Randomized Trial

Dexamethasone Effectively Reduces the Incidence of Post-neurotomy Neuropathic Pain: A Randomized Controlled Pilot Study

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Background: Radiofrequency neurotomy (RFN) of facet or sacroiliac joints is widely used for the treatment of chronic axial pain and can provide long-term pain relief in well-selected patients. The most common side effect is transient neuropathic pain at the paravertebral level of interest. Pain physicians commonly administer corticosteroid post-neurotomy to reduce the risk of post-neurotomy neuropathic pain, yet it remains unclear if this provides a true reduction in incidence.

Objectives: To determine the efficacy of corticosteroid administration post-lesion in preventing the development of post-neurotomy neuropathic pain after cervical, thoracic, lumbar, and sacroiliac joint radiofrequency denervation.

Study Design: Randomized, placebo-controlled, double-blind prospective study.

Setting: Ambulatory Surgical Center within a Tertiary Hospital System.

Methods: This trial is registered on ClinicalTrials.gov (NCT03247413). Permission to conduct human research was obtained from the Institutional Review Board. Eligible patients included those with cervical, thoracic, or lumbar facet or sacroiliac joint pain who had positive concordant medial branch blocks (thus scheduled for bilateral RFN), at least 18 years of age, and English-speaking. Patients received dexamethasone vs saline (control) at each lesion site, serving as their own control (with laterality). Follow-ups were completed at 4- and 8-weeks post-intervention to evaluate the incidence of post-procedure pain (questionnaire) and function using the Oswestry Disability Index (ODI) or the Neck Disability Index (NDI).

Results: At the time of data analysis, 35/63 patients completed the study protocol. There was a statistically significant reduction in the incidence of post-neurotomy pain in the steroid group vs the control group (20/35 control group vs 3/35 steroid group, $P < 0.001$). ODI/NDI scores changed differently over time depending on the spinal level of neurotomy, showing statistically significant improvement in ODI/NDI in the cervical subgroup and lumbar subgroup at 4-week ($P = 0.05$) and 8-week time points ($P < 0.01$), respectively. There was no improvement of ODI scores in the sacral subgroup. The incidence of post-neurotomy neuropathic pain was not significantly different among patients with different spinal levels of neurotomy. Patients who developed post-neurotomy neuropathic pain did not differ in ODI/NDI scores at any time point.

Limitations: This study has several limitations, most notably the number of patients lost to follow-up, the use of a single corticosteroid, and the use of laterality for incidence reporting. Additionally, all procedures were performed by a single interventionalist using one neurotomy system.

Conclusions: A statistically significant reduction in post-neurotomy pain was observed in the steroid group. This protocol can be feasibly conducted in an effective and resource-efficient manner. Additional research is needed to increase the power of the study.

Key words: Post-neurotomy neuropathic pain, radiofrequency ablation, corticosteroid, dexamethasone, facetogenic pain

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Chronic neck and back pain (1) has become one of the leading causes of disability and productivity loss in the United States. This pain is often associated with poor quality of life, depression, anxiety, and sleep disorders (1-3). Conservative measures, such as physical therapy and medications, are first-line treatment options and can provide pain improvement in some individuals. However, for patients who failed conservative management, interventional procedures offer another treatment modality. For patients with facet- or sacroiliac joint-mediated pain who responded positively to prognostic nerve blocks, radiofrequency neurotomy (RFN) can provide long-term relief (4). RFN is a relatively safe procedure with minimal risk of adverse events (5). However, as with any procedure involving damage to the peripheral nervous system, there is a risk of post-neurotomy neuropathic pain (PNN). Following lumbar facet and sacroiliac joint RFN (7), PNN has been documented at a rate ranging from 0.5% to 9.2% per lesion (6).

PNN is often described as a "burning," "numbness," and "shooting" sensation at the paravertebral level of the lesion (6,7). In patients who have undergone lumbar facet or sacroiliac joint RFN, these symptoms can last anywhere from 2 to 6 weeks (7). The reported incidence (19%) of PNN is higher in patients who have undergone cervical facet RFN. The average duration is 2.6 months and can drastically affect a patient's quality of life during this phenomenon (8). Transforaminal epidural and intraarticular steroid injections (17) are commonly used in interventional procedures to decrease inflammation and pain at nerve roots and facets, respectively (1,4). Similarly, interventionalists commonly administer corticosteroid post-neurotomy to reduce the risk of PNN; however, it remains unclear if this provides an actual reduction in incidence. Two previous retrospective reviews (9,10) demonstrated conflicting views regarding the benefit of steroid administration after neurotomy. However, both studies discussed the need for a large prospective trial to make a sound recommendation. To date, only one small randomized controlled trial suggested the benefit of pentoxifylline or methylprednisolone administration (11) after lumbar medial branch neurotomy to reduce PNN. Therefore, the purpose of this study was to determine if corticosteroid (dexamethasone) injections (22), delivered at the time of lesion(s), effectively prevent the development of PNN through a placebo-controlled, double-blind, randomized trial in patients undergoing cervical, thoracic, lumbar, and sacroiliac joint RFN.

Methods

Permission to conduct human research was obtained from the Johns Hopkins University School of Medicine Institutional Review Board. The main trial is registered on ClinicalTrials.gov (NCT03247413). Patients were recruited from the eligible pool of patients seen in the pain management clinic through the Department of Physical Medicine and Rehabilitation. The current standard of care determined candidacy for bilateral neurotomy: achieving greater than 50% pain relief after 2 concordant prognostic medial branch blocks (12). Eligible patients were either consented in the office or on the day of their first neurotomy. Resident/fellow co-investigators remained unblinded to coordinate the study and blind both the interventionalist and patient.

Patients received unilateral lesion(s), followed by the lesion(s) on the contralateral side no sooner than one week apart. Contents of the initial injection (steroid vs control) and laterality (right vs left) was determined by computer randomization (Randomizer application). After randomization, the patient would receive an injection of a steroid (dexamethasone 4mg/mL, 1 mL) at each lesion site during their first neurotomy, followed by an injection of a normal saline (1 mL) at each lesion site during their second neurotomy on the contralateral side, or vice versa. For example, a 3-level neurotomy would require 4 needle sites and a total of 16 mg of dexamethasone for that side. The patient and the interventionalist were both blinded to the contents of the injections. Patients were then followed up at 4- and 8-week time points in the clinic or via telephone encounter after their second neurotomy to monