which low or high tissue volumes were removed, no differences in VAS, analgesic use and activities of daily life were found. When

patients with single level treatment were compared with patients undergoing treatment of 2 levels, the latter were less satisfied ($p < 0.05$) and had more limitations in their activities of daily life ($p < 0.05$) after 6 months. The analgesic usage of single level treated patients was lower after 12 months ($p < 0.05$).

Discussion

As noted above, discogenic leg pain is one of the primary causes of health care expenditure. Choosing the most effective and safest treatment option is a great challenge and an unsolved problem. Open surgical decompression has complication rates of up to 13%, including discitis in 1%, serious neurological complications in 0.3-0.6% or death in 0.06-0.21% (Ramirez et al., 1989, Ramirez et al., 1989, Stolke et al., 1989, Adams et al.,2000, Southern et al.,2000, Amoretti and Huchot 2005, Alo and Wright 2004, Scanloon et al., 2007). Several less invasive methods of discectomy were introduced over the years, all techniques sharing the same disc access approach as applied for discography. From injection of papain into the disc, to percutaneous nucleotomy using special cutters or laser, all these systems were difficult to use.

Among the major advantages of the new Dekompressor® system is the low diameter of the canula, making sure to minimize the injury at disc insertion. Unlike all other available systems, the device removes material from the disc that can be quantified and examined histologically. The removal of this tissue decreases the intradiscal pressure and relieves compressed nerves (Amoretti and Huchot 2005). In a first case series published by Alo et al., percutaneous discectomy with the Dekompressor® resulted in a significant improvement in functionality, pain scores (VAS), and patient satisfaction in patients with radicular pain (Alo and Wright 2004).

In 2005, Alo et al. published data on a one year follow-up of their initial cohort of fifty patients. We are now able to confirm the persisting improvements concerning a reduction in pain and analgesic intake. With seventy-seven percent (compared with ninety percent) after 1 year, self-reported improvements in functional status were lower in our study, possibly reflecting different attitudes and expectations in various countries. Surprisingly we also find a tendency to further improvement between 6 and 12 months after the procedure. This might be due to the lack of

accelerated disc degeneration after the Dekompressor® procedure (Smith et al., 1995, Adams et al., 2000, Southern et al., 2000, Chen 2002, Caragee et al., 2003, Amoretti and Huchot 2005). Also Amoretti et al noted an improvement of more than 70% in 79% of the posterolateral foraminal or extraforaminal hernias over 180 days using the Dekompressor system (Amoretti et al., 2006).

Currently there are no specific recommendations on the amount of tissue to be removed. In an animal study the volume reduction seemed to correlate with the decrease of intradiscal pressure (Alo and Wright 2005). We therefore compared the effect on patients, in which low or high tissue volumes had been removed, but found no relationship between volume reduction and outcomes. Direct visual control of the bulging disc during the procedure might lead to a beneficial relationship between the removed volume and the size of the herniation. Further studies to enhance the understanding of this relationship are necessary.

Due to the fast and gentle procedure, it is possible to treat multiple levels of the lumbar spine at the same time. But patients with multiple levels showed to benefit less in various outcome parameters. Like in any other procedure, choosing patients with the right indication is crucial. We therefore recommend considering that patients with a disc herniation limited to a single level can expect better outcomes.

If standardized patient selection criteria are used, treatment of patients with radicular pain associated with contained disc herniation using the Dekompressor® is a safe and efficient procedure.

