

# SCIENTIFIC NEWSLETTER - January 1997

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**GUEST LECTURE**  
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This is the first of a series of discussions regarding the neurological evaluation as it relates to the Spine Pain patient. My friends and colleagues in ISIS frequently express a sense of insecurity when it comes to the Neuro exam, the possibility of undetected neuro deficit, and the interpretation of neurological tests such as myelography, electromyography (EMG), nerve stimulation studies (NSS or NCV), evoked potential testing (EP) and so forth. A good, reliable, basic neurologic exam for everyday use is discussed here. Future discussions may focus on localization within the neuraxis, common peripheral neuropathies and entrapment syndromes, the use of electrophysiologic testing, how EMG and other tests complement the injection data, decision making in spinal syndromes with neurological implications (i.e., there is a neurologic deficit to monitor or consider in the clinical decision making), and any other areas of interest to the ISIS members.

The value of skill in performing and interpreting a good neurologic exam may or may not be obvious to many of our readers. Often patients come to the Spinal Diagnostic Specialist without a sophisticated exam. It may not be correct to assume there is no neurologic deficit, or that the findings described are accurate. The patient may be "neurologically unstable" (a changing neurologic picture) while the workup progresses. The extent of neuro deficit may determine the urgency and order of indicated tests. It is often neither practical nor helpful to have a neurologic consult or follow your cases. So it is helpful to learn a basic exam and get good at it. Consider observing a neurologist friend.

Rule Number 1: You must have a basic exam you perform in the same order every time. This need not be an elaborate exam and can take only a few minutes, but you must cover all parts of the exam every time or neurologic abnormalities will be missed. It is also much easier to become skilled, swift, and smooth at this if you do it every time. After you perform your basic exam, you can then expand the analysis of specific areas of interest. Obviously, I am referring here to the first time examination of the New Patient, which need not be repeated in its entirety on subsequent visits.

To give an example: consider the patient with possible cervical radiculopathy. This may be a 52-year old attorney's wife with shoulder pain, vague hand numbness, and difficulty using the hand (weak grip?) by history. There is moderate spondylosis on MRI with borderline spinal and foraminal stenosis. Your history reveals no clear myelopathic symptoms such as Lhermitte's or balance disturbance. You perform a basic screening neuro exam to rule out spasticity, ataxia, loss of position or vibration sense (dorsal column function), and bilateral or diffuse weakness. This helps narrow down the differential diagnosis, eliminating B12, peripheral neuropathy, and other central problems that may coexist with her painful cervical spondylosis. Now you can focus on the symptomatic limb (specific area of interest) and consider: Is a nerve root involved or is an entrapment neuropathy presenting in a similar fashion? The examination of the limb will be more detailed and specifically designed to answer those questions.

What are the elements of the Basic Neurologic Exam? I would suggest the following.

1. Mental Status. This is usually evaluated during the history taking by noting the patient's ability to tell the story of his/her illness, memory for details, etc. If a spouse does all the talking, a flag should go up in your mind. The best single question in a micro mental status

exam is the exact date. The second best test is serial 7's.

2. Cranial Nerves. Use a penlight that the patient follows so that you test conjugate gaze, rule out nystagmus, and check pupil symmetry and response to light. Ask the patient to grimace and stick out his/her tongue. CN 3, 4, 6, 7, and 12 are tested in 15 seconds. Add quick Visual Fields, sensation on cheeks, and gag reflex for 2, 5, 9 and 10 (optional).

3. Motor. Check upper extremity shoulder shrug (trapezius), deltoid, biceps, brachioradialis, infraspinatus, radial and ulnar wrist extensors, grip, wrist flexors, triceps, thenar group (I prefer APE but many test Opponens pollicis), interossei. Look for scapular winging. Look for atrophy/fasciculations/tremor.

4. Motor. Check lower extremity hip flexors, quads, tibialis anterior, extensor hallucis longus, peroneus longus, hamstrings with patient seated. Then stand to test gait/station, and have the patient raise on tiptoe on each foot for gastrocnemius test.

5. Reflexes. Check reflexes after evaluating muscle strength, since this slightly increases reflexes and asymmetries will be more obvious. Check reflexes at slightly different muscle tensions about 3-4 times. Use Jendrassic's maneuver (patient grips and bites down to accentuate reflexes) before calling reflex absent. Check for Babinski's response. Get yourself a good reflex hammer - preferably German. Check at this time for appropriate Tinel's signs (shock in the distribution of a peripheral nerve when lightly tapping that nerve over a site of entrapment).

6. Gait/Station. Ask patient to tandem walk 6-8 feet. Check Romberg by having them stand with feet together and eyes closed while you stand ready to catch patient (do they always fall towards you no matter where you stand?)

7. Sensory. - Check pin detection (keep a Petrie dish full of disposable straight pins by the exam table). Check vibratory sense over the lateral malleolus with large tuning fork. Check light touch.

This entire exam should take about five to ten minutes or less if normal. I have not included a description of the best method of testing each muscle, myotomes and peripheral nerves tested, or what conclusions to draw if elements of the exam are abnormal (like Romberg tests dorsal columns with eyes closed but if the patient cannot stand with feet together and eyes open cerebellar, dorsal column, peripheral nerve, and even labyrinthine function could be implicated). I am more than happy to go into it in a future newsletter or via E-Mail (drdisco@msn.com).

Rule Number 2: You have not determined a muscle's strength unless you have overcome that muscle. 90 pound lady neurologists and physiatrists learn this and learn to break any muscle by testing at the point in the muscle's excursion where the tester has just enough mechanical advantage. I see patients almost every day who have subtle triceps weakness missed by the referring physician because of failure to observe this simple rule.

Rule Number 3: Remember that the general goal of the neurologic exam is to seek a unifying lesion of the nervous system that will explain the patient's findings and complaints. A single lesion is best but a multifocal or diffuse process should not be missed, especially if a surgical procedure is contemplated. This process is seen in its simplest terms in the differentiation between an entrapment neuropathy and a

radiculopathy, Both present with limb pain and sensory/motor signs and symptoms. The clinician determines the deficit on exam, then considers whether this is best explained by one or the other. For example, in the case of median nerve entrapment versus C6 radiculopathy, the sensory complaints are similar so the exam seeks to discover weakness of C6 nonmedian muscles (such as brachioradialis) which would implicate the C6 root. Alternatively, weakness of non-C6 median muscles (such as the thenar group muscles) will suggest a peripheral problem of the median nerve.

If the Spine Diagnostician has the ability to perform a solid exam, this process becomes easier even fairly simple. Neurologic sophistication tends to increase as skill in performing the Neuro Exam increases. Selecting the appropriate testing (especially when to inject versus image versus obtain EMG/NSS) can be based on a clearer understanding of the questions to be answered when a more clearly developed differential diagnosis has been considered.

Attached is a Template for the standard Neurological Exam that is used in our office.

