

Safety and Efficacy of Lumbar Spine Radiofrequency Neurotomy in the Presence of Posterior Pedicle Screws

Stephan Klessinger

ABSTRACT

Objective: To determine the safety and the efficacy of lumbar spine radiofrequency neurotomy performed in the presence of pedicle screws in patients with chronic low back pain. **Methods:** Retrospective practice audit. Review of charts of all patients who underwent lumbar radiofrequency neurotomy in the presence of pedicle screws. Patients were tested with a minimum of two controlled medial branch blocks and treated with radiofrequency neurotomy. A successful outcome was defined as at least 50% pain reduction for a minimum of three months. **Results:** Thirty eight patients were identified with pedicle screws present at the time of the neurotomy. No adverse effects were observed and no patients reported a worsening of the pain after RFN. No clinical effect related from heating of the metal devices was observed. A pain reduction of at least 50% for a minimum of three months was achieved in 20 patients (52.6%). Pain in the index segments and also in adjacent segments was treated with no difference in success. **Conclusion:** Some 50% of the patients with pedicle screws benefits from radiofrequency neurotomy for about six months. This potential benefit for the patient must be offset against the risk of the procedure, which might be higher because of the increase in temperature of the metal devices. Still, no adverse effects were observed. Selection of treatment level and positioning the electrode next to the pedicle screws are challenging.

1. Nova Clinic, Neurosurgery,
Biberach, Germany.
2. Ulm University, Neurosurgery,
Ulm, Germany.

Address for correspondence:
1. Nova Clinic, Neurosurgery,
Biberach, Germany.
2. Ulm University, Neurosurgery,
Ulm, Germany.
klessinger@nova-clinic.de

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INTRODUCTION

Patients with history of lumbar spine fusion often present with persistent back pain. The causes of this pain may be elusive, but one possibility is pain stemming from the lumbar zygapophysial joints, either at segments adjacent to the fusion, or at the fused segment itself, because of residual mobility.

RFN has been shown to be an effective treatment option for pain arising from the zygapophysial joints [1]. The available data vindicate the use of lumbar medial branch neurotomy provided that the correct technique is applied and patients are selected rigorously using controlled blocks [2, 3]. The efficacy of RFN has also been demonstrated for certain subgroups, such as patients with spondylolisthesis [4] or patients after spine surgery [5]. However, no study exists about RFN in patients after fusion with pedicle screws.

With the increase in spinal instrumentation surgery interventional spine practitioners are likely to encounter patients with symptomatic zygapophysial joint pain [6]. However, hazards to the safe conduct of RFN arise in patients in whom pedicle screws have been used to facilitate fusion. A study in cadavers has shown that pedicle screws could serve as a possible source of tissue heating and thermal injury during radiofrequency neurotomy (RFN) [6, 7]. In these patients, it must be considered that the pedicle screws conduct the heat energy along the entire shaft of the screw [6, 7]. Even

if the radiofrequency cannula is not in direct contact with the metal, there is potential for transfer of heat energy to the hardware [6, 7].

This risk has to be weighed against the potential benefit of RFN for chronic low back pain in the presence of pedicle screws. However, no clinical studies have explored the risk, safety, or effectiveness of RFN in patients with pedicle screws. The present study was, therefore, undertaken to address these issues.

METHODS

An electronic medical record system was used to identify all patients in a single spine center, who had received a lumbar RFN in the presence of dorsal pedicle screws. The RFN procedures were performed between January 2005 and December 2014. All patients were tested before the neurotomy with minimum two medial branch blocks at different time points each with a combination of triamcinolone (5 mg) and bupivacaine (0.25%). Injections were performed with fluoroscopic visualization using an established techniques [2]. RFN was only considered after positive testing (at least 80% pain relief). Patients came through referral by a physician or on their own initiative.

Patients with metal devices but without pedicle screws (e.g. patients with disc prosthesis or interspinous devices), and patients after removal of the pedicle screws were excluded.

Target joints for testing with medial branch blocks were identified by the pain pattern, local tenderness over the area, and provocation of pain with deep pressure. This study differentiated between levels with and without movement and between pedicles with and without screws. Fusion level means that both vertebra of the motion segment contain pedicle screws and a cage in the intervertebral space with the intention to immobilize this segment. For example, fusion level L4/5 means screws in the pedicle of L4 and in the pedicle of L5 and a cage in the intervertebral space L4/5. In this example the adjacent cephalic level would be L3/4. This motion segment can move, however, L4 contains pedicle screws. A distant cephalic level would be L2/3. None of the two vertebrae contains screws. In some patients the levels above the fusion (either adjacent cephalic or distant cephalic) or the level below the fusion (either adjacent caudal or distant caudal) were found to be painful, but in most patients at least one fusion level was included in the diagnostic test with medial branch blocks.

RFN treatment was performed in levels with a positive result after medial branch blocks. For RFN, a NeuroTherm JK3 generator (NeuroTherm, Wilmington, Massachusetts) was used. The cannulae used were 20-gauge with a 10-mm active tip. The total time of the lesion at 80°C was 60 seconds for each cycle at each level. At each level the needle was placed parallel to the nerve; multiple lesions were made in parallel for each medial branch. Each neurotomy was performed with fluoroscopic visualization (Figure 1) using an established techniques [3]; In all cases intravenous access was established. Lidocaine was used as local anesthetic. Nerve stimulation was not performed prior to radiofrequency lesioning.

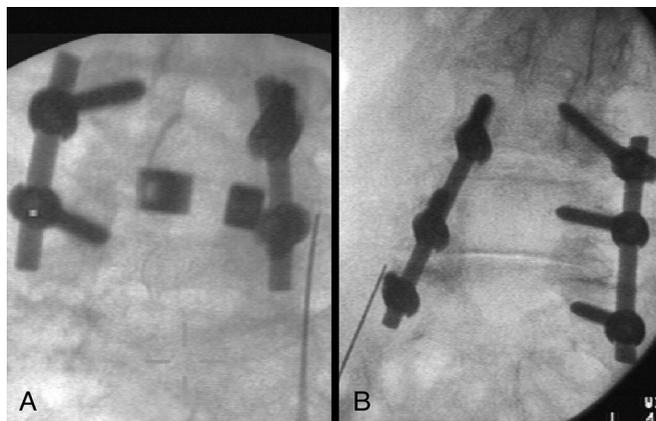


Figure 1. Positioning of the electrode for an RFN procedure in two different patients. A: L5 RFN in a patient after laminectomy L4 and L5 and spondylodesis L4/5/S1 seven months earlier. B: Patient with a transitional vertebra lumbosacral and spondylodesis in the level above.

For every patient the first follow up examination was between two and four weeks after the intervention. Further examinations were arranged according to the needs of the patients. Each time a physician interview and a clinical examination was used to capture information. A positive treatment response was defined if at least 50% reduction of pain had been achieved, or if the patient was sufficiently satisfied with the relief. A statistical analysis was performed.

Chi-square-tests was used to compare patients with favorable response to treatment and patients with negative treatment response and to investigate subgroups of patients (e.g. the different levels being treated). Welch's t-Test [8] was used to test the hypothesis that two populations had equal means (e.g. age or duration of symptoms). $P < 0.05$ was set as the threshold to interpret the results as significant.

RESULTS

In a 10-year period between 2004 and 2014, 2,520 RFN procedures were performed on the lumbar spine. Forty of these patients (1.6%) had lumbar fusion surgery with pedicle screws being present at the time of the neurotomy. Two patients were lost to follow-up. Therefore, 38 patients could be evaluated. Patient's ages were between 34 and 76 years, the mean age being 58.9 years. Nineteen men and 19 women were treated. In 50.0% of patients the fusion affected one segment, most frequently L4/5 (nine cases). Two segments were included in the spinal fusion in 28.9%, most frequently L4/5/S1 (six cases). Moreover, 18.4% of patients had a three level fusion and one patient a four level fusion. The mean number of surgeries before RFN was 2.1 (between 1 and 6). 14 patients (36.8 %) had 3 or more surgeries in history. Patients were referred for chronic pain syndrome. They were all dissatisfied with the pain situation despite multiple pain therapies.

All patients complained of back pain, and 55.3% of additional pain in one or both legs. The duration of symptoms before RFN and the mean time between fusion surgery and onset of symptoms was wide spread. The median of the duration of symptoms before RFN was 13 months, the interquartile range (IQR = $Q_3 - Q_1$) was $36 - 4 = 32$ months. The median of the time between fusion surgery and onset of symptoms was 36 months, the interquartile range (IQR = $Q_3 - Q_1$) was $48 - 12 = 36$ month. RFN was performed only at the symptomatic side. 57.9% of patients had pain on both sides (Table 1).

