Retrospective Review

A Retrospective Review of Spinal Radiofrequency Neurotomy Procedures in Patients with Metallic Posterior Spinal Instrumentation – Is it Safe?

Stephen Ellwood, BS, Peter Shupper, MD, and Andrew Kaufman, MD

From: Rutgers- New Jersey Medical School, NJ

Address Correspondence:
Stephen Ellwood, BS
Doctors Office Center
90 Bergen Street, Suite 3400
Newark NJ 07103
E-mail: sjellwoodnj@gmail.com

Disclaimer: None of the authors have any conflicts of interest to report. None of the authors of the manuscript received any remuneration. Further, the authors have not received any reimbursement or honorarium in any other manner. However, all the authors are members of the Rutgers New Jersey Medical School Division of Pain Management and practicing interventional pain physicians except for Stephen Ellwood, who is a medical school student. Dr. Kaufman is the Director of The Comprehensive Pain Management Center of Rutgers New Jersey Medical School.

Manuscript received: 02-05-2018
Revised manuscript received: 03-09-2018
Accepted for publication: 04-03-2018

Free full manuscript:
www.painphysicianjournal.com

Background: Recent studies have shown that medial branch radiofrequency neurotomy (RFN) procedures done at the level of a pedicle screw can increase pedicle screw temperature, and it has been speculated that pedicle screw heating may cause thermal injury. There has been a limited amount of investigation into the real-world safety profile of RFN procedures in patients with pedicle screws.

Objectives: We aim to demonstrate that the occurrence of serious adverse events is rare for a medial branch RFN procedure completed at a level with metallic spinal hardware when performed according to the Spine Intervention Society practice standards.

Study Design: This study involved retrospective chart reviews of every patient who received an RFN procedure for spinal facet joint pain during the 5-year time period from 2012-2016.

Setting: The research took place within a single university-based interventional pain management center.

Methods: The study sample included 507 patient charts. Data collection included patient demographics, RF denervation sites at a level with metallic hardware, and all serious RF-related complications that could be attributable to heated metallic hardware. The research team developed medical-chart abstraction criteria for each of the following categorized complications: a) superficial burns, b) deep burns, c) denervation of dorsal ramus, d) denervation of ventral ramus, and e) coagulation of a spinal vascular structure.

Results: Of the 36 patients who met the inclusion criteria for this study, 43.6% were men and 56.4% were women. The mean age was 59.5 years old, with an age range of 25 to 87 years. There were a total of 56 ablations performed at a level with metallic spinal hardware, of which 11 were cervical, 44 were lumbar, and 1 was thoracic . There were zero documented complications found among our patient population in any of the 5 categories of serious complications.

Limitations: As a retrospective chart review, this study was dependent on the availability and accuracy of medical records. Chart abstraction criteria for each outcome measure were developed by the research team without scientific testing.

Conclusions: There have been no reported complications attributable to hardware temperature increases when performing medial branch RFNs at the level of a pedicle screw. For safety, it is important to use multiplanar fluoroscopic imaging techniques to ensure that the RFN cannula is not in contact with the pedicle screw.

Key Words: Radiofrequency neurotomy, medial branch nerve ablation, safety, thermal injuries, metallic spinal hardware, pedicle screws, lateral mass screws, cervical facet joints, severe complications, adverse events

Pain Physician 2018: 21:E477-E482

Interventional pain physicians often encounter patients with a history of posterior spine instrumented fusion and persistent pain located near the surgical site. One potential cause of this pain is facet joint arthropathy (FJA) at or adjacent to the level of fusion, and it is known that patients with posterior pedicle screws are at risk for FJA (1). In patients without instrumentation, facet joint pain is often successfully treated with medial branch nerve radiofrequency neurotomy (RFN), and therefore, patients with posterior spine instrumented fusion and facet joint pain may be candidates for RFN (2-8). There is limited data, however, on the real-world safety profile of RFN procedures in patients with posterior spinal instrumentation, as many studies that analyze the safety and efficacy of RFN procedures exclude patients with a prior history of spinal surgery or metallic instrument placement (4,6,9).