The following reading list is recommended:

1. Clinical Examinations in Neurology. Mayo Clinic and Foundation. WE Saunders.
2. The Neurological Examination. DeLong. Harper & Row.
3. Principles of Neurology. Adams and Victor. McGraw Hill. Chapter 1, "The Clinical Method of Neurology".
4. "Aids to the Examination of the Peripheral Nervous System." Medical Research Council Memorandum No. 45, London: Her Majesty's Stationery Office, 1976.

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## **NEUROLOGICAL EXAMINATION:**

### **MENTAL STATUS:**

Patient alert, oriented. Affect, abstract thought, judgment, memory, speech intact.

### **CRANIAL NERVES:**

2 - VF full. Fundiscopic wnl. 3,4,6 - FOM full. PERRLA. 5 - intact motor and sensory. 7 - good facial symmetry. 8-12 - intact.

### **MOTOR:**

#### **Muscle Strength Tests:**

Upper Extremity:	R /5	L /5	(5/5=wnl)
Supraspinatus			
Infraspinatus			
Deltoid			
Biceps			
Brachioradialis			
Wrist Ext Rad			
Wrist Ext Uln			

Triceps  
APB  
ADQ

Lower Extremity:

Hip Flex  
Quad  
Quad  
Tib Ant.  
EHL  
Peroneus Long.  
Gastrocs.  
Hamstrings  
Gluteus Max.

Reflexes	R	L	(0-4 4=clonus)
Biceps			
Brachioradialis			
Triceps			
Patellar			
Achilles			

Pathological Reflexes: None Babinski R L

Gait/Station	wnl	abnl
Tandem Walking:		
Romberg		

Cerebellar:

Finger/Nose	wnl	abnl
Heel/Shin	wnl	abnl

**SENSORY:**

Intact to primary sensory modalities. Pin, light touch, vibratory, and position tested.

**ADDITIONAL TESTING:**

SLR  
SI JOINT  
SACRAL THRUST  
FACET EXAM  
ETC

## ONGOING RESEARCH

### **Discograms Can Predict Surgical Outcome**

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We present a protocol for grading the sensitivity of the disc annulus and use the protocol to predict surgical outcome. Discs are classified on a scale from zero to four depending on the sensitivity of the annulus to pressurization by injected contrast solution (Table 1). Patients who have significant concordant pain provocation to minimal pressure are classified as grade 4 chemically sensitized. Those patients who have their pain provoked at pressures between standing and lying (30 to 50 psi) are classified as mechanically sensitive. To validate the classification scheme we hypothesized that patients with a chemically sensitized outer annulus would not get better following a posterior fusion, discectomy or both, but would get better following an interbody fusion with or without posterior stabilization. We further hypothesized that patients with radiologic instability or patients with one or more mechanically sensitized disc and clinical instability would get better with a posterior fusion alone.

**Table I: Disc Classification**

	Intradiscal Pressure at Pain Provocation	Pain Severity	Pain Concordancy
0 Normal	>100 psi	No pain	
1	50 psi or greater	>6/10	Concordant
Asymptomatic	>50 psi	>5/10	Discordant
2	50 to 100 psi	>5/10	Concordant
Indeterminant	<50 psi	>5/10	Discordant
3 Mechanical	30 to 50 psi or >15 psi above opening pressure	>5/10	Concordant
4 Chemical	<30 psi and <15 psi above opening pressure	>5/10	Concordant

## **Methods:**

Discs were injected using a device that delivered .5 ml solution per revolution of a screw attachment. A pressure gauge attached to the syringe recorded pressures on both a digital display and a hard copy graph of pressure vs time. After each .5 ml incremental injection of nonionic contrast solution, we recorded intradiscal pressure, contrast location, and pain provocation. An opening pressure was recorded when contrast was first seen entering the disc nucleus.

For the purpose of correlating surgical outcome with discogram provocation, a patient was classified by the disc with the most sensitive annulus.

Surgery outcome was graded as much better, better, same, or worse by combining the NASS patient satisfaction index, pain scale, medication use, and medical system usage. To reduce the likelihood that a patient would not admit dissatisfaction to the primary care giver, we excluded patients who were referred from the first authors' spine group. Clinical instability was considered present when a patient could not arise comfortably from flexion without assistance and the patient reported an increasing frequency and duration of back pain flares set off by minor unguarded movements.

## **Results:**

A nurse research assistant interviewed 50 patients by telephone who had discography 12 to 18 months prior to interview. There were 24 men and 26 women with an average age of 44 referred by 32 different physicians. Twenty one patients had prior back surgery and of those 11 had prior fusions. All patients had pain for greater than six months prior to discogram. Fifty eight per cent of the patients were Worker's Compensation injury cases.

Thirty five patients underwent spinal surgery an average of 10 months (range 6 to 16 months) prior to interview. The surgeries were performed by 30 different spine surgeons. All discograms were performed by the first author. Three patients had discectomy, 17 patients had a discectomy and posterior fusion, 4 patients had an interbody fusion and 10 patients had combination anterior fusion and posterior fusion with pedicle screw instrumentation. There were similar numbers of patients who underwent one, two, or three level fusions in both the interbody

group and the posterior fusion group. Identifying three or more symptomatic discs was the most common reason for not offering surgery.

Twenty nine patients had one or more discs with a class 4 sensitized annulus. The cross-tabulation of surgical outcome vrs surgery type shows that when the anterior column surgery was included, 80% of the patients were better or much better. In contrast, posterior surgery had a 27% success rate and of the three who were better one had radiologic instability and one had a moderate sized disc herniation and complete relief of back and leg pain following a selective nerve root block (Table 2). One patient who did not have surgery and who was better at follow up had a radiofrequency intranuclear burn procedure performed in her two symptomatic discs.

**Table 2: Chemical - Class 4**

Surgery Type	Much Better	Better	Same	Worse
No Surgery		2	5	
Diskectomy				1
Diskectomy + Posterior		3	4	4
Fusion				
Interbody Fusion		2		
Interbody Fusion + Posterior	4	1	2	
Fusion				
P<.01				

Twelve patients had one or more discs with a class 3 mechanically sensitized annulus. All patients who underwent posterior fusion and had a good result had either radiologic, clinical instability, or both. The only group of patients who did not do well were the ones who underwent a diskectomy and those who did not have surgery.

**Table 3: Mechanical - Class 3**

Surgery Type	Much Better	Better	Same	Worse
No Surgery			5	
Diskectomy			1	
Diskectomy + Posterior		3		
Fusion				
Interbody Fusion		1		
Interbody Fusion + Posterior	1	1		
Fusion				

P<.01

Six patients had discs with an indeterminant classification (Table 4). The one patient who was better after a laminotomy and diskectomy had a moderate sized disc protrusion and 70/30 leg vrs back pain.

