



## Nerve Root Stimulation as an Alternative to Spinal Cord Stimulation in the Treatment of Chronic Radicular Pain in Human

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### Abstract

Epidural Spinal Cord Stimulation (ESCS) is a well-established non-destructive intervention to control human chronic pain conditions. Persisting pain after lumbar disc surgery is one of the most frequent indications to carry out ESCS. This type of pain which mainly is caused due to epidural fibrosis can also be treated by the method of Nerve Root Stimulation (NRS). We used both treatment approaches by patients with chronic radicular pain due to epidural fibrosis after disc surgery. We observed the advantage of the NRS over the ESCS. There is usually a better match between stimulus paresthesia and pain radiation with the NRS and that there is no change in the stimulus paresthesia when the patient changes position, which can play a major role in professional life.

**Keywords:** Pain treatment; CT; Chronic radicular pain; NRS; ESCS

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### Introduction

With the beginning of modern pain research and the declared commitment to pain therapy from the 1960s and thanks to rapid technological progress, numerous new minimally invasive methods of pain therapy were developed, such as percutaneous Epidural Spinal Electrostimulation (ESES), which was first described by Shealy [1] in 1968 and was used for the first time in Austria in 1979 [2-4] and has been developed further worldwide in many aspects over the past 50 years. In 1999 Alo et al. [5] first demonstrated the possibility of percutaneous electrode implantation for Nerve Root Stimulation (NRS) as an alternative to ESES. Lumbar and sacral NRS represent anatomic approaches and neurostimulation techniques for the treatment of ilioinguinal neuralgia, discogenic low back pain and interstitial cystitis pain and monoradicular pain due to epidural fibrosis, foraminal stenosis and facultatively also in (herpes zoster) radiculitis [5,6]. We performed this minimal invasive technique for the treatment of chronic pain, especially in low back pain, in persistent pain after laminectomy, in stump and phantom limb pain after extremity amputation and traumatic plexus lesions, in complex regional pain syndromes (Mb. Sudeck) and in pain due to peripheral arterial occlusions. An aim of the work was to evaluate, retrospective, the output of the pain treatment using NRS and ESES by patients with persistent chronic radicular pain. The work was presented in part in an abstract form [7,8].

### Patients and Methods

#### Patients

Fourteen patients, 7M/7F, at age of  $51.2 \pm 2.1$  years, min 37 years and max 67 years, with chronic radicular pain due to epidural fibrosis after disc surgery were involved. This is a prospective comparative study. All the patients' privacy and data were maintained confidentially throughout the research process. Approval from the Institutional Review Board Commissions of Lower Austria was obtained, including a written informed consent. The patients were informed about this procedure and accepted to use the data. Diagnosis of pain was based on the clinical pain profiles, physical examination and CT or MRI.

#### Criteria for pain relief visual analogue scale (VAS)

Pain intensity was measured using Visual Analogue Scale (VAS) for pain from 0 to 10, where

0 is no pain and 10 is the worst pain imaginable. Using VAS patients determine the pain intensity, two times before NRS and after NRS until 21 months.

### Epidural spinal cord stimulation (ESCS)

Lead implantation is performed usually percutaneously due to a Tuohy cannula and the electrode are forwarded through the cannula and placed under fluoroscopic control dorsomedial in the epidural space at the level Th9-11 (Figure 1) for lower extremity pain conditions and at the level C5-7 for upper extremity pain conditions. Stimulation sensations should cover the painful region in order to receive optimal pain control [6].

### Fluoroscopic guided lumbar NRS

In lumbar NRS the Tuohy needle insertion and lead placement is performed under fluoroscopic control in a rostro-caudal direction (Figure 2), perpendicular to the Tuohy needle insertion as practiced in ESCS. The electrode is guided caudal into the nerve root sleeve and even beyond though the neural foramen, as can be seen in Figure 3. This technique also can be used for S1 to S3 NRS, as shown in Figure 4. The procedure of NRS was carried out under sterile conditions, in local anesthesia and under fluoroscopic control. The puncture of the epidural space was carried out at the level of L2/L3 in patient's prone position using a Tuohy cannula, which was introduced into the spinal canal in a caudal direction (Figure 2). A quadripolar lead (4 electrode outlets) was introduced through the cannula and forwarded to the neuronal foramen of the affected nerve root (Figure 3, 4). After placement of the lead in the nerve root sleeve (transforaminal) test stimulation is performed.

### Statistical methods

The value of VAS was expressed as a mean ± SEM and analyzed using independent samples Students't test and one-way ANOVA analysis t were applied. P<0.05 was considered significant.

Four groups of VAS were used for statistical analysis: VAS value of patients' numbered from 1 to 7 before and after NRS; VAS value of patients' numbered from 8 to 14 before and after ESES. All data

represents means ± SEM. Number of independent measurements are given in parentheses; \*\*\*P < 0.001 vs. corresponding control (VAS data before stimulation), (Table 1).

### Results

In 14 patients with chronic radicular pain due to epidural fibrosis after disc surgery the value of VAS was 6.67857 ± 0.20032 (min 5, max 7.5), (Table 1). Significant reduction of pain has been found after stimulation with NRS and/or ESCS, thus the VAS value was 3.00714 ± 0.38949 (min 1, max 6) and the pain reduction was by 45%, P=7.28566E-9. One way ANOVA between both groups revealed the significant differences (F=70.26777 p=7.28566E-9).

As shown in Table 1 in patients numbered from 1 to 7 the introduction of the lead could be performed successfully, the effect of NRS in these patients was positive and statistically significant, and patients reported a marked pain relief due to NRS from 6.714 to 1.857 on the VAS, respectively. 72% (P=9.59423E-8) of pain relieve could be measured. One-way ANOVA analysis revealed significant pain reduction (F=127.26606, p=9.59423E-8). In the following patients from 8 to 14 the NRS was not possible to apply and ESCS was followed (Table 1). After ESCS the pain relieve could be seen too, and the VAS value reduced from 6.643 to 4,157 respectively. We found 37% of pain relieve and the effect was statistically significant (P=1.37345E-4). One- way ANOVA analysis revealed significant pain relive (F=30.19548, p=1.37345E-4). One-way ANOVA analysis of VAS value between the four groups of data revealed significant differences, F=55.13483, p=6.487663E-11. No significant difference of VAS value was observed between group of patients from 1 to 7 and from 8 to 14, (P=0.86669) before stimulation. One-way ANOVA analysis revealed no significant differences (F=0.02941, p=0.86669). The data indicated similar pain degree of both patients group. Comparing VAS value of groups after stimulation significantly (P=3.4051E-4) higher therapeutic value was observed by patients with succeeded NRS stimulation, by 223% respectively. One-way ANOVA analysis revealed significant differences (F=24.43073, p=3.40051E-4). In respect to used procedures it is important to convey

**Table 1:** Pain relief by using Nerve Root Stimulation (NRS) and/or Epidural Spinal Electrical Stimulation (ESES) in patients with persisting pain after lumbar disc surgery.