There are various possible etiologies for low back pain in the context of prior lumbar fusion. These include pain arising from within the fused level, discogenic pain, as well as posterior element pain at a level adjacent or distant to the fused segments. The data of the patients with favorable response and with negative response to treatment are shown in Table 1. In six patients the adjacent cephalic level level was considered to be the pain source. This means that the two levels cranial the fusion were treated with RFN. A distant caudal level was the pain source in another nine patients. Here, both levels caudal to the fusion were treated with RFN. In these two constellations the RFN was not performed in the level with the fusion, still metal devices are present at the site of RFN. Treatment of a level with fusion was performed in 23 patients. In these cases, pain is arising either from within the fused level or from the adjacent caudal level, the radiofrequency probe has to be positioned close to the metal devices (Figure 1).

Table 1. Patient characteristics in relation to treatment success

	All patients		Response to Treatment			
			Favorable		None	
	N	%	N	%	N	%
	38		20	52.6	18	47.4
Men	19	50.0	7	35.0	12	66.7
Women	19	50.0	13	65.0	6	33.3
Age (years)						
Min–Max	34–76		46–76		34–76	
Mean ± SD	59 ± 11		60 ± 10		58 ± 13	
Number of fusion levels						
1	19	50.0	11	55.0	8	44.4
2	11	28.9	4	20.0	7	38.9
3	7	18.4	4	20.0	3	16.7
4	1	2.6	1	5.0	0	0.0
Mean ± SD	1.7 ± 0.9		1.6 ± 0.8		1.7 ± 0.8	
Mean number of surgeries before RFN	2.1 ± 1.3		2.0 ± 1.3		2.2 ± 1.3	
Median pain duration (month): IQR = Q3 – Q1	13 32 = 36 – 4		22 31 = 36 – 5		11 20 = 24 – 4	
Median time between surgery and RFN (month): IQR = Q3 – Q1	36 32 = 48 – 12		39 39 = 54 – 15		22 41 = 49 – 7	
RFN side						
both	22	57.9	11	55.0	11	61.1
left	9	23.7	5	25.0	4	22.2
right	7	18.4	4	20.0	3	16.7
IQR: Interquartile Range						

In the report of the radiofrequency intervention of eight patients, difficulties with the positioning of the electrode because of the screw and the metal devices were mentioned. In these patients the ideal position of the electrode could not be found or the desired number of lesions was not possible to perform.

Despite difficulties in positioning the electrode because of obstructed view or obstructed access in some patients, no adverse effects were observed and no patients reported a worsening of the pain after RFN. A clinical effect from heating of the metal devices was not observed. A pain reduction of at least 50% for a minimum of three months was achieved in 20 patients (52.6%). Fourteen patients did not respond to radiofrequency neurotomy. In addition, four patients with a positive response to RFN but with a pain relief lasting less than three months were treated as negative outcome. The mean duration of pain relief after the first RFN was 6.2 month. Eleven patients were treated with a second RFN. Eight of these patients had a mean pain relief of at least 50% for 5.3 month. Six patients had more than two treatments. The duration of pain relief of all RFN procedures is shown in Figure 2. Although, initially a good effect was achieved in 20 patients, these patients needed continuing health care. Some of these patients were treated

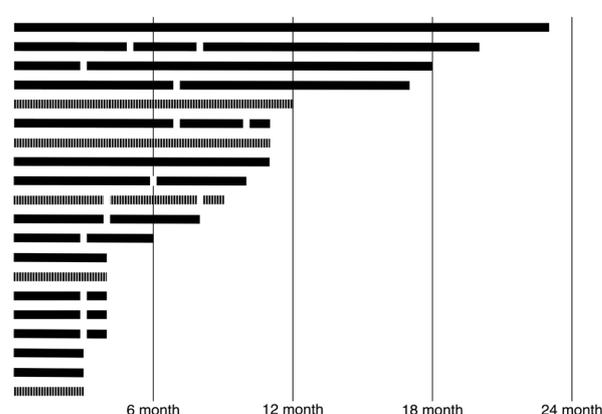


Figure 2. Duration of pain relief reported by patients treated successfully with RFN. Each bar represents one patient and indicates the duration of relief following a single treatment. The results of the three subgroups are shown. Black bar: 50 % pain relief, dashed bar: 80 % pain relief.

in our practice for several years (mean time 36 month) after RFN. Often a progress of the pain syndrome was observed. Five patients with positive response after RFN used opioids already before the RFN and they continued afterwards. No patient maximized pain medication or started with opioids while the effect of the RFN lasted on. But 10 patients

started with opioids later (mean 20 month) after RFN; two patients were provided with a spinal cord stimulator several years after RFN.