**Table 4: Indeterminant - Class 2**

Surgery Type	Much Better	Better	Same	Worse
Diskectomy		1		
Diskectomy + Posterior			2	1
Fusion				
Hardware Removal		2		

**Conclusion:**

This study presents a protocol for classifying the sensitivity of the disc annulus and using the protocol we could predict short term surgical results. Patients having one or more discs sensitive to low pressure stimulation may have a chemically irritated annulus and perhaps a diskectomy and posterior fusion either

inadequately unweights the remaining annulus or the remaining annular tissue continues to cause chemical irritation. This conclusion may explain the poor surgical results following a discectomy and posterior fusion in contrast to 80% good surgical results with interbody fusion . Patients who could sustain higher testing pressures before concordant pain provocation and have clinical or radiologic instability may do well with a posterior fusion alone.

## **APLD A Prospective Study In An Outpatient Surgical Setting**

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### **ABSTRACT**

Automated Percutaneous Lumbar Discectomy (APLD) is a viable option for the surgical management of herniated disc in the lumbar spine. In this prospective study, Automated Percutaneous Lumbar Discectomy was performed in 45 patients, following a defined protocol of physical and diagnostic evaluation.

Patient evaluations were performed at the MD SpineCenter-PSI in Lancaster, Pennsylvania. All 45 patients presented with a lumbosciatalgia and had failed to have symptomatic relief following an acute low back program for 61+ days post injury. In each case. Discography with CT Nucleography was performed on the suspect disc level and at least one other level (6,11). Flexion-Extension views of the lumbar spine were also obtained following the Discogram procedure.

Patients had follow-up for six months post-APLD and data regarding pain scale comparison, need for medication. improvement in activities of daily living (ADL's) and return to work status is discussed. No patient suffered neurovascular compromise or infection. The advantages include avoidance of complications associated with open surgery, rapid recovery and reduced morbidity and mortality. In all cases, the procedure is done under IV sedation in an outpatient surgical setting .

\* No benefits in any form have been received or will be received from a commercial party directly or indirectly to the subject of this article.

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### **INTRODUCTION**

Backache is second only to headache as the most common medical complaint, and is second only to the common cold as a reason for missed work(1). Herniation of the intervertebral disc is the most common cause of sciatica. The

nucleus of the disc can be placed under so much pressure that it can cause the annulus to herniate or rupture. When this occurs, it may create pressure against one or more of the spinal nerves which can cause pain in the back, leg or foot(2). The primary treatment for disc herniation with associated sciatica is conservative(3). However, if conservative therapy fails to relieve the pain, a surgical procedure may be considered. Surgical treatments for herniated lumbar discs include automated percutaneous lumbar discectomy (APLD), the open surgery procedures of microdiscectomy, laminectomy and laminectomy arthrodesis(2).

Risks of open disc surgery include: infection, arachnoiditis, dural tears, adhesions around the nerve roots, and spinal instability(8). Joseph A. Barr(6) advised that we must find another technique to remove the disc material with fewer complications.

Percutaneous discectomy was developed to reduce complications of disc surgery. Hijikata first described percutaneous nucleotomy in 1975(4). In 1985, Onik et al. introduced a nucleotome for percutaneous automated discectomy(5). The nucleotome system was also used by Rezaian and Ghista(7) in a 1995 study on percutaneous discectomy. It is the present authors opinion that APLD is a viable surgical treatment for non-sequestered disc herniations. For our purposes, we prefer the Nucleotome System by Surgical Dynamics for performance of APLD.

## **MATERIALS and METHODS**

APLD criteria were met by 45 patients. All had complaint of back and/or leg pain resulting from a variety of domestic, vehicular and work related injuries. All had undergone a complete history and physical examination including a thorough musculoskeletal and neurologic examination. Patient evaluations were performed at the MD SpineCenter- PSI in Lancaster, Pennsylvania. Average patient age was 38 with a range of 18-50. There were 20 females and 25 males.

In association with the exam, all 45 patients completed a pain drawing and a pain scale. All were a minimum of 61 days post-injury and had unresolved physical complaints following a conservative program of therapy. CT or MR imaging was performed of the lumbar spine (typically L1-S1) to rule out HNP, fracture, stenosis, etc., as well as other significant pathologies that might be causal, including space occupying lesion, infection, renal disorders, hernia, and abdominal aortic

aneurysm. Serum analysis including CBC with differential. Chem 20, sed rate, PT, PTT, bleeding time and PSA (male > 40) were also performed to assess for infection, anemia, electrolyte imbalance, diabetes, prostate cancer, coagulopathy and other blood dyscrasias.

MRI, CT, and Myelography have long been considered the means by which demonstrated pathology visible on these studies and data derived from history and physical, has been used to diagnose pathology of the spine. Where sciatic pain is the primary source of complaint, discography and pain provocation tells us which level requires ZPLD(7).

Discography explicitly determines whether or not a disc is Painful(11,12). Further, our experience has shown that discography will often reveal annular disruption or herniation in instances where more standard imaging studies have failed to identify this.

Discography will prove or disprove an association between visible pathology and the patient's subjective sciatic pain in a single diagnostic test. The key feature of discography is the patient's pain provocation (response), not the appearance of the disc(12,13). A study by Walsh and Weinstein et al(12) revealed a 0 percent false-positive rate for discography involving seven symptomatic and ten asymptomatic subjects. The study further revealed that in a positive discogram, stimulation of the disc reproduces the patient's exact subjective sciatic pain. This is important when considering the 1968 study of Holt(14) in which there existed a large false-positive rate in the subjects tested. Several important aspects of this study have been since called into question, although some still refer to this study in showing discography: to be unreliable and inferior to MRI for the purposes of diagnosing disc pathology.

Patients over 50 years of age typically have age related degenerative changes involving the annulus fibrosis and nucleus. Patients in this age group will respond best to a combination of treatment programs. Patients with Diabetes Mellitus should be excluded from consideration for APLD due to compromised healing ability and increased risk of post-operative infection.

## **ANESTHESIA**

All 45 patients had evaluation of current and past medical problems through the

history and physical examination including social and family history, medications, allergies and sensitivities, review of systems, and anesthesia history. None had history of significant reaction to intravenous anesthetics. All patients had an average physical status classification of 1, as described by the American Society of Anesthesiologists(9). All were able to lie prone on the procedure table without fear of airway compromise due to body habitus or other problems. All patients received IV sedation, delivered by licensed anesthesia providers. Each patient was constantly attended in association with ECC, pulse oximetry and blood pressure monitoring.

