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Reprinted from
SPINE

Vol. 31, No. 24, November 15, 2006
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Transforaminal Posterolateral Endoscopic Discectomy With or Without the Combination of a Low-Dose Chymopapain: A Prospective Randomized Study in 280 Consecutive Cases

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Study Design. A prospective randomized study involving 280 consecutive cases of lumbar disc herniation managed either by an endoscopic discectomy alone or an endoscopic discectomy combined with an intradiscal injection of a low dose (1000 U) of chymopapain.

Objective. To compare outcome, complications, and reherniations of both techniques.

Summary of Background Data. Despite a low complication rate, posterolateral endoscopic nucleotomy has made a lengthy evolution because of an assumed limited indication. Chemonucleolysis, however, proven to be safe and effective, has not continued to be accepted by the majority in the spinal community as microdiscectomy is considered to be more reliable.

Method. A total of 280 consecutive patients with a primary herniated, including sequestered, lumbar disc with predominant leg pain, was randomized. A clinical follow-up was performed at 3 months, and at 1 and 2 years after the index operation with an extensive questionnaire, including the visual analog scale for pain and the MacNab criteria. The cohort integrity at 3 months was 100%, at 1 year 96%, and at 2 years 92%.

Results. At the 3-month evaluation, only minor complications were registered. At 1-year postoperatively, group 1 (endoscopy alone) had a recurrence rate of 6.9% compared to group 2 (the combination therapy), with a recurrence rate of 1.6%, which was a statistically significant difference in favor of the combination therapy ($P = 0.045$). At the 2-year follow-up, group 1 reported that 85.4% had an excellent or good result, 6.9% a fair result, and 7.7% were not satisfied. At the 2-year follow-up, group 2 reported that 93.3% had an excellent or good result, 2.5% a fair result, and 4.2% were not satisfied. This outcome was statistically significant in favor of the group including chymopapain. There were no infections or patients with any form of permanent iatrogenic nerve damage, and no patients had a major complication.

Conclusions. A high percentage of patient satisfaction could be obtained with a posterior lateral endoscopic discectomy for lumbar disc herniation, and a statistically significant improvement of the results was obtained

when an intradiscal injection of 1000 U of chymopapain was added. There was a low recurrence rate with no major complications. The method can be applied in any type of lumbar disc herniation, including the L5-S1 level.

Key words: endoscopic discectomy, chymopapain, Chymodiactin, chemonucleolysis, HNP, disc herniation, percutaneous nucleotomy. **Spine 2006;31:E890-E897**

It can be assumed that worldwide, dorsal mini-open and microdiscectomy is the most widespread procedure for the decompression of a radicular syndrome caused by disc herniation. A breakthrough of less invasive decompressive procedures was made by the introduction of chymopapain by Smith.^{1,2} After the Food and Drug Administration approval of chymopapain in 1982, the intradiscal injection of chymopapain received worldwide popularity, but after several years, the enthusiasm regressed because of a few serious complications, like transfers myelitis (most likely due to false intrathecal injections) and anaphylactic reactions. In addition, transient postoperative back spasms in up to 35% of the cases occurred, and a failure rate of about 20% occurred^{3,4} requiring subsequent surgery. This has faded the enthusiasm cipher of the enzyme in favor of microdiscectomy. As more recently published,⁵ the application of chymopapain should still be considered an effective and safe treatment for the herniated discs. A number of other transforaminal percutaneous treatments emerged^{6,7} as transforaminal decompression appeared to cause less instability compared to posterior decompression.⁸ In 1975, Hijikata *et al*⁹ published their first experiences with the closed percutaneous nucleotomy with a 2.6-mm cannula, where as Kambin *et al*¹⁰⁻¹⁹ used a 4-mm Craig²⁰ cannula. Onik *et al*²¹ introduced a suction probe having an outer diameter of 2.5 mm for removal of nuclear tissue. This procedure was extensively studied and reported with limited results.²²⁻²⁴ Choy²⁵ introduced percutaneous laser nucleolysis of the lumbar disc herniation, and many authors^{26,27} reported the results. Additional percutaneous techniques were developed.^{28,29} Comparative studies, however, did demonstrate that chemonucleolysis appeared to be more effective than percutaneous nucleotomy or percutaneous laser decompression.³⁰ Disappointment with the outcome of central nuclear evacuation evolved the technology that permitted transforaminal access to the herniation site and the compressive elements, resulting in cannulas of a 6.5 and

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Acknowledgment date: January 12, 2006. First revision date: June 7, 2006. Acceptance date: July 10, 2006.

The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

No funds were received in support of this work. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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8.5-mm outer diameter.¹⁰⁻¹⁹ In addition, arthroscopes³¹ and endoscopes^{32,33} were introduced to visualize the intraforaminal nerve root, thereby avoiding postoperative radiculitis. With the until recently available instruments, the main disadvantages of the percutaneous transforaminal procedures have been: (1) its limited indication for patients with a contained and small-sized subligamentous lumbar disc herniation³⁴⁻³⁶ and (2) a 10% reoperation rate.³⁷ Access to the L5-S1 level can be difficult, particularly in males because of interference of the iliac crest. In 1994, new instrumentation was introduced in our institution,³⁸⁻⁴¹ enabling the enlargement of the foramen with special reamers so that the anterior spinal canal could be made accessible for endoscope and instruments also for the L5-S1 level, and avoiding injury to the exiting nerve root, a problem that has been reported after the regular transforaminal approach. At that point, all types of disc herniations became accessible with the lateral percutaneous approach.⁴² A total of 137 patients with a 1-year follow-up was reported with this technique in 1998, with a 88.3% success rate.⁴³ In September 1995, the indication was extended to all types of disc herniations, and the present study was initiated to evaluate the effect of an additional injection of a low-dose chymopapain. As in 1 study⁴⁴ in open lumbar discectomy, the adjunct did reduce the recurrence rate. Both the endoscopic discectomy and the treatment with chymopapain are established treatments in Germany for herniated discs, and, besides specific informed consent regarding the potential complications, including an anaphylactic reaction with chymopapain, no specific approval of the ethical committee was required.

■ Materials

From January 9, 1996, until January 7, 1998, 280 patients were randomized in 2 groups. Inclusion criteria were: (1) primarily radicular pain; (2) magnetic resonance imaging (MRI) or computed tomography proven disc herniation corresponding to the neurologic findings; (3) a clear nerve-root tension sign with a straight leg raising sign of less than 45, or a positive neurologic finding in terms of an absent knee or ankle reflex, corresponding dermatomal numbness or weakness of quadriceps, foot-toe-dorsiflexors or triceps-weakness; and (4) in all patients, conservative treatment had failed. Exclusion criteria were: (1) obesity (patients that had an excess weight of 30 kg over: body weight minus body length minus 100 cm \times 1 kg); (2) previous disc surgery; (3) symptomatic herniations at more than 1 level; (4) patients younger than 18 years; and (5) patients older than 60 years. A total of 280 consecutive patients that met the inclusion criteria were randomized into 2 groups according to their birthday. Patients with an even birthday (group 1: 142 patients) underwent the endoscopic discectomy alone, and patients with an uneven birthday (group 2: 138 patients) had the combination with 1000 U of intradiscal chymopapain.

■ Methods

All patients were treated as a day case or with one overnight stay and the first outpatient follow-up on the next day. The procedure was performed with local anesthesia, intravenous sedation with opioid anesthesia, and 2-10 mL midazolam se-

dition. The procedure was performed with the patient lying on his opposite site on a radiolucent table in the operating suite. The back of the patient was disinfected, and a sterile screen drape was applied. A biplane fluoroscopy was used for radiograph imaging. Then the entrance point was determined with a metal rod that was projected with imaging guiding toward the isthmus of the upper lamina of the involved level. Depending on the size of the patient, gender, and level, the entrance point was located at the L5-S1 level at 12-16 cm from the midline, at the L4-L5 level at 11-14 cm from the midline, at the L3-L4 level 8-10 cm from the midline, and at L2-L3 level 7-9 cm from the midline. Then the skin was infiltrated with local anesthesia, and an 18-gauge needle was aimed at the isthmus of the upper lamina for the L4-L5 and L5-S1 levels, and it was aimed at the facet joints of the affected levels in herniations at the L3-L4 level or above. Once the isthmus was reached, a second, longer 22 curved needle was introduced and guided into the extruding or sequestered fragment. Then the first needle was advanced over the second needle up to disc height. The second needle was then withdrawn and again introduced with the curve pointed laterally entering the disc space. With the second needle, the disc space was usually entered into the center of the disc. Subsequently, up to 3 cc of iohexol (240 mg/mL) contrast was injected, and pain reaction, dye leakage, and resistance were recorded. In patients in group 2, it was determined whether a low-resistant massive dye leakage was present. In group 2, out of the 138 patients, 8 did demonstrate a massive leakage of low dose, meaning that an intradiscal injection of chymopapain was fruitless and possibly dangerous, and these patients were excluded from the study and only had an endoscopic decompression and fragment removal without chymopapain injection. If no massive low-pressure leakage was present, in group 2, all patients first received an intradiscal injection of 1000 U of chymopapain. At that point, the second needle was withdrawn and replaced by a guidewire. Over the guidewire, a stab incision of about 8 mm was made, and stepwise guiding and dilatation rods were introduced. The first guiding rod was a straight rod that was introduced up to the isthmus of the lamina. Subsequently dilating cannulas of 3.5, 5, and 6 mm were advanced up to the facet joint, then the facet joint capsule was infiltrated with 5 cc of lidocaine 2% with adrenaline. Following this, the rod and cannulas were removed except for the guiding wire, and, under imaging, a curved guiding rod of 2 mm then was advanced into the extruding or sequestered fragment. Subsequently, a 3.5-mm tube was pushed over the curved rod up to the facet joint area (Figures 1-3).

At that point, the first cannula was docked at the facet capsule or bone. Over this rod, a 4.5-mm hand reamer was then introduced over the cannula and the resisting capsule, and bone was reamed away until resistance faded, meaning that the spinal canal was about to be entered. This was checked with an anteroposterior image view. At this point, except the guiding wire, all instruments were removed, and a second, thicker, guiding rod was reintroduced over the guiding wire. At the level of the isthmus, the guiding wire was then removed, and the guiding rod was introduced deeper and advanced with the aid of a mallet advancing the tip of the guiding rod into the direction of the herniated fragment. The position of the tip of the guiding rod was inspected in 2 directions with the image intensifier, and it was ensured that the guiding rod came in the vicinity of the extruding or protruding fragment. In case this could not be achieved, the first step of the operation was re-

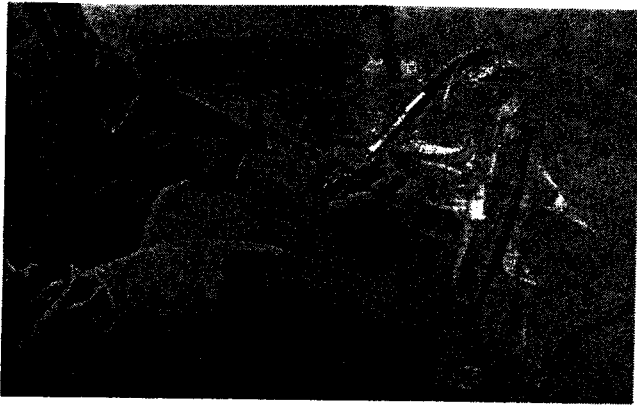


Figure 1. Endoscopic approach.

peated. After that, guiding rod No. 2 was again introduced and advanced toward the aimed fragment of the disc herniation. At that point, a corresponding 4.5-mm cannula was introduced over the guiding rod. This again was blocked at the facet level, and a larger 5.5-mm reamer was then used to, subsequently, open and enlarge the foramen. After the second reaming, all instruments were again removed except for the guiding wire, and a third guiding rod 5.5 mm in diameter was introduced again up until the isthmus. The guiding rod was then advanced with a mallet under imaging in 2 directions toward the fragment to be removed. Subsequently, a 6.5-mm cannula and 7.5-mm reamer were introduced, yielding in a foraminal opening of 7.5 mm. In difficult cases with difficult access to the fragment, particularly in the presence of foraminal stenosis, a fourth step was performed with a reamer of an outer diameter of 8.5 mm. As a rule, after the third reaming step, a working cannula of 7.5 mm was then advanced. Image intensifying controlled all steps, and the working cannula with a 1-sided opening was directed exactly up to the area of the extruding or sequestered fragment. As a rule, it takes 10–15 minutes between the intradiscal chymopapain injection and the final placement of the working cannula. In group 1, all steps were

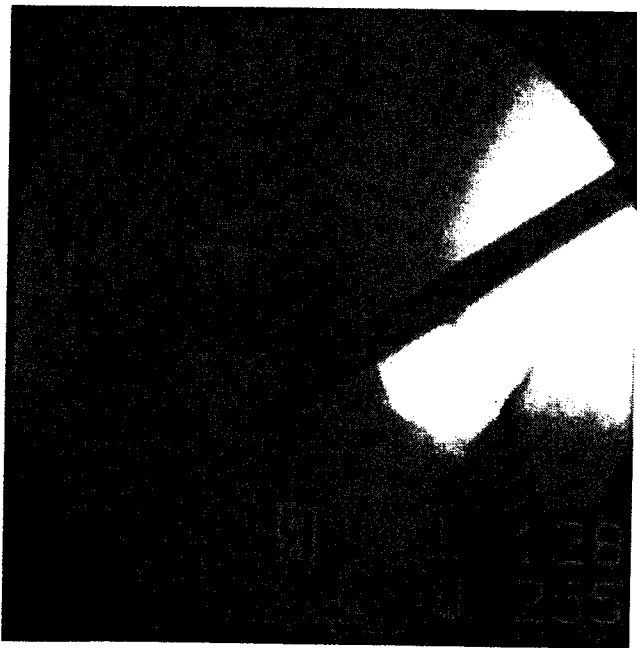


Figure 2. Radiographic view.

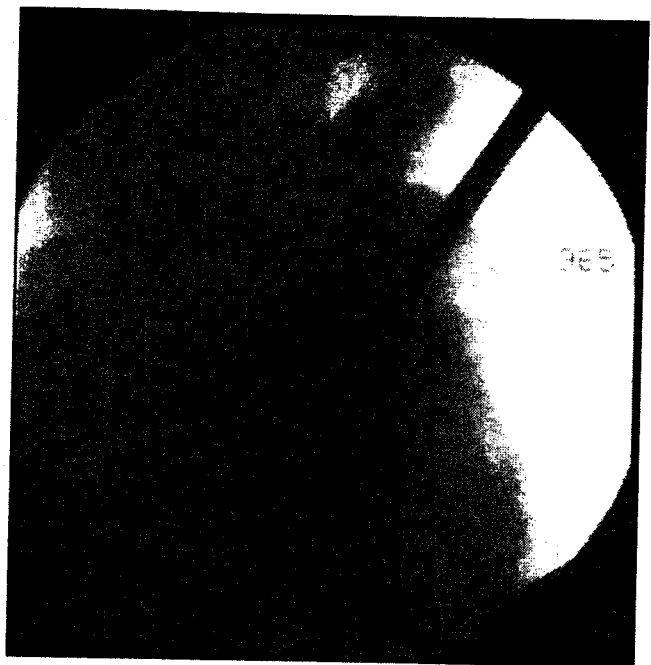


Figure 3. Radiographic view.

identical, except for the enzyme injection. At this point, a special spine scope was introduced and the reached area inspected. As a rule, an extruding or sequestered disc fragment could be observed. Occasionally, a small part of the affected nerve root was visible. In cases where the nerve root was also visible, a working forceps was introduced through the endoscope that has a lumen of 2.8 mm, and under endoscopic view, the fragments underneath the nerve root were removed. The cannula was then rotated so that the closed part of the cannula was protecting the nerve root. Subsequently, the endoscope is removed, and the large forceps is introduced, grabbing the remaining disc fragments and sequester. When at the introduction of the endoscope, no nerve root could be seen, at that point, the endoscope was removed, and a large grasping forceps was introduced, and the position of the instrument was controlled and checked with the image intensifier in 2 directions. If the isthmus was exactly at the site of the extruding fragment, according to the MRI or computed tomography scan, then a firm bite was taken, usually resulting in the extraction of the most important compressing disc fragment. Once a considerable disc fragment could be extracted, the endoscope again was introduced, and the nerve root was inspected. Remaining fragments were then removed under endoscopic vision. When the localization of the instruments was uncertain, the position of the instruments was checked with the image intensifier in 2 directions. At all times at the end of the procedure, the freed nerve root could be identified, and it always could be visualized that the nerve root was mobile with the heart rate (not with the breathing rate) (Figures 4 and 5).

After the extruded or sequestered fragment had been removed, the working cannula was then directed at disc level with the opening away from the spinal canal, and with small forceps, the hole in the disc was entered. All attainable loose disc material in the posterolateral segment of the ruptured disc was then removed. During this maneuver, usually the center of the disc was not bothered. An intradiscal irrigation was performed with a mixture of saline and nebacetin. Steroids were not used. Then the cannula was removed, and the skin was



Figure 4. Removal of disc material in endoscopic view.

closed with one stitch. Patients were then observed for 2 hours in the recovery room and discharged with a flexible back brace. A postoperative checkup was performed the next day, and at that point, the patient did receive extensive instructions about postoperative restrictions and rehabilitation according to a standardized program.

Follow-up. The day after surgery, all patients received a follow-up booklet, including 3-month, 1-year, 2-year, and 5-year questionnaires and preaddressed envelopes. Three months after surgery, all patients returned for a clinical follow-up, except for 2 patients with an early recurrence and treatment elsewhere. At the 3-month follow-up, the patients returned a questionnaire to evaluate possible complications, including infection, wound healing, thrombosis, recurrent or persistent radicular pain, numbness, or weakness. Also, a checkup MRI was made to exclude re-prolapse or re-herniation. The clinical