One proposed risk of performing an RFN procedure in patients with posterior spinal instrumentation is the transmission of heat through the metallic hardware, causing thermal injury to surrounding structures. A cadaver study showed that it is possible for pedicle screws to heat significantly when in direct contact with an RF cannula (10). Additionally, a prospective study showed pedicle screws are capable of temperature increases (11). Despite the potential for the transfer of heat energy to hardware, there have been no reported cases in the literature of RFN-related adverse events directly attributable to the heating of metallic instrumentation (10,11). A retrospective study evaluating the safety and efficacy of RFN procedures in the presence of lumbar posterior pedicle screws reported no adverse events or worsening pain (12). Similarly, we present a retrospective chart review study designed to evaluate evidence of serious adverse events/complications that may be directly attributable to performing a medial branch RFN procedure at a level with metallic instrumentation. This is the first study to include patients with cervical and thoracic pedicle screws in the analysis of the safety of RFN procedures.

Methods

This study was approved by the Rutgers-New Jersey Medical School Institutional Review Board. All patients at a single comprehensive pain center who had received an RFN procedure for spinal facet joint pain during the 5-year time period of January 1, 2012-December 31, 2016 were identified using CPT (Current Procedural Terminology) billing codes designated for spinal radiofrequency ablation procedures of the medial branch nerves. Procedures selected were those that included RF electrode placement from C2-C3 (Fig. 1) to the sacral ala. Patients were included in the study if they met the following criteria: a) the patient had one diagnostic

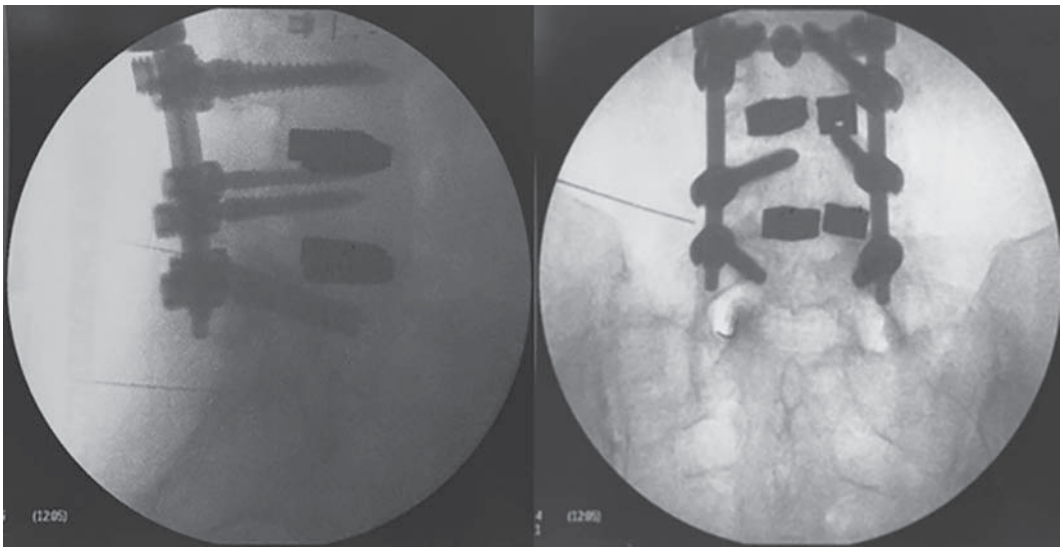

Fig. 1. *Fluoroscopic cervical images demonstrating the positioning of the electrode for a medial branch nerve RFN procedure in a patient with lateral mass screws.*

medial branch block using bupivacaine (0.5%, 0.5 mL) with at least 80% temporary pain relief; b) the patient had undergone a medial branch nerve RFN procedure at a level with a metallic posterior pedicle screw or lateral mass screw; c) there was clear documentation in the patient's chart confirming the location of the posterior instrumentation as determined by either fluoroscopic imaging or radiologic report; and d) patients had either no sedation or minimal sedation, as defined by obtaining less than or equal to a total of 2 mg of versed and/or 100 mcg of fentanyl and being able to interact appropriately with the operating physician to complete sensory and motor testing. Patients were excluded if they did not have pedicle screws at the level of RFN, were pregnant or under the age of 18, did not have at least 2 documented follow-up appointments with the clinic, required excessive sedation, or if the RFN procedure was aborted at the level of spinal instrumentation due to the practitioner's inability to reproduce the pattern of pain at 50 Hz.