## **PROCEDURE**

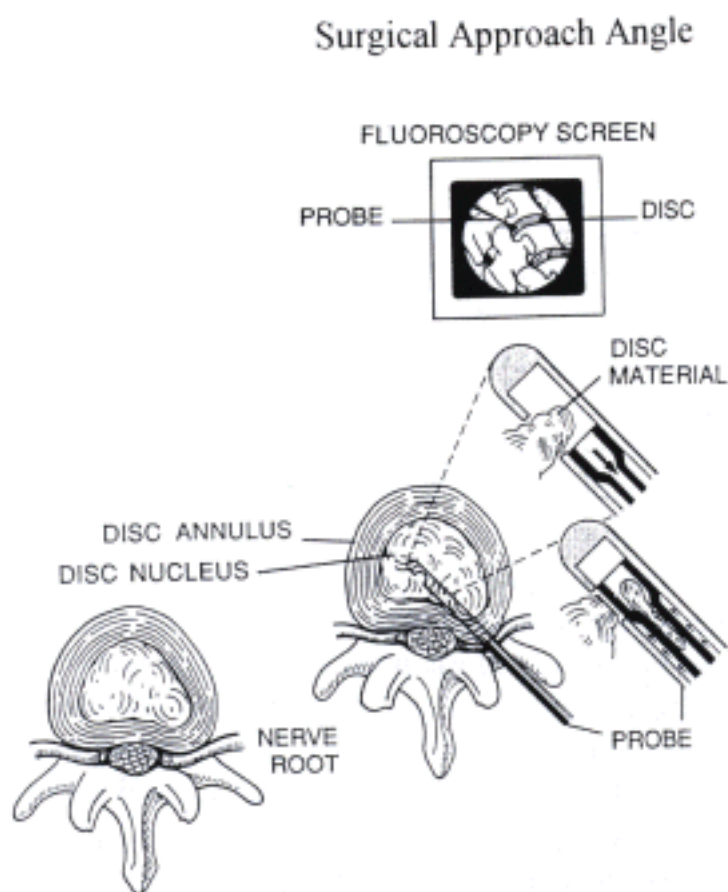
A special radiolucent C-Arm table was used in association with a prone patient position. The table has cut-outs in the lumbar region, so as to allow the C-arm to be angled 45-50 degrees (from posterolateral to anteromedial) toward the annulus fibrosis, 9-12 cm from midline, at the difficult L5-S1 level. The approach angle should be both parallel and midway between the endplates of the involved disc. It should also be lateral to an imaginary line drawn between the medial borders of the pedicles on an AP view, so as to avoid the thecal sac which lies medial to that line. (see figure A)

The field is prepped and draped in a sterile manner. The C-arm head is also covered with a sterile clear plastic drape. The C-arm is then positioned so as to create an approach window to the involved disc as described above. The spinal needle is used to establish the skin entry point within the approach window created by the C-arm and a sterile skin marker is used to mark this point. Once adequate anesthesia is achieved, 1% Xylocaine with Epinephrine is injected into the skin and musculature of the approach pathway with a long spinal needle.

A 3mm skin incision is made at the entry point and a 17 gauge X 6 inch spinal needle with stylet is inserted on the side of the herniation. Under strict fluoroscopic control, the needle is advanced along the central beam of the C-arm within the established window. Optimally, the head of the needle is superimposed over the point, creating a "dot". This will minimize the possibility of the needle drifting posterior and inferior toward the adjacent nerve root, resulting in radicular pain. When the fibrous texture of the annulus is felt, further advancement of the needle is halted. An AP and lateral view is obtained to document the position of the needle at the posterolateral border of the annulus

and that it is not traversing the thecal sac. A local anesthetic is then placed at the annulus to avoid discomfort associated with cannulation of the annular fibers. Upon confirmation of the position, the needle is then advanced through the annulus toward the center of the disc based on AP and lateral views. The stylet is then removed. A Discogram is carried out for purposes of further validating proper positioning within the disc.

A 18 gauge X 16 inch spinal needle with removable hub and stylet will act as a guidewire and is inserted through the existing spinal needle, held manually in place to avoid altering its position. The hub of the long guidewire is removed and the 6 inch needle is removed over the guidewire. A straight cannula with tapered dilator and removable hub is passed over the guidewire down to the wall of the annulus. The position of the dilator is confirmed fluoroscopically in both AP and lateral views.



The approach angle should be both parallel and midway between the endplates of the involved disc. It should also be lateral to an imaginary line drawn between the medial borders of the pedicles on an AP view, so as to avoid the thecal sac which

lies medial to that line.

The Nucleotome has a blunt end, is 8 inches long, and is available in 2.0, 2.5 and 3.5mm diameters. A small opening at the tip of the Nucleotome in combination with a cutting blade allows nuclear material to be pulled into the opening, cut, and transferred to a suction canister and control console via a closed system of sterile saline irrigation.

Careful attention is paid to prevent alteration in the position of the guidewire within the annulus while advancing the dilator. Once the cannula is in position, the dilator is removed and a trephine is inserted through the cannula and advanced to the posterior annular border. While stabilizing the cannula with one hand, the trephine is used to create a 2.0-3.5mm opening in the annulus (depending on the size tray being used).

After penetration of the annulus, the trephine is removed from within the cannula and the nucleotome is introduced. The Nucleotome has a blunt end, is 8 inches long, and is available in 2.0, 2.5 and 3.5mm diameters. A small opening at the tip of the Nucleotome in combination with a cutting blade allows nuclear material to be pulled into the opening, cut, and transferred to a suction canister and control console via a closed system of sterile saline irrigation. This system is an important aspect of the procedure in that it represents the means by which infection rates are markedly reduced. This is compared to earlier methods of percutaneous disc surgery in which the disc was repeatedly entered with forceps or rongeurs(10).

The cutting blade is driven by nitrogen gas and controlled via a foot pedal attached to the console. The cut rate of the blade is also controlled through the console. The nucleotome is operated for 10 minutes, manipulating the tip up, down, anterior and posterior. Special attention is given to removing nuclear material from the posterolateral aspect of the disc.

At the end of the procedure, the Nucleotome is removed and 80mg of Depo-medrol mixed with 0.25% marcaine is instilled into the operative disc and the lateral epidural region to reduce inflammation induced by the surgery. Additionally, all patients receive prophylactic Kefzol 1gm. or Erythromycin 500mg. IV during the procedure. Two hours post-procedure, all patients undergo CT scanning of the operative level to assess for the presence of bleeding. Patients

are discharged 3 hours post-op with prescriptions for 5 days of prophylactic oral antibiotics, a medrol dose-pack, and Hydrocodone 5 mg. with Acetaminophen (Vicodin). All patients universally had pain relief in the recovery room.

It is important to note that once the Nucleotome is placed, we typically operated the cutter for 10 minutes, based on the work of Shea et al(3), in which significant decreases in intradiscal pressure were found to have occurred following annular puncture by the trephine and 10 minutes of automated percutaneous discectomy. No significant decreases in pressure occurred with an additional 30 minutes of percutaneous discectomy

The average amount of disc material removed in each of the 45 patients was 1.5-2.0 gms. The goal in this regard was to decompress the disc, through use of the trephine and 10 minutes use of the automated cutter, but not significantly alter disc height so as to increase the load across the facet Joints(3).