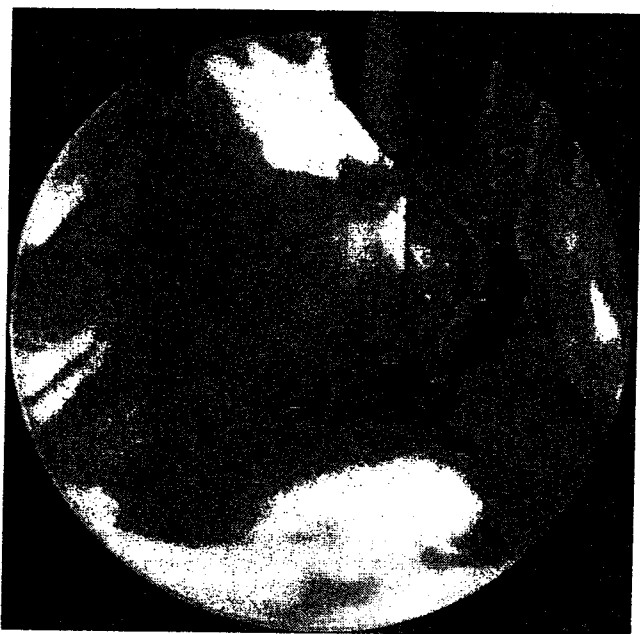


Figure 5. Endoscopic view of the freed nerve.

evaluation included a straight leg raising test and check of the strength of the quadriceps, foot and toe extensors, as well as triceps strength in order to detect possible persistent or re-herniation. The 1-year follow-up questionnaire first of all included a subjective rating about the result of the operation, being excellent, good, fair (somewhat improved), or not satisfied. On a 10-point visual analog scale (VAS), the amount of preoperative and postoperative back pain was plotted, the same as for leg pain. Numbness was rated as: (1) vanished, (2) improved, (3) unaltered, or (4) worse. Weakness was rated as: (1) vanished, (2) improved, (3) unaltered, or (4) worse. An identical questionnaire was completed 2 years postoperatively with additional questions pertaining to the MacNab^{4,5} score. Patients indicated the amount and frequency of pain medication, their work ability, and activities of daily life. Furthermore, at 2 years, a sport activity evaluation was performed, including intensity and type of sport before the symptomatic herniation, the interval to sport resumption, intensity of sport activities at 2 years, and comparison to pre-herniation level. All patients were asked to whether they would undergo the same procedure again for the same problem. All patient data were implemented into Microsoft Access (Microsoft, Corp., Redmond, WA) and evaluated with SPSS software (version 8.0; SPSS, Inc., Chicago, IL). Monthly, a computer check was performed as to whether the patients had returned their 1 and 2-year questionnaires in a timely manner. If not, a reminder was sent out. If no response occurred in 4 weeks, the patient was called, and the questionnaire was completed by telephone. Since 1995, all German and Dutch-speaking patients operated on at the spine department of the Alpha Klinik are included in follow-up systems, as described above. The statistical evaluation of the results and of the recurrence rates was performed with SPSS (version 8.0; evaluating the χ^2 test).

Complications. At 3 months, all patients returned for the clinical follow-up, and the perioperative and postoperative complications were evaluated.

Group 1 (endoscopic discectomy alone). In group 1, there were 2 patients with a superficial skin infection, both healed in 3–4 weeks with prolonged dressing care. One patient had a 2-month nerve root irritation that cleared with diclofenac and codeine medication. There were 5 early recurrences after 3, 4, 6, 8, and 9 weeks. All 5 were reoperated on with microdiscectomy. One patient had a postoperative allergic reaction to cephalosporin antibiotic, with a skin reaction that cleared with antihistamines.

Group 2 (endoscopic discectomy + enzyme). Two patients reported significant postoperative nerve root pain without nerve root tension signs and no evidence of recurrence. Both patients were treated with tramadol and diclofenac for 4 and 5 weeks. The radicular pain subsided after 6 and 10 weeks, and both patients were pain free at the 3-month follow-up. One patient had a superficial wound infection that cleared with prolonged dressing care in 3 weeks. There was 1 patient who had an early recurrent herniation 3 weeks postoperatively, which was successfully treated with microdiscectomy. One patient had a recurrence at 11 weeks and was successfully reoperated one with a second endoscopic discectomy.

Neither patients in group 1 nor in group 2 had signs of deep vein thrombosis, discitis, increased weakness of quadriceps, foot/toe extensors, or triceps strength.

■ Results

Demographics

Group 1—Endoscopy Group (n = 142). Of the 280 patients that entered the study, 142 were randomized into group 1 (even birthday). Of these 142 patients, 130 (92%) returned their 1-year questionnaire, and 119 patients (83.8%) returned their 2-year questionnaire. The average age of these patients was 41 years, and 35% were female, and 65% were male. Of patients, 62% were operated on at level L5–S1, 31% at level L4–L5, 4% at level L5–L6, 2% at level L3–L4, and 1% at level L2–L3.

Group 2—Endoscopy in Combination With Chymopapain Group (n = 138). A total of 138 patients were randomized in group 2 (uneven birthday). Of these 138 patients, 8 patients appeared to have massive dye leakage during diskography and were, therefore, excluded from the study. Of the remaining 130 patients, all returned for the 3-month follow-up, and 125 (96.2%) returned the 1-year and 116 (89.2%) returned the 2-year questionnaires. In group 2, 32% were female and 68% were male, with an average age of 40.3 years. Of patients in this group, 60% were operated on at level L5–S1, 36% at level L4–L5, and 4% at level L3–L4.

A questionnaire was used to evaluate all patients at 1 year for the following criteria: (1) subjective patient satisfaction, classified as excellent, good, fair, or not satisfied; (2) leg pain level according to the 10-point VAS; (3) back pain according to the 10-point VAS; and (4) subjective grading of sensibility disturbances.

On the 2-year follow-up questionnaire, the same criteria were inquired with additional questions regarding MacNab criteria and sporting activities.

Subjective Satisfaction of the Patients

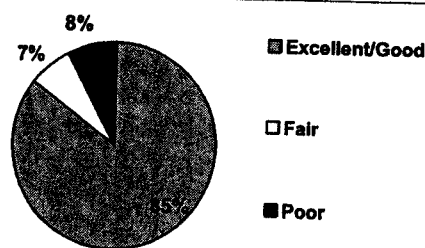
In group 1, 63.1% of the patients rated the operation result as excellent after 1 year, 23.1% as good (top 2 = 86.2%), 6.1% as fair, and 7.7% as not satisfied. Questioned after 2 years, 59.2% of the patients in group 1 rated the result of the operation as excellent, 26.2% as good, 6.9% as fair, and 7.7% were not satisfied.

Questioned after 1 year, 68% of the patients in group 2 rated the operation result as excellent, 25.6% as good (top 2 = 93.6%), 1.6% as fair, and 4.8% as not satisfied. Questioned after 2 years, 70.6% of the patients in group 2 rated the result of the operation as excellent, 22.7% as good, 2.5% as fair, and 4.2% as poor (Tables 1, 2).

Leg Pain (VAS)

The average 10-point VAS improvement of back pain 1 year postoperatively in group 1 amounted to 6.3 points. Three patients in group 1 complained about a slight increase of 1–3 points. Two years postoperatively, patients in group 1 noticed an improvement in leg pain, averaging 6.03 points according to the VAS (preoperative 8.05 and postoperative 2.02 points).

Table 1. Subjective Satisfaction of the Patients in Group 1 Two Years Postoperative



One year after the operation, the average improvement of leg pain according to the 10-point VAS amounted to 6.4 points in group 2. There were no patients that had a worsening of leg pain. Two years postoperatively, the average improvement of leg pain in group 2 amounted to 6.37 points (preoperative 8.22 points, postoperative 1.85 points).

Back Pain (VAS)

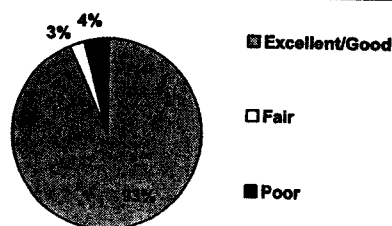
The average improvement of back pain according to the 10-point VAS amounted to 5.7 points. Four patients in group 1 complained about a slight increase of 2–3 points. Two years postoperatively, patients in group 1 noticed an improvement in back pain, averaging 5.6 points (preoperative 8.2 and postoperative 2.6 points).

In group 2, the average improvement of back pain according to the 10-point VAS amounted to 5.7 points 1-year postoperatively. One patient complained about a slight increase of back pain of 2 points, 1 patient complained about an increase of 4 points, and 1 of 7 points. Two years postoperatively, group 2 reported an improvement in back pain, averaging 5.35 points (preoperative 8.19 points; postoperative 2.84 points) according to the 10-point VAS.

Subjective Grading of Sensibility Disturbances

Of the 130 patients in group 1, 94 had complained about a preoperative sensibility disturbance. One year after the treatment, 68% quoted having no sensibility disorder, 28% felt that the disorder improved, 3% felt that the sensibility disorder was unaltered, and 1% felt that it had worsened.

Table 2. Subjective Satisfaction of the Patients in Group 2 Two Years Post Operative



A total of 112 patients in group 2 had complained about a preoperative sensibility disturbance. Of these patients, 70% were quoted as having no sensibility disorder 1 year after the percutaneous endoscopic discectomy, 21% felt that the disorder improved, 7% felt that the sensibility disorder was unaltered, and 2% felt that it was somewhat worse.