Outcome measures were selected from potential serious complications/adverse events suggested in recently published papers (10,11). Chart abstraction criteria were developed by the research team based on these outcome measures (Table 1).

Data were collected directly from patients' paper medical charts (i.e., operative reports, postoperative notes, clinic follow-up notes, radiology reports, and other specialists' notes). Data collected included patient demographics, RF denervation sites at a level with metallic hardware, and all RF-related complications that could be attributable to the heating of metallic hardware (Table 1). Before being classified as a complication, the chart was reviewed and adjudicated by at least 2 physicians. Descriptive statistical analysis was performed and is reported as means and percentages.

Radiofrequency Lesioning Protocol

All RFN procedures were performed as closely as anatomically possible (given the hardware impediments) to the techniques described in the International Spine Intervention Society (ISIS) practice guidelines of 2004. For lumbar procedures, "the target point for placement of the electrode is the lateral surface of the superior articular process just above its junction with the root of the transverse process," with the exception of the L5 dorsal ramus, which "is targeted where it crosses the ala of the sacrum" (13). For cervical procedures, "the target point is the centroid of the articular pillar with the same segmental number as the target nerve" (13). Prior to RFN, each patient completed sensory testing done at 1 V and 50 Hz with the patient reporting no radicular pain, and motor testing done at 3 V and 2 Hz with no extremity movement. A lesion temperature of 80°C was used for 90 seconds per ablation, and only one lesion was made at each level. For each

Table 1. *Chart Abstraction Criteria*

Outcome Measure	Required Documentation Findings
1. Superficial Burn	- Physical examination findings of localized skin changes near the RF site that can be characterized by erythematous changes that blanch with pressure and are tender to palpation (with or without blistering).
2. Deep Burn	- New onset of moderate to severe localized (near the area of the RFN procedure) pain lasting more than 2 weeks. - Pain is different in character from previous pain or is worsening, and prompts a workup that yields findings directly related to thermal injury.
3. Denervation of Dorsal Ramus*	- New onset of neuritic or deafferentation pain/dysaesthesia/allodynia/numbness in the paravertebral skin and/or new onset fibrillation of paraspinal muscles at the level of RFN lasting for more than 2 weeks.
4. Denervation of Ventral Ramus*	- New onset of/development of neuritic pain/dysaesthesia/sensory loss with or without muscle weakness/wasting/fibrillations in a somatic dermatome/myotome distribution lasting more than 2 weeks and correlating with a level at which an RFN procedure was done.
5. Damage to a Spinal Cord Vessel*	- New onset clinical symptomatology consistent with an acute spinal cord infarction (ASCI) with new imaging findings. -For cervical RFN procedures: New onset symptomatology consistent with either clinical features of ASCI or stroke due to a vertebral artery infarction with new imaging findings.
* For the above complications, a further workup must have been completed and the determination made that it was not possible to rule out thermal injury from the heating of metallic hardware as the likely cause.	