## **COMPLICATIONS**

All 45 patients followed for 6+ months post-APLD had no evidence of infection, bleeding or neurologic compromise from APLD.

## **FOLLOW UP**

Patients were followed at 1,2,4,6,12, and 24 weeks. Pain scales were obtained at 6,12 and 24 weeks. Physical therapy was initiated at week 2 and continued typically for 4-6 weeks. All patients underwent gadolinium enhanced MRI (CT where contraindicated) at six weeks post-APLD to assess for interval change of the operative level and to assess for complications.

## **RESULTS**

Patient outcomes were classified as Excellent, Very Good, Good, Fair and Poor. Data regarding the patient need for pain medication, the level of work or ADL that they returned to post-surgery and the number of weeks required for return to that level was also studied. Outcome criteria included the following information:

1. Did the patient have reduction in their sciatic pain and to what extent? (SEE FIGURE 1)

2. What type of pain medication, if any, did the patient require?
3. Did the patient return to their pre-injury level of work or ADL's?  
(SEE FIGURE 2)
4. How many weeks elapsed before the patient returned to their pre-injury level of work or ADL's? (SEE FIGURE 3)

The pre-APLD and the 24 week post-APLU Visual Analog Scores were compared to calculate a percentage change. This data was used to address criteria #1 above. Data necessary to address criteria #2 and #3 above, was obtained through direct questioning of the patient during the 6 month follow-up period. Criteria #4 was addressed through calculating the time elapsed from the date of injury until the date the patient was released back to work or resumed their pre-injury ADL's.

Excellent results were seen in 18 patients (40.0%). Patients in this group reported complete relief of their sciatic symptoms 6-months following APLD. They required no pain medication. 7 patients returned to their pre-injury level of work/ADL's in 0-4 weeks and 11 patients returned in 5-8 weeks.

Very Good results were seen in 6 patients (13.3%). Patients in this group reported 75%-90% relief of their sciatic symptoms and required PRN Acetaminophen or Ibuprofen for relief of their residual discomfort. These patients returned to their pre-injury level of work /ADL's in 5-8 weeks.

Good results were seen in 13 patients (28.9%). Patients in this group reported 50%-70% relief of their sciatic symptoms and required some type of NSAID or non-schedule pain reliever such as tramadol HCL (Ultram), though less frequently than before their surgery. 8 of these patients returned to their pre-injury level of work /ADL's in 5-8 weeks. The remaining 5 patients returned in 9-15 weeks.

Fair results were seen in 4 patients (8.9%). Patients in this group reported 25%-45% relief of their sciatic symptoms and required an NSAID and/or a class 4 controlled substance. 3 of these patients returned to their pre-injury level of work /ADL's in 5-8 weeks. The remaining patient had not returned to work as of the writing of this paper, however, they are self-care in their ADL's.

Poor results were seen in 4 patients (8.9%). Patients in this group reported less than 25% relief of their sciatic symptoms. Two of these patients had no subjective relief but did return to light duty greater than 15 weeks post-surgery. 1 patient returned to work in 9-15 weeks. The remaining patient had not returned to work as of the writing of this paper, however, the patient is self-care in their ADL's. Medication usage in this group was less defined, though these patients generally require ongoing use of a class 3 or class 4 controlled substance (Vicodin or Darvocet).

## **Conclusions**

Automated Percutaneous Lumbar Discectomy (APLD) is a viable option for the surgical management of herniated disc in the lumbar spine. 82.2% of the patients that underwent APLD had an excellent, very good or good result. Of the remaining patients all but three had sufficient relief to return to at least sedentary work.

No patient was found to have suffered infection, bleeding, or neurovascular compromise during the 6+ month post-op period.

Our primary patient goal was relief of pain caused by lumbosacral sciatica. Imaging studies were necessary to focus our search for pain foci, to assess for sequestered disc fragments and extra-spinal pathology manifesting itself as sciatic pain. Pain provocation testing, performed in association with Discography was the single most important factor in deciding whether a patient was a candidate for APLD. If we could not reproduce the patient's sciatic pain with this test, thereby isolating the offending disc, then we would not consider the patient for APLD.

## **REFERENCE LIST**

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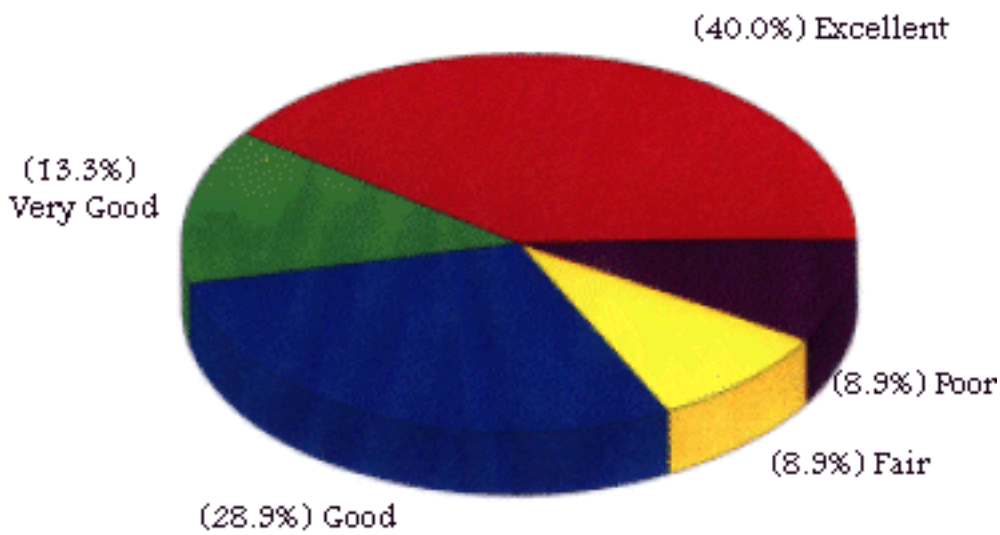
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**Figure 1**