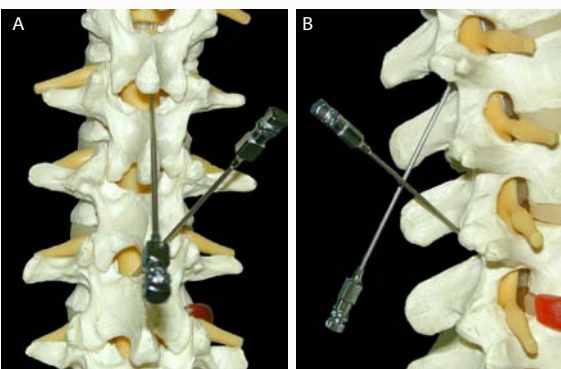
Patients number	Nerve	Method	Additional procedures	VAS before NRS	VAS after NRS
1.	S1 left	NRS S1 left	-	5.0	2.0
2.	S1 left	NRS S1 left	SCS lead could be explanted	7.5	2.5
3.	L3 left	NRS L3 left	SCS lead could be explanted	6.5	2.0
4.	S1 left	NSR S2 left	-	6.0	1.0
5.	S1 left	NRS within the spinal canal (U-shape)	SCS lead additional	7.5	(3.0) 1.0
6.	L5 right	NRS		7.5	2.5
7.	L4 left	NRS	Ascending NRS lead position	7.0	2.0
<b>Total</b>	<b>7 permanent NRS implantations</b>			<b>6.714 ± 0.359 (N=7)</b>	<b>1.857 ± 0.237 (N=7)***</b>
8.	L4 right	NRS not possible	SCS was followed	7.0	3.5
9.	L5 right	NRS ex after 6 months		6.5	3.0
10.	L5 right	NRS not possible	SCS was followed	7.0	4.5
11.	L5 left	NRS not possible	SCS was followed	6.5	3.5
12.	L5 left	NRS not possible	SCS was followed	6.0	6.0
13.	L5 left	NRS not possible	SCS was followed	7.5	5.0
14.	L5 left	NRS not possible	SCS was followed	6.0	3.5
<b>Total</b>	<b>7 times NRS was not possible</b>			<b>6.642 ± 0.210 (N=7)</b>	<b>4.157 ± 0.400 (N=7)***</b>



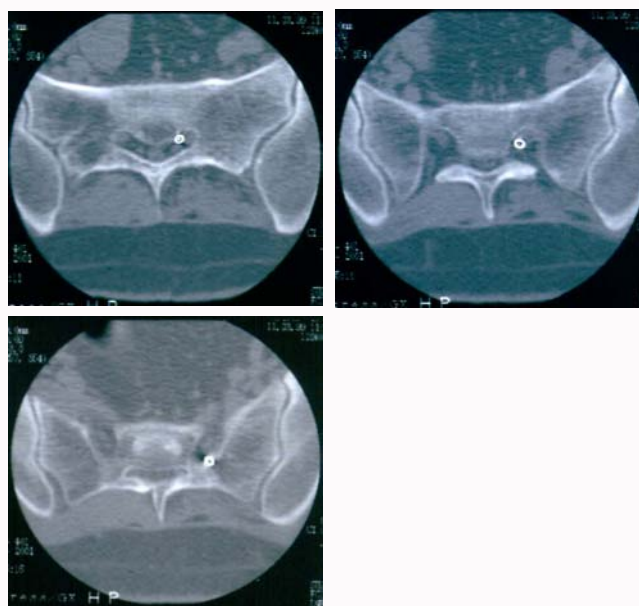
**Figure 1:** Medtronic Quad lead for Epidural Spinal Electrical Stimulation (ESES) in AP (left) and lateral (right) view of a patient. The electrode is placed paramedian to the right in the dorsal epidural space with the tip at the level of the middle of the vertebral body of Th10.



**Figure 4:** Electrode placement for the Nerve Root Stimulation (NRS). Medtronic Quad in the left nerve root sleeve S2.



**Figure 2:** Model of Tuohy needle represents positioning for Epidural Spinal Electrical Stimulation (ESES) and Nerve Root Stimulation (NRS). Positioning the Tuohy cannulas for electrode placement for ESES, the Tuohy cannula is inserted rostral into the epidural space (2A), and for NRS, the cannula is placed caudally into the epidural space (2B).



**Figure 5:** CT images of lead placement in the neural foramen S1. The positional relationship between the electrode outlet and the nerve root can best be seen in the CT image.