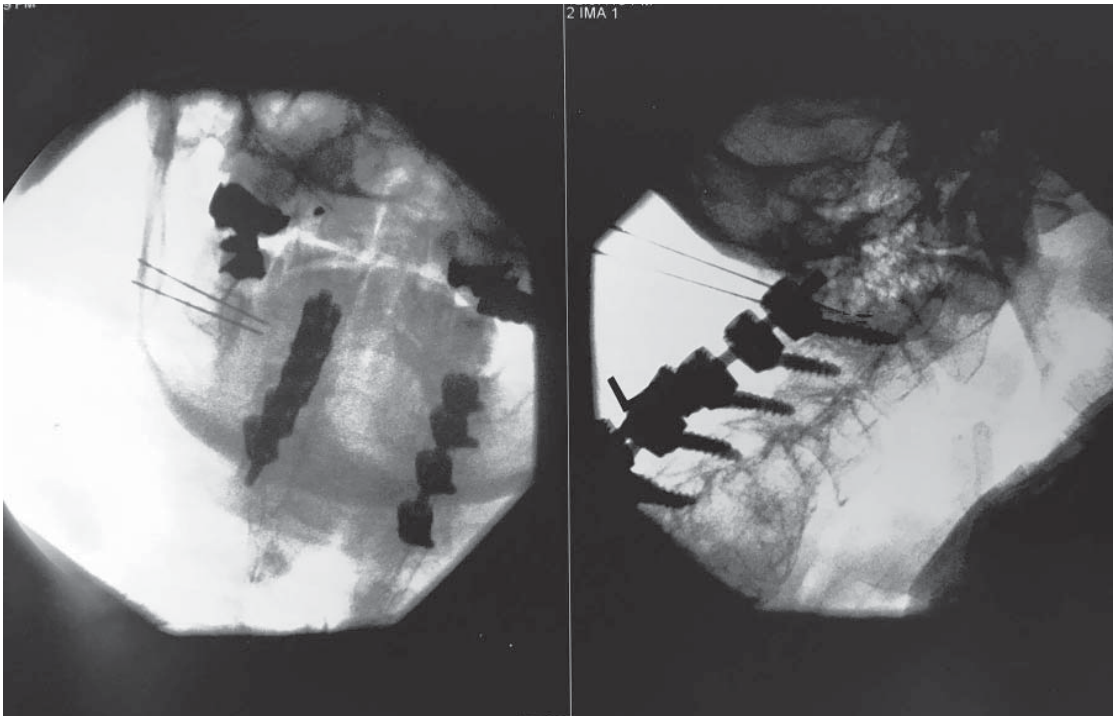

Fig. 2. *Fluoroscopic lumbar images demonstrating the positioning of the electrode for a medial branch nerve RFN procedure in a patient with lumbar pedicle screws.*

RFN, a Stryker Radiofrequency Generator (Kalamazoo, MI) was used with a 22-gauge, 100-mm cannula with a 10-mm straight active tip for lumbar sites (Fig. 2); a 22-gauge, 100-mm curved cannula with a 10-mm active tip for thoracic sites; and a 50-mm straight cannula with a 5-mm active tip for cervical sites.

Results

In the 5-year time period between January 2012 and December 2016, 507 patients received at least one medial branch spinal RFN procedure at our interventional pain practice. Of these 507 patients, 39 completed at least one medial branch RFN procedure at a level with metallic spinal hardware. Three patients were lost to follow-up and were therefore excluded from the study. Patients ranged in age from 25 to 87 years, with a mean age of 59.5 years old; 43.6% were men and 56.4% were women. Of the 36 patients who met inclusion criteria for this study, a total of 56 ablations were performed at a level with metallic spinal hardware: 11 were cervical, 44 were lumbar, and 1 was thoracic (Table 2). Four patients had 2 consecutive medial branch nerve ablations at a level with metallic hardware completed on the same day, and 2 patients had 3 consecutive medial branch nerve ablations at a level with metallic hardware completed on the same day. Seven patients received bilateral ablations at a single level with metallic hardware.

In this study, there were no documented findings of any of the 5 investigated types of severe complications. We found 2 documented cases in which there was a post-procedural adverse event (Table 3). However, neither of these adverse events appears to have been related to the potential temperature increase in pedicle screws or even to the RFN procedure itself. Therefore, we report a complication rate of 0% with no observable adverse events directly attributable to the heating of spinal instrumentation in our select patient population.

Discussion

Only one other study has evaluated the safety of RFN procedures in patients with pedicle screws and

lumbar spinal fusions (12). Our study is the first to evaluate the safety of RFN performed on patients in all spinal segments. We found no procedural complications related to the heating of posterior metallic instrumentation.