References

1. Smith SE, Darden BV, Rhyne AL Wood KE. Outcome of unoperated discogram-positive low back pain. Spine 1995; 20: 1997-2000.
2. Coppes MH, Marani E, Thomeer RT, Groen GJ. Innervation of the painful lumbar discs. Spine 1997; 22: 2342-2350.
3. Lee CK, Vessa P, Lee JK. Chronic disabling low back pain syndrome caused by internal disc derangements: The results of disc excision and posterior interbody fusion. Spine 1995; 20: 356-60.
4. Alo` K. Interventional algorithm for back and leg pain: A clinicians guide to success. 6th International Neuromodulation Society World Congress/6th annual meeting of the Spanish Society of Pain live interactive cadaver course. Madrid, Spain; June 24th, 2003
5. Lierz P, Felleiter P, Alo K. CT-controlled percutaneous lumbar discectomy in therapy of radicular pain. Anästhesiologie Intensivmedizin Notfallmedizin Schmerztherapie 2005; 40: 179-183
6. Holdenrieder J: Comparative Evaluation of Long-term Care Policies for the Elderly in the EU. Peter Lang Publ., Frankfurt am Main, 2003
7. Ramirez LF, Thisted R. Using a national health care data base to determine surgical complications in community hospitals: lumbar discectomy as an example. Neurosurgery 1989; 25: 218-25.
8. Ramirez LF, Thisted R. Complications and demographic characteristics of patients undergoing lumbar discectomy in community hospitals. Neurosurgery 1989; 25: 226-30.
9. Stolke, D, Sollmann WP, Seifert V. Intra-and postoperative complications in lumbar disc surgery. Spine 1989; 14: 56-9.
10. Adams MA, Freeman BJ, Morrison HP, Nelson IW, Dolan P. Mechanical initiation of intervertebral disc degeneration. Spine 2000; 25: 1625-36.

11. Southern EP, Fye MA, Panjabi MM, Patel TC, Cholewicki J. Disc degeneration: A human cadaveric study correlating magnetic resonance imaging and quantitative discomanometry. Spine 2000; 25: 2171-2175.

12. Amoretti N, Huchot F. Percutaneous nucleotomy: preliminary communication on a decompression probe (Dekompressor) in percutaneous discectomy. Ten case reports. Clinical Imaging 2005; 29: 98–101

13. Alo K, Wright R. Percutaneous Lumbar Discectomy: Clinical Response in an Initial Cohort of Fifty Consecutive Patients With Chronic Radicular Pain. Pain Practice 2004; 4: 19–29

14. Scanloon GC, Moeller-Bertram T, Romanowsky SM, Wallace MS. Cervical transforaminal epidural steroid injections: more dangerous than we think? Spine 2007; 32: 1249-1255.

15. Alo K, Wright R. Percutaneous Lumbar Discectomy: One-Year Follow-Up in an Initial Cohort of Fifty Consecutive Patients with Chronic Radicular Pain. Pain Practice 2005; 5: 116-124

16. Chen Y. Nucleoplasty for chronic discogenic back pain with and without sciatica: 1-year clinical follow-up study. In: International Spinal Injection Society, 10th Annual Meeting, September 7, 2002. Austin, Texas

17. Caragee EJ, Hahn M, Suen P, Kim D. Clinical outcomes after lumbar discectomy for sciatica: The effects of fragment type and annular competence. J Bone Joint Surg Am. 2003; 85-A:1; 102-108.

18. Amoretti N, David P, Grimaud A, Flory P, Hovorka I, Roux C, Chevallier P, Bruneton JN. Clinical follow-up of 50 patients treated by percutaneous lumbar discectomy Clin Imaging. 2006 Jul-Aug;30(4):242-4

Fig. 1: CT-image of the needle during positioning into the disc

Fig. 2: CT-image of the needle in the disc during the discectomy

Fig. 3: Dekompressor® details (Courtesy of Stryker Corp.)

Percutaneous lumbar discectomy using the Dekompressor®-system under CT-control

Peter Lierz MD [1], Kenneth M Alo MD [2], Peter Felleiter MD [3]

[1] Department of Anaesthesiology and Intensive Care Medicine

Marienkrankenhaus Soest

Germany

[2] Houston Texas Pain Management

Palladium for Surgery- Houston

Houston, Texas USA

[3] Department of Intensive Care Medicine

Swiss Paraplegic Centre Nottwil

Switzerland

Corresponding author: Peter Lierz, MD

Marienkrankenhaus Soest

Widumgasse 5

59494 Soest, Germany

Tel +49-2921-3911201

Fax +49-2921-3911209

anaesthesie@marienkrankenhaus-soest.de

Short title: Percutaneous discectomy under CT-control

Key words: Percutaneous; lumbar; discectomy; Dekompressor; CT-control;

Figures and Illustrations

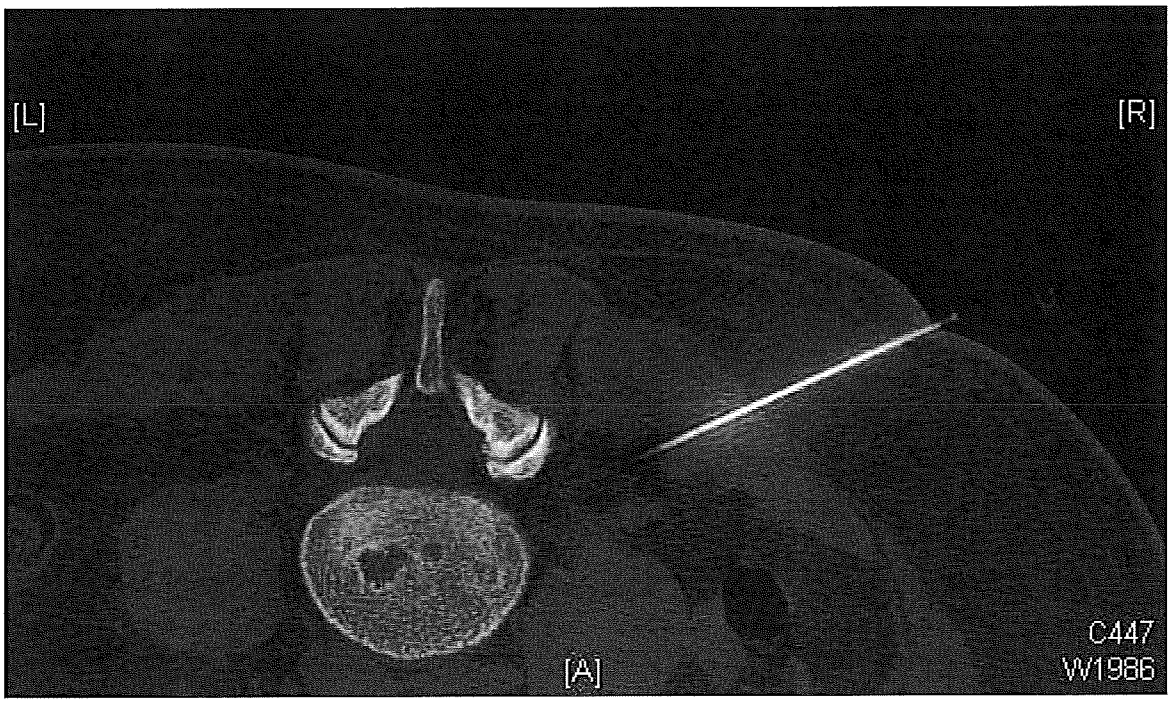


Fig. 1

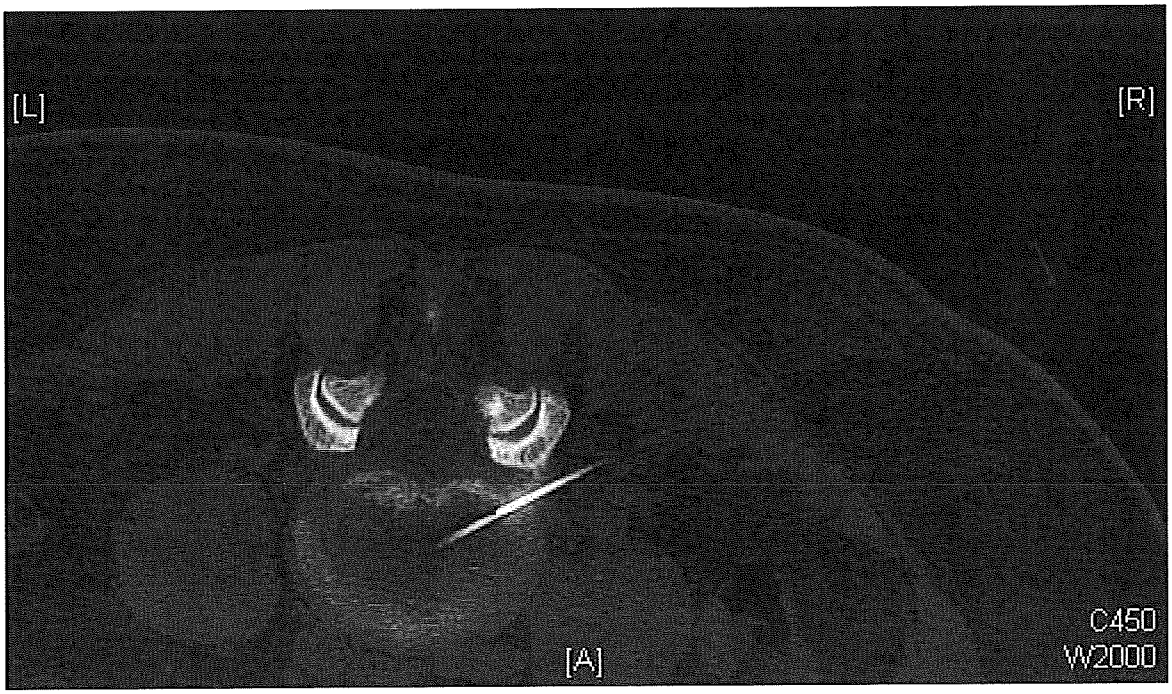
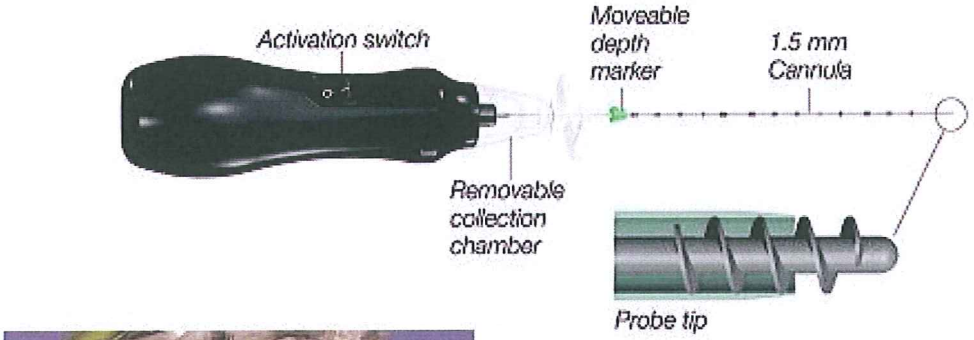
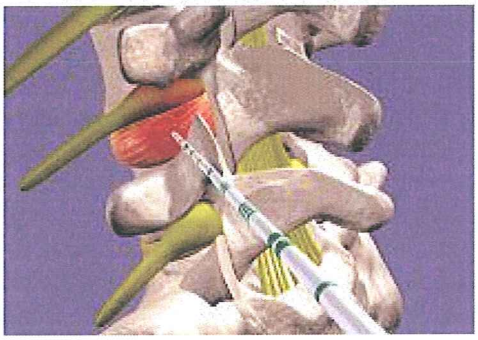


Fig. 2


Activation switch
Moveable depth marker
1.5 mm Cannula
Removable collection chamber
Probe tip



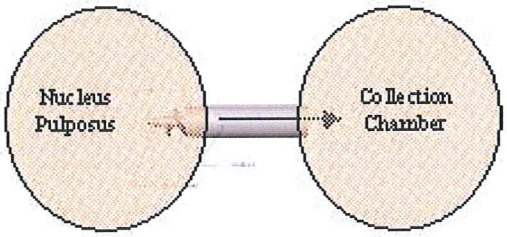

Nucleus Pulposus
Collection Chamber

Fig.3

Tables

n =	64	
Male	34	
Female	30	
Age (y)	53	min 26, max 76
Treated levels	76	
L2/3	2	3 %
L3/4	7	9 %
L4/5	35	46 %
L5/S1	32	42 %

Table 1: Patient data