MacNab Score at 2 Years

- Excellent: No pain, no restriction of activity.
- Good: Occasional back or leg pain of sufficient severity to interfere with the patient's ability to do normal work or capacity to enjoy him/herself in leisure hours.
- Fair: Improved functional capacity but handicapped by intermittent pain of sufficient severity to curtail or modify work or leisure activities.
- Poor: No improvement or insufficient improvement to enable increase in activities; further operative intervention required.³⁶

According to this classification, 50.8% of patients in group 1 had an excellent result, 33.8% a good result, 14.4% had a fair result, and 0.9% (1 patient) had a poor result. According to this classification 62.7% of group 2 had an excellent result, 27.7% a good result, 9.2% had a fair result, and 0.9% (1 patient) had a poor result.

Sporting Activities

Of patients in group 1, 73 engaged in sporting activities before their slipped disc. At the 2-year follow-up, 7 of these patients no longer engaged in sporting activities after the endoscopic discectomy.

Of patients in group 1, 35 engaged in sporting activities after surgery, of whom 18 (21.2%) had not engaged in sporting activities before their slipped disc. This increase means that after the postoperative rehabilitation endeavors, additional patients could be motivated for sporting activities; 71.2% were able to perform at the same or higher level, 20.2% at a lower level, and 8.3% did quit sport activities. The activities began after an average of 10.6 weeks.

A total of 69 patients in group 2 engaged in sporting activities before their slipped disc. At the 2-year follow-up, 3 of these patients no longer engaged in sporting activities after the endoscopic discectomy, and 84 patients were engaged in sporting activities (an increase of 18 patients = 12.9%). A total of 71.2% of patients were able to perform at the same or higher level, 24.5% at a lower level, and 4.3% did quit their sporting activities. The activities began after an average of 11.9 weeks.

Statistical Significance

A statistical evaluation with the Microsoft Access and the SPSS 8.0 system was performed comparing the results of both groups pertaining to: (1) recurrence rate in the first year (2) recurrence rate in the second year, (3) subjective satisfaction of the patient at 2 years, and (4) MacNab criteria at 2 years.

Recurrence Rate in the First Year

In the first postoperative year, a clear re-herniation (recurrent significant leg pain and an MRI proven re-herniation) occurred in 9 patients (6.9%) in group 1, 8 of them requiring reoperation. Two patients (1.6%) in group 2 developed a re-herniation, both of them requiring reoperation. Statistical evaluation (SPSS 8.0/ χ^2) shows a significant ($P = 0.045$) reduction of recurrences in the group receiving additional enzyme.

Comparison Results of Endoscopy With Enzyme Versus Endoscopy Alone (Table 3)

Recurrence Rate in the Second Year. In the second postoperative year, there were 2 recurrences (1.5%) in group 1 and 3 recurrences in group 2 (2.4%). The comparison did not show statistical significance.

Subjective Satisfaction of the Patients at 2 Years

When comparing the subjective satisfaction of patients in groups 1 and 2, a statistically significant result ($P = 0.025$ according to χ^2) in favor of the enzyme group could be reported. Of the patients in group 2, 93.3% had a top 2 result, rating the outcome of their operation as excellent or good. Only 85.4% of the patients in group 1 (no enzyme) had a top 2 result, a discrepancy of 7.9%.

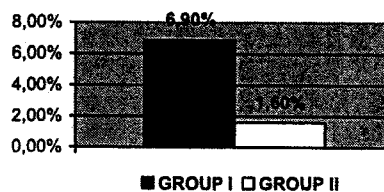
MacNab Criteria at 2 Years

A comparison of the 2-year outcome of both groups according to MacNab did not show statistical significance.

Discussion

In 2002, Yeung and Tsou³² reported the outcome and complications in 307 cases of posterolateral endoscopic discectomies with a minimal follow-up of 1 year (average follow-up was 19 months). They reported an 83.6% excellent or good result and a 9.3% rate of poor results. Their reoperation rate was 5%, with an average follow-up of 19 months. These results are comparable to the results in our group of endoscopic discectomy alone. The additional intradiscal injection of 1000 U of chymopapain in the second group of our study yielded a significant improvement of patient satisfaction and decreased recurrence rate. Although there were no complications related to the use of 1000 U chymopapain, there is a basic complication risk with the use of intradiscal chymopapain, primarily in the form of potential anaphylactic reaction. The standard dose of intradiscal chymopa-