A recent cadaver study showed that direct contact between an RF cannula and a pedicle screw, heated to 80°C for 90 seconds, produced substantial temperature changes throughout the length of the screw (mean range: 4.4°C -16.72°C above baseline temperature)(10). However, when the RF cannula was placed at the conventional RF cannula target position (the junction of the transverse process and the superior articular process) and not in direct contact with the pedicle screw, these dramatic increases in the temperature of the pedicle screw did not occur (mean range: 0.32°C -1.84°C above baseline temperature) (10). Therefore, a clinically meaningful increase in pedicle screw temperature seems to be largely dependent on whether the RF probe is in direct contact with the screw.

Following the aforementioned cadaver study, an in vivo prospective study was performed that measured intraoperative pedicle screw temperature during 10 lumbar medial branch RFNs conducted at 80°C for 90 seconds at the conventional RF cannula target position. Reported temperature changes from a pre-procedure baseline to intra-procedure ranged from no change to an increase of up to 6°C (for a reported temperature of 42°C, at which point the ablation was terminated) in 2 patients (11). This increase in pedicle screw temperature appears to be incongruent with the temperature increase observed in the cadaver study.

Importantly, in the in vivo study, pedicle screw temperature was measured by placing a second RF cannula in direct contact with the dorsal aspect of the pedicle screw and "as close as possible to the expected medial branch for each particular level," implying a more lateral placement on the pedicle screw. This placement of the temperature probe at the lateral aspect of the dorsal surface of the pedicle screw and very near the ablating RF cannula may yield temperature findings that are confounded by expected temperature increases in the surrounding soft tissue. Therefore, we suggest that placement of a temperature probe on the direct center or medial aspect of a pedicle screw may provide a more accurate assessment of screw temperature. Unfortunately, we were not able to assess the significance of additional temperature monitoring in our study, as this was a retrospective study conducted at an interventional pain practice that did not use additional temperature probes to monitor pedicle screw temperatures during RFN procedures.

Despite theoretical risks, to our knowledge there have been no reported RFN-related adverse events attributable to medial branch nerve RFN at a level with metallic posterior pedicle screws, when a) conducted according to ISIS practice guidelines and b) when the RF cannula is not placed in direct contact with the ped-

Table 2. *Patient Demographics*

Total Patients		**36 (56 ablation procedures)**
Age (years)	Mean ± SD	59.5 ± 14.8
	Range	25-87
Gender	Men n (%)	15 (41.7)
	Women n (%)	21 (58.3)
RFA Location	Cervical n (%)	11 (19.6)
	Thoracic n (%)	1 (1.8)
	Lumbar n (%)	44 (78.6)

Table 3. *Post-radiofrequency neurotomy procedure adverse events*.

Patient #	**Finding**	**Location of Performed RFN***	**Details**
1.	Increased Back Pain	Right L3	Severely localized back pain that was different in character from her prior facet joint pain and lasted for more than 2 weeks following RFN. Further workup discovered that she had a new pancreatic stone.
2.	Radicular Pain (New Onset)	Right L4	Right-sided acute radicular symptoms with "numbness, weakness, and a shooting-type pain" down the back of the patient's leg starting 8 weeks after the completion of his RFN procedure. Physical exam findings were consistent with a new radiculopathy in a right L4/L5 dematome/myotome distribution. Further workup discovered a new herniated disk at the level of L4-L5.

* Location is based on the level of the pedicle screw

icle screw (13). Our findings are consistent with those presented by Klessinger et al; RFN procedures in the presence of metallic spinal hardware are indeed safe, despite the suggested theoretical risks (12).

Our research has several limitations. First, the study was dependent on the availability and accuracy of medical records. Second, there is potential for bias in the study design with respect to the abstraction criteria for outcome measures; these criteria were developed by the research team and not externally validated. Finally, there exists the possibility of confirmation bias; data abstractors were all members of the research team and not blinded to our own hypotheses.