There was no significant difference between patients with positive response to RFN and patients with negative response to RFN in terms of age, sex, the number of segments included in the fusion, duration of symptoms, and time between surgery and RFN (Table 1). Comparing the three subgroups of patients (treatment in a level with fusion or without fusion), no statistically significant difference was found as regards the amount or duration of pain relief.

DISCUSSION

This is the first study to determine whether RFN is safe and effective for patients with pedicle screws after lumbar spine fusion surgery. Although evidence exists that both titanium and stainless steel pedicle screws are capable of sustaining significant increases in temperature during RFN in the clinical setting [6, 7], no effect from heated metal devices was detected. The patients reported no adverse effects or worsening of pain. Therefore, despite the potential risk, RFN in the presence of pedicle screws appears to be a safe procedure.

Effectiveness of RFN in patients with the condition after lumbar fusion surgery and in the presence of pedicle screws exists. However, both the number of patients with improvement and the duration of pain relief are not as good as in other studies [1, 9–11]. In this study, 52.6% of patients had minimum pain relief of 50% for a mean duration of 6.2 month. In contrast, in the study of Dreyfuss et al. [10], 60% of the patients treated with RFN experienced 80% pain relief lasting at least 12 months and 80% experienced 60% pain relief. Similar outcomes were found in a study of Gofeld et al. [11]. Sixty eight percent of patients maintained at least 50% pain relief for between 6 and 24 months. The recent study of MacVicar et al. [1] showed pain relief for over 12 months, and for much longer if RFN was repeated. They suggested complete relief of pain with no need for other health care as the benchmark for successful lumbar RFN. This objective was definitely not reached in this study.

For the success of RFN the technique of parallel needle placement and the selection of patients are important [9]. Parallel needle placement or even the exact visualization of the anatomical structures can be challenging in patients with metal devices and pedicle screws. Sometimes compromises have to be made. In some patients less than the optimum number of lesions was performed and in others the position of the electrode was not ideal and therefore the length of the nerve being coagulated was shorter than desired. This might be the reason for the shorter duration of pain relief observed in the present study.

Another reason for the lower success rate of this study might be the patient selection. RFN was performed after controlled medial branch blocks. Nevertheless, the patient selection in this study is exceptional. All patients had chronic back pain and all underwent up to 6 surgeries because of back

pain without success. The fusion of two or more vertebrae was often the last resort after various types of treatment, but again without satisfactory result. Failed back surgery is a condition in which a diagnosis is often not forthcoming, and for which there is no proven treatment. Against this background, providing relief in a small proportion of patients is not insignificant. RFN in patients with pedicle screws provides possible pain reduction for a limited time period. Unfortunately, often a progression of the pain syndrome was observed when the affect of the RFN subsides. The results of this study are comparable with a study on patients after microsurgical disc removal in which 58.8% patients experienced at least 50% reduction in pain for a minimum of six months [5]. Still, the nature of surgery (discectomy, laminectomy or fusion) has to be considered.

Finding the symptomatic joints for medial branch blocks and also, therefore, for RFN is a challenge particularly in patients after fusion surgery. No aspect of the patient's history or physical examination characteristics exists to identify a zygapophysial joint as a pain source [12, 13] To identify index joints by the pain pattern, local tenderness over the area or provocation of pain with deep pressure might be difficult in the presence of extensive scar tissue. Imaging of the spine is important to identify the type and extent of spondylodesis, and it is possible to identify degenerative changes adjacent to the level of instrumentation. However, imaging cannot identify the pain source. The majority of published clinical investigations report no correlation between the clinical symptoms of low back pain and degenerative spinal changes observed on radiological imaging studies [14 – 16]. In this study, pain in the index segments and also in adjacent segments was treated with no difference in success. When selecting the level of treatment, the technical feasibility of positioning the electrode next to pedicle screws must also be considered.

In conclusion, RFN offers pain relief for some 50% of the patients treated. This potential advantage for the patient must be offset against the risk of the procedure, which might be higher because of the increase in temperature of the metal devices. Still, no adverse effects were observed. The selection of the level of treatment and the positioning of the electrode next to pedicle screws are challenging. Further studies with better outcome measures would be desirable. This study could show that RFN in the presence of pedicle screws is a safe procedure. This is a prerequisite for further studies to be performed.

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