Change in Pain Rating\*  
Percentage change in patients



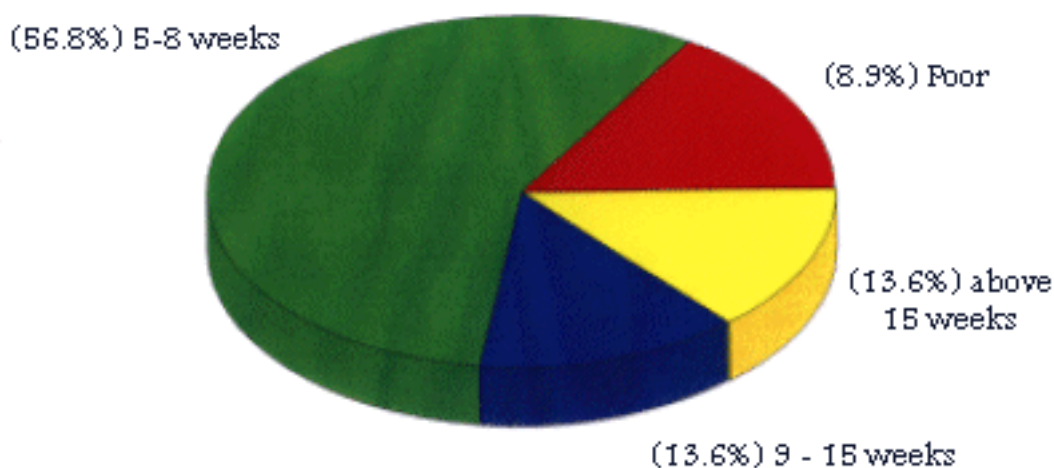
**Figure 2**

Return to Existing Work Level  
Percentage of Patients Returning



**Figure 3**

### Return to Existing Work Level Number of Weeks to return to Work Level



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## **ONGOING RESEARCH**

### **RADIOFREQUENCY LESION FOR INTERNAL DISC DISRUPTION**

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Fluoroscopy is not medically necessary for the performance of an epidural steroid injection. Currently, one of the most difficult diagnoses to treat for low back pain is internal disc derangement(IDD). Although there is a lot of experimental and clinical research into the cause of this problem, little is really known of the mechanism of pain production. Many options have been advanced for this problem including physical therapy, chiropractic manipulation, opiate therapy, Prolo therapy, operation fusion and/or discectomy. The results are varied from 50% to greater than 80% depending on the study(2) because of the great expense and difficulty in determining the anatomic lesion. Those that don't respond to conservative care are often told to just live with the problem, because the complications of surgery are often worse than the original problem. These patients may be diagnosed by discography, and until recently, no good low morbidity procedure was available to help these patients. Surgical treatment including discectomy and fusion has had some success in treating this problem, but because of the great expense, other less costly alternatives are being sought to treat this problem. A few years ago, a procedure was described by Dr. Meno Sluijter(3), whereby using radiofrequency (RF), a lesion was created in the nucleus of the disc and pain relief was attained. RF electrodes develop a high alternating current density in a controlled discrete manner, and have been used in the past to make a focal lesion of a nerve to achieve pain relief.(5,6) No prospective studies have yet been published, so a study was undertaken involving 29 consecutive patients with discogram positive IDD who underwent discal RF of the lumbar spine for one, two or three level disease.

#### **METHODS**

All patients underwent provocative discography at multiple levels to determine the extent of their disease. This was done using pressure monitoring (Merit Intellisystem) and patients underwent post-discography CT scanning to determine the anatomy of the nucleus. Only one patient had had a prior back operation. Patients were selected on the basis of refusal of open spinal surgery, or if they were not deemed a surgical candidate. Selection was also based on a well-hydrated disc on MRI scan, as it was felt a severely degenerated disc would not be easily coagulated. Patients had either one, two or three level disease. Lesioning was done using a Radionics 3C generator and a 15cm, 15mm active tip SMK needle. Three to four lesions were made at 90 degrees centigrade for 4 minutes each. Lesions were made from posterior to anterior, and right and left-sided.

Follow-up was done by an office nurse who was not familiar with any of the patients, with a minimum follow-up of 9 months. All patients were able to be contacted, and results were determined by a questionnaire consisting of self-rating of functional capacity now versus pre-lesion, medication use now versus pre-lesion, and whether they would undergo the procedure again.

#### **RESULTS**

Single level lesions were made on 18 patients ages 23 to 42. Levels done were L3-4 (2 patients), L4-5 (8 patients), and L5-S1 (10 patients). There were ten male and eight female patients. Follow-up on this

group was as long as 14 months. For this group 11/18 are still much improved (off daily medication for pain and back to normal activity), 4/18 are improved (taking reduced daily medication and back to normal activities), and 3/18 were unchanged.

Two level lesions were made on 8 patients ages 29 to 43. Levels done were L3-4 and L5-S1 (one patient), and L4-5 and L5-S1 (seven patients). There were 2 male and 6 female patients in this group. Follow-up was as long as 9 months. For this group, 4/8 were much improved, 2/8 were improved, and 2/8 were changed.

Three level lesions were made on three patients ages 42 to 52. Levels done were L3-4, L4-5 and L5-S1 (two patients), and L2-3, L3-4 and L4-5 (one patient). Follow-up was as long as 10 months. For this group, 1/3 was much improved, 1/3 was improved, and 1/3 was changed.

## **DISCUSSION**

Many different procedures have been advanced for the treatment of degenerative disc disease. To date, there has been no one therapy that is effective in all patients, probably because this is a multifactorial disease. In this prospective study, good results were obtained using a low morbidity procedure. It probably works by changing the biochemical milieu of the nucleus, and not by an annular denervation that has been proposed by some. In a study done by Houpt, et al.(4), it was clearly shown that the heat produced by an RF lesion at 70 degrees C is not sufficient to cause a lesion of the annular nerves, however, most people now use 80-90 degrees C for their lesioning, and further studies will need to be done to see if the higher temperatures will transmit further within the disc, and perhaps cause neurolysis of the annular nerves. In addition, electrode placement will have a great impact on where the lesion is made. In another study done by Troussier, et al.(1), it was shown that in cadaveric discs using bipolar Radiofrequency (RF) lesions there was intense and homogeneous coagulation of the nucleus without necrosis. There is the question of how this heals over time. These studies help confirm that when properly done, good results in the treatment of internal disc disruption, with low morbidity are possible. Certainly long term studies are needed to determine whether the good short term results will continue over time. In addition, criteria for appropriate candidates for this procedure need to be determined. Hopefully, a better understanding of the mechanism of low back pain will help to elucidate how these new procedures work and how they should be best applied.

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## TOPICS OF CONTROVERSY

The Question:

Is fluoroscopy medically necessary for the performance of translaminar (interlaminar) lumbar epidural steroid injections?

In Response:

"Con Response" Mark Kraft, MD

"Pro Response" Eric Eckman, MD

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### "CON" RESPONSE

MARK KRAFT. M.D.

Fluoroscopy is not medically necessary for the performance of an epidural steroid injection. I must, however, qualify this immediately by saying there can be no question that accuracy of injection is clearly superior when performed fluoroscopically. All practitioners of epidural steroid injections should avail themselves to experience under fluoroscopy for the performance of epidural injections. Fluoroscopy is indicated in certain patients who require epidural steroid injections. Individuals who are new to injection practice should have experience before performing these procedures under fluoroscopy.

With this said, I believe that fluoroscopy should not be made a requirement for the performance of epidural steroid injections at any location in the spine. I support this position based on pragmatic aspects of practice. There are certain specific disadvantages with the use of fluoroscopy. While there is a scientific basis for improved accuracy of fluoroscopic translaminar epidural steroid administration, there is not compelling evidence that fluoroscopically placed translaminar epidural steroids are, in fact, more effective than unguided epidural injection.

In the hands of an experienced practitioner, there appears to be greater than an 85% chance that the epidural injection itself will be appropriately placed. Does a potential 10 to 15% miss rate justify the additional time and expense of

fluoroscopic application? This is a question that has to be addressed in each practice scenario individually.

Fluoroscopic translaminar epidural injections are more time consuming, expose the practitioner and the patient to ionizing radiation, and are not always appreciated for their increased level of accuracy. If I were undergoing a series of planned epidural steroid injections, I am not sure I would want the radiation dose associated with fluoroscopic guidance. I would personally find a 10 to 15% miss rate acceptable in preference to multiple exposures to ionizing radiation. The use of translaminar epidural steroids should be examined in all practices as to its appropriateness given the availability of more specific diagnostic injections such as transforaminal epidural steroids in associated with selective nerve root blocks.

There are numerous areas of injection practice where the tradeoffs of accuracy and efficacy can be difficult to make. In the environment where standard of care, reimbursement, and radiation hazard speak loudly against fluoroscopic translaminar epidural steroid administration, the practitioner must look at his practice preference realistically.

This is one of the many crossroads in medicine where science meets reality. As this relates to a procedure that lacks definition of improved efficacy when fluoroscopically performed versus when performed non-fluoroscopically, my preference would be to limit my patients and my own tissue exposure to ionizing radiation to those circumstances where there is a clear and compelling necessity for fluoroscopy. If practitioners choose to use fluoroscopy in all cases, I have no objections to this as it is a personal decision. I would object, however, to standards being set that require fluoroscopic placement of translaminar epidural steroids as a medical necessity until persuasive scientific evidence accumulates demonstrating improved efficacy. Until then, the ultimate assessment of risk versus benefit and the appropriate application of specific procedures to specific patients lies in the hands of the individual practitioner.

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## **"PRO" RESPONSE**

**ERIC ECKMAN, M.D.**

Fluoroscopy is not medically necessary for the performance of an epidural steroid

injection. The answer to the question: "Is the use of fluoroscopy medically necessary for the administration of translaminar lumbar epidural steroid injection (ESI)?" is undecided, but not moot. While never previously proposed as medically necessary, it is considered valuable by some(1-4) and by others as ideal.(5-6) The question is undecided because no controlled studies have been published testing the clinical efficacy of this methodology. Despite its increasing acceptance, clinicians will have to make their judgments as to which technique is best based on the available evidence, their experience and the availability of equipment and facilities. Thus, at the present time, the choice to use fluoroscopy is a matter of preference.

The question is not moot because of the rising tide of skepticism surrounding many spinal treatments, surgical and conservative, as well as specific questions surrounding ESI altogether. In "Spinal Update -- Epidural Steroids," Bogduk(7) raised several incompletely answered questions regarding epidural steroids including:

1. If epidural steroids reduce forms of spinal pain, by what mechanism?
2. What is the proper technique of administration?
3. What are the risks and complications of the procedure and their incidence?
4. What is the efficacy of the procedure?
5. What is the appropriate information to offer patients so that the patients' acceptance of the therapy is rendered with the informed consent?

Fluoroscopically guided injections will help us address all of these questions.

Bogduk(7) highlights the consequences of these unanswered questions by pointing out that in Australia, governmental health care regulators were enough concerned about safety and efficacy of ESI that extraordinary informed consent is now required. My personal experience in Oklahoma, and that relayed by a colleague in California, is similar. In California and Oklahoma, treatment guidelines with strict limits on the use of ESI are employed and were arrived at in the context of discussion to eliminate their use altogether.(8) Fortunately, ESI was not proscribed. The suggestion to eliminate its use is an inappropriate extreme as the use of ESI for the treatment of sciatica is generally positive. My purpose here is to not to review the evidence demonstrating the efficacy of ESI. Others have done this comprehensively(11,15-17) and the balance favors lumbar ESI without fluoroscopy as a useful treatment. Bogduk(11) states: "The bulk of

published opinion, the circumstantial evidence, and the little direct evidence that is available, thus favors the view that epidural steroids have a place in the treatment of radicular pain due to nerve-root inflammation." However, when one examines the data, most but not all of the more than 70 published studies are open-ended clinical trials without controls. The few controlled studies performed without fluoroscopic guidance are not unanimous in demonstrating the benefits of lumbar ESI.(29-31) The results are reported to range from 18% to 90%.(11) What are the causes of this wide disparity in results? Is the disparity due to sub-optimal placement of steroid? To insure that a non-fluoroscopically guided (blind) ESI is not simply an expensive intramuscular injection, shouldn't one insure that the epidural space is actually reached? My point is that the use of fluoroscopy should further enhance the erratically demonstrated efficacy of ESI and open up new treatment possibilities moving fluoroscopic guidance beyond the "interesting" and "ideal" to "medically necessary".

ESI is not the first line treatment for sciatica in most cases. Less invasive means of delivering anti-inflammatory medication are often sufficient, but when these fail and progress is not achieved by about six weeks, epidural injection of steroids is an appropriate treatment. The premise for the use of epidural steroids rests on the idea that corticosteroid delivered closely to the site of localized pathological inflammation will be more effective than p.o. or i.m. (systemic) corticosteroid, and the idea was first reported in 1952 by Robechhi and Capra.(18) After the therapeutic benefit to the patient was empirically observed, it was some time before evidence that sciatica has an inflammatory component was demonstrated. In 1981, Ryan and Taylor(10) described patients with sciatica with neurologic deficit as having "compression radiculopathy" and those with sciatica alone as having either "irritative radiculopathy" or "referred pain" mimicking sciatica. Patients with acute irritative radiculopathy were found to have elevated CSF protein supporting the notion that inflammation was the cause of the "irritation" of the nerve root(s). These patients responded best to ESI. Thus, when conservative therapy for sciatica is failing, how best can we deliver an anti-inflammatory agent to the epidural space?

What data exist indicating that "blind" ESI injections are sometimes misplaced? The incidence of failure to reach the epidural space due to a false loss of resistance using blind translaminar techniques is approximately 13% to 30%.(12,32,33) 100% of these failures could be eliminated with the use of

fluoroscopy and epidurography. (Epidurography is the injection of radiographic contrast media into the epidural space to observe the shape of the spinal canal and the direction and distribution of solutions injected.) Therefore, it is not a huge stretch of the imagination to hypothesize that the use of fluoroscopy with epidurography will increase the efficacy by as much as 13% to 30% based on the avoidance of misplacement. Even if the epidural space is entered, inadvertent intravenous injection is expected to be less efficacious. Renfrew(2), for instance, showed the incidence of inadvertent epidural venous administration with negative aspiration of blood in a series of 316 fluoroscopically guided ESIs as 9.2%. Avoidance of unsuspected inadvertent epidural venous injection could, therefore, result in an additional 9% successful injections. Not only can one observe and avoid intravenous injection, but one can reposition the needle to actually observe if the flow will be to the left or right, or dorsal or ventral. Further, it is generally agreed that due to the preferential cranial flow of solutions in the epidural space, the needle should be placed one level below the site of suspected pathology and that without fluoroscopy, one may erroneously determine the targeted interlaminar space by one or more levels.(9,22) Therefore, even without proof of superior efficacy, the fluoroscopically guided injection techniques are very likely to improve efficacy by as much as 40%.

Concerning the matter of risks and complications, the cardinal rule of the Hippocratic Oath by which we all subscribe is "First do no harm!" That ESI carries risks is well-known. Bogduk(7) cites the risks of the procedure itself as, "Not substantially different from those of epidural anesthesia:" dural puncture leading to spinal headache, and intrathecal administration of steroid, preservatives of local anesthesia leading to nerve root injury, hypotension or dyspnea. Injection of corticosteroids into the subarachnoid space may result in significant complications, and all measures to avoid this should be pursued.(21) The incidence of spinal headache following dural puncture has been reported from 7.5% to 75% depending on technique, experience and needle size(22,23) which may require treatment with an epidural blood patch.(1,24) Because the use of fluoroscopy allows the injector to carefully match the "feel" of the injection process with visual data seen on the fluoroscope and also involves epidurography, fluoroscopy should reduce the incidence of serious complication caused by dural puncture and intrathecal injection. Furthermore, by using epidurography, one can reposition the needle when intravascular flow of contrast is observed, or when the epidurogram shows preferential flow to the opposite side of the dominant

symptomatology. Andrade and Eckman presented data on normal volunteers comparing the distribution of radiographic contrast using CT scanning after epidurography.(20) In comparison to the foraminal approach which showed good ventral flow, the translaminar method showed predominantly dorsal flow which is more remote from the usual site of inflammation. Finally, fluoroscopy also allows real time appreciation of fusion masses, congenital abnormalities, scoliosis curves, spinal stenosis, fusion hardware, laminectomy defects, and likewise, the ability to choose almost any needed view for angling the injection needle. Awareness of these factors should increase accuracy and safety, and produce less trauma and discomfort to the patient. Logically, fluoroscopy with epidurography will increase safety and comfort with administration of ESI as compared to "blind" injections for the difficult as well as the uncomplicated patient undergoing ESI.

Does fluoroscopy and epidurography add any additional risk to ESI? What about radiation and the iodinated contrast used with the epidurogram? I routinely record the fluoroscopy time and exposure factors for every procedure I perform. It takes, on average, about 21 seconds of fluoroscopy to perform a translaminar ESI including filming for epidurography.(25) This is testimony to the speed of the procedure, and the radiation associated with 21 seconds of fluoroscopy time is a clinically acceptable dose to the patient, and an insignificant dose to the injectionist using proper radiation precautions. The patient's skin entrance dose is less than or equivalent to the radiation dose for an AP and lateral lumbar spine and due to proper tight collimation, the absorbed dose even smaller.(26)

A preliminary epidurogram adds the introduction of radiographic contrast media to the procedure. This carries the additional risk of allergic reaction which if anaphylactic, can be fatal.(27) One must use only contrast approved for intrathecal use to avoid the potentially catastrophic risk of subarachnoid ionic contrast media. The subclass of water soluble contrast media generally approved (but not in all concentrations) is nonionic and either of low osmolality or iso-osmolar with body fluids. The risk of serious anaphylactic reaction, in a very large multi-center study of low osmolar contrast medial injections, is reported to be 0.04% or 4 in 10,000 with only 1 death in 337,647 cases, which could not be directly attributed to the contrast medial with certainty.(27) Therefore, the risk of death to non- intravenously injected non-ionic contrast media is exceedingly small and not a significant risk factor.

Questions as to the additional cost can be raised regarding fluoroscopically guided injections, specifically, a fluoroscope or C-arm unit, film, supplies, developer, contrast media and a radiographic technologist. Costs vary and I will not go into that issue in detail here, however, there are numerous potentially offsetting savings for accurate fluoroscopically guided injections that need to be pointed out. First, insuring that the epidural space has in fact been reached should reduce the need for a second injection as much as 13% to 39% of the time by avoiding misinjection into the perispinal soft-tissue planes or epidural veins. Improved accuracy should also reduce the need for second injections when the initial injection has no therapeutic response. Because the injector knows exactly where the steroid was applied with epidurography, patients can be contacted in follow-up to determine if a second injection is indicated, knowing that a preliminary failure to respond or meager partial response was in fact a true treatment failure and not due to misplacement. The timing and number of ESIs is not standardized(11) so that in my practice, if the patient has had an accurate injection and less than 30% relief of pain at one week telephone follow-up evaluation, as a general rule, I do not repeat the injection. In a practice audit of patients, Andrade and Eckman(31) found that generally patients who obtained little relief with the first ESI also showed little benefit with the addition of second and third injections given with fluoroscopy. Potentially numerous superfluous ESIs can therefore be eliminated at a substantial savings which could offset or even outweigh the added costs incurred with the use of fluoroscopy.

Finally, what other potential enhancements are offered by fluoroscopy for the administration of injected steroids for back pain with sciatica? Two of them may already be here. Most of us use diagnostic/therapeutic selective epidural nerve root blocks (SENRB) with local and steroid. It may well prove that for radiculopathy, the SENRB, being more specifically targeted than the translaminar or caudal ESI is more effective. Andrade and Eckman showed the potential benefit of the foraminal approach using computed tomography following translaminar and foraminal selective injections.(20) We have no published data, as yet, to support the hypothesis that a selective L5 ESI is any more effective than a translaminar injection at L5-S1. Yet many of us have experienced the superiority of a selective block at L5 under a fusion mass as opposed to a caudal or translaminar injection at L3-4? How many of us will go on to more specifically target our steroids to a left L5 SENRB for a left L4-5 HNP with radiculopathy

when the clinician has requested merely an ESI? Schellas(13) has shown promising therapeutic results by selectively injecting HIZs with local and steroid using fluoroscopic guidance. HIZs are thought to be outer annular fissures seen on MR1, and may be associated with symptomatic inflammation and sciatica conveyed through the overlying nerve root.

In conclusion, the questions of "medical necessity" regarding the use of fluoroscopy with the administration of ESI is, at the moment, partially answered, but a review of the extant data supports:

1. The probability that fluoroscopic guidance will enhance the efficacy of ESI.
2. That the use of fluoroscopy is leading to new treatment options.
3. That the use of fluoroscopy adds no unnecessary risk.
4. That the use of fluoroscopy may not add to the overall costs of ESI, it may even reduce them.
5. That the use of fluoroscopy may well be medically necessary for the simple and complex case.

I call upon the members of ISIS to further the work thus far accomplished to more fully substantiate that fluoroscopy is indeed medically necessary for the safe and efficacious delivery of lumbar ESI.

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