Table 3. Comparison Results of Endoscopy With Enzyme Versus Endoscopy Alone



pain as a single treatment for herniated disc is 4000 U. Incidents of anaphylaxis with this dose have been documented to be 0.4%.⁵ In our institution, we have injected a low dose (1000 U) of chymopapain in 3645 cases,⁴⁶ and we have seen 2 cases of anaphylactic reactions that were appropriately treated, including intubation. Both female patients could be extubated the next morning and discharged in a stable condition, with no sequela. We believe that when a careful, slow intradiscal injection of chymopapain is preceded by a 2-direction image intensifier documentation of central intradiscal needle placement, diskography with 2 cc of contrast dye to exclude intravenous, or intravascular dye leakage or massive epidural dye leakage, will avoid the additional (rarely reported) complications of transverse myelitis and subdural hemorrhage. The overall safety of the use of chymopapain, when properly applied, has been documented in many studies.^{5,47-49} The majority in the spine surgeon community does consider microdiscectomy to be the gold standard operative treatment for lumbar disc herniation that is not adequately responding to conservative treatment.⁵⁰⁻⁵² The main objections against percutaneous procedures include the inferior efficacy, higher recurrence rate, and limited indication of percutaneous procedures.⁵³ This study as well as the previously reported series³² do, however, demonstrate that posterolateral endoscopic discectomy has an equal efficacy as microdiscectomy, and in combination with chymopapain, it might even exceed the results of microdiscectomy. In terms of efficacy, a multicenter randomized study can only prove the superiority of one procedure over the other. From a practical standpoint, however, such a comparative study does not appear to be feasible, as proven by the effort trial by Haines *et al.*⁵⁴ The advantages of a transforaminal endoscopic discectomy over a microdiscectomy are, however, obvious: (1) no need for general anesthesia; (2) less/no cases of iatrogenic neurologic damage; (3) significantly less infections; (4) a direct approach to the extruded disc fragment; (5) no sacrifice of ligamentum flavum or intracanal capsule structures, therefore less scar formation; and (6) no disturbing scar tissue in case of re-intervention. As a matter of fact, in case of recurrence after a dorsal procedure, the posterolateral endoscopic operation is preferred over a repeated dorsal approach.

Since the introduction of the arthroscopic microdiscectomy in 1992,¹⁰⁻¹⁹ many authors have reported the results of the transforaminal endoscopic discectomy. There is extensive literature regarding the results of microdiscectomy after its introduction.⁵⁴⁻⁵⁹ In terms of complications, there is a large variety in the incidence of dural tears, infection, reoperation rate, vascular injury, neural injury, and the complication rate may well be surgeon dependent.⁶⁰ Nevertheless, the complication rate of percutaneous procedures is, in all aspects, significantly smaller than any type of discectomy through the dorsal approach. It is obvious that a nonsuccessful minimal invasive percutaneous procedure does not exclude or compromise a second dorsal, more extensive procedure.

A study³⁶ in 1993 reported the superiority of percutaneous, endoscopic discectomy over microsurgical discectomy in a small group of patients and limited indication. An equally good efficacy of open *versus* arthroscopic transforaminal discectomy was reported in 1999.⁶¹

The applied technique is an extended version of techniques described by Kambin *et al.*,¹⁷ and Yeung and Tsou,³² being a uniportal outside-in technique, whereas Kambin *et al.*, and Yeung Tsou use the inside-out uniportal or biportal technique. Modern instrumentation, as developed by the senior author, allows a stepwise enlargement of the intervertebral lateral foramen, allowing a working cannula to be introduced up to the spinal canal and creating access to the anterior epidural space in order to remove sequestered fragments.

This study has demonstrated the efficacy of this procedure, and showed that the addition of a low-dose chymopapain yields a statistical improvement of outcome and a statistically significant reduction of the early recurrence rate.

■ Conclusions

Transforaminal endoscopic discectomy performed by an experienced spine surgeon can be as effective as dorsal microdiscectomy with less potential complications. Significant improvement of the outcome and recurrence rate can be obtained with the addition of an intradiscal injection of a low-dose of chymopapain enzyme.

■ Key Points

- A prospective randomized study involving 280 consecutive cases of lumbar disc herniation compared the outcome managed either by an endoscopic discectomy alone or an endoscopic discectomy combined with an intradiscal injection of a low dose (1000 U) of chymopapain.
- A high percentage of patient satisfaction could be obtained with a posterior lateral endoscopic discectomy for lumbar disc herniation, and a statistically significant improvement of the results was obtained when an intradiscal injection of 1000 U of chymopapain was added.
- There was a low recurrence rate with no major complications. The method can be applied in any type of lumbar disc herniation, including the L5-S1 level.
- This study has demonstrated the efficacy of this procedure, and showed that the addition of a low-dose chymopapain yields a statistical improvement of outcome and a statistically significant reduction of the early recurrence rate.

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