**Figure 3:** Medtronic Quad lead in the left nerve root sleeve L3 with implanted stimulator for NRS. The stimulation electrode lies epidural in the spinal canal and exits caudally through the neuroforamen L3/4 extraforaminally. The neurostimulator is on the left side.

the conclusion that although the technique of lumbar NRS is not applicable in all anatomic conditions, we have experienced extremely positive results. We also experienced that with this implantation technique there is a lower risk of lead migration, there is much less

current intensity affordable (increasing stimulator battery life time) and there are constant stimulation sensations under body motions achievable. Whereas during the test stimulation period by patients with ESCS and also during long term stimulation patients frequently report diminished or changed sensations and in fluoroscopic and CT controls lead migrations could be detected easily and to equal extent. We report also some important observation made during our clinical work. CT guided lumbar lead implantation for NRS has been carried out in a small number of patients but this technique has the disadvantage of frequent lead displacement, as the lead is guided from a lateral angle through muscle tissue and cannot be fixed as in the above-mentioned techniques. CT guided sacral lead implantation for NRS also has been carried out in our institution for perineal and pelvic pain and this technique seems to us to be more practicable than the direct approach under fluoroscopic control. Exact controls of electrode placement in the foramen and in close vicinity to nerve root could be better estimated by means of CT (Figure 5) than with fluoroscopic controls (Figure 3).

## Discussion

Technically, the NRS method is relatively sophisticated and difficult to carry out. We experienced that under image intensifier control the stimulation electrode is introduced into the epidural space *via* an insertion cannula and directed caudally to the affected nerve root and was successful only in about half of the cases. Since this technique of lumbar NRS is not applicable in all anatomic conditions we experienced in seven out of fourteen patients with definitive implanted systems extremely positive results and significant pain reduction by 72%. Patient with not successful NRS were immediately introduced to ESES. This group of patient's has experienced pain relief due to ESES too, but to less extends by 37%. We found that in the case of monoradicular and homolateral biradicular pain due to therapy-resistant radiculitis or epidural fibrosis a better result can be achieved with the type of electrical stimulation, which is carried out in the further steps in the same way as ESES. If the cannula insertion in the rostro-caudal direction is unsuccessful or if the electrode cannot be directed caudally into the desired root pocket ESES can be attempted in the same session. NRS and ESES can be ideally combined and we observed particularly benefits of NRS. The advantage of the NRS over the ESCS thus as there is usually a better match between stimulus paresthesia and pain radiation with the NRS and notably that there was no change in the stimulus paresthesia when the patient changes position. Furthermore, the NRS also has a clear economic advantage over the ESES since the expensive battery-operated stimulation system has to be replaced less frequently due to the current being up to two thirds lower. Compared to ESCS, the NRS method requires only 1/3 the stimulus current, which is a significant advantage in the long-term course of patient management. In addition, NRS provides constant stimulus sensations during body movement. Importantly, no electrode displacement was observed in an observation period of up to 21.5 months. Levine and co-worker reported excellent therapeutic output by patients using NRS, too [9]. The decision as to which type of stimulator to choose for uni-, bi- or quadripolar ESES depended on the indication. Frequent use of the stimulation system and the need to frequently adjust the stimulus intensity make it necessary to opt for a radio-transmitting system. Several novel devices including rechargeable generators (lifetime up to 25 years), new stimulation modalities including radiofrequency technology, dorsal root ganglion stimulation, burst stimulation and other paradigms have been introduced in recent years [10,11]. The high frequency stimulation with kHz showed a significant positive effect compared to the ESES with low frequency, especially for back pain [10,11]. The procedures to manage the approach for successful pain relive is complex and require not only support from industry but experienced team with excellent anatomical knowledge. From a clinical perspective, large, non-industry sponsored clinical trials comparing available options to determine which stimulation paradigms are superior for particular disorders are urgently needed. In addition, more attention should be paid to better understanding the loss of efficacy that occurs over shorter or longer periods of time. Future studies should also try to better clarify the treatment failure in addition to the successes. The advantage of NRS compared to ESES is that the correspondence between stimulus paresthesia and

pain radiation is generally better with NRS and that when the patient changes position, there is no change in stimulus paresthesia, which is a problem in professional life can play a prominent role.

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B. Kepplinger was responsible for pain management and therapeutic application. B. Kepplinger carried out the pain treatment and P. Kalina provided clinical details and supported CT and MRI work. All authors contributed to and have approved to the final manuscript.

## Conflict of Interest

All authors have no conflict of interest.

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