To date, there are no studies investigating the effects of metallic spinal hardware on RF lesion size, and there are no prospective studies addressing the safety profile of this procedure in the context of pedicle screws (14). Additional in vivo studies are warranted to evaluate the possibility of thermal energy transfer to posterior pedicle screws in patients undergoing RFN at all levels of the spine. We believe that the optimal temperature probe placement for future in vivo studies is directly on the posterior-medial aspect of the pedicle screw; such placement avoids potentially confounding temperature readings resulting from surrounding soft tissue temperature increases. Patient safety is paramount, and while more evidence is needed to determine the risks associated with medial branch nerve RFN at the level of posterior pedicle screws, we believe the presence of posterior pedicle screws may not contraindicate medial branch RFN treatment at that level.

References

1. Lawrence BD, Wang J, Arnold PM, Hermsmeyer J, Norvell DC, Brodke DS. Predicting the risk of adjacent segment pathology after lumbar fusion: A systematic review. *Spine* 2012; 37:S123-S132.
2. Manchikanti L, Kaye AD, Boswell MV, Bakshi S, Gharibo CG, Grami V, Grider JS, Gupta S, Jha SS, Mann DP, Nampiaparampil DE, Sharma ML, Shroyer LN, Singh V, Soin A, Vallejo R, Wargo BW, Hirsch J. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain. *Pain Physician* 2015; 18:E535-E582.
3. MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Cervical medial branch radiofrequency neurotomy in New Zealand. *Pain Med* 2012; 13:647-654.
4. Klessinger S. Zygapophysial joint pain in post lumbar surgery syndrome. The efficacy of medial branch blocks and radiofrequency neurotomy. *Pain Med* 2013; 14:374-377.
5. Boswell MV, Trescot AM, Datta S, Schultz DM, Hansen HC, Abdi S, Sehgal N, Shah RV, Singh V, Benyamin RM, Patel VB, Buenaventura RM, Colson JD, Cordner HJ, Epter RS, Jasper JF, Dunbar EE, Atluri SL, Bowman RC, Deer TR, Swicegood JR, Staats PS, Smith HS, Burton AW, Kloth DS, Giordano J, Manchikanti L; American Society of Interventional Pain Physicians. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111.
6. Leon JF, Ortiz JG, Fonseca EO, Martinez CR, Cuellar GO. Radiofrequency neurolysis for lumbar pain using a variation of the original technique. *Pain Physician* 2016; 19:155-161.
7. Kornick C, Kramarich SS, Lamer TJ, Sitzman BT. Complications of lumbar facet radiofrequency denervation. *Spine* 2004; 29:1352-1354.
8. Manchikanti L, Singh V, Vilims BD, Hansen HC, Schultz DM, Kloth DS. Medial branch neurotomy in management of chronic spinal pain: Systematic review of the evidence. *Pain Physician* 2002; 5:405-418.
9. Moon JY, Lee PB, Kim YC, Choi SP, Sim WS. An alternative distal approach for the lumbar medial branch radiofrequency denervation: A prospective randomized comparative study. *Anesth Analg* 2013; 116:1133-1140.
10. Gazelka HM, Welch TL, Nassr A, Lamer TJ. Safety of lumbar spine radiofrequency procedures in the presence of posterior pedicle screws: Technical report of a cadaver study. *Pain Med* 2015; 16:877-880.
11. Lamer TJ, Smith J, Hoelzer BC, Mauck WD, Qu W, Gazelka HM. Safety of lumbar spine radiofrequency procedures in patients who have posterior spinal hardware. *Pain Med* 2016; 17:1634-1637.
12. Klessinger S. Safety and efficacy of lumbar spine radiofrequency neurotomy in the presence of posterior pedicle screws. *Progress in Orthopedic Science* 2016; 2:30-34.
13. Bogduk N. *Practice Guidelines for Spinal Diagnostic and Treatment Procedures* 1st ed. International Spine Intervention Society, Hinsdale, IL, 2004.
14. Eckmann MS, Martinez MA, Lindauer S, Khan A, Ramamurthy S. Radiofrequency ablation near the bone-muscle interface alters soft tissue lesion dimensions. *Reg Anesth Pain Med* 2015; 40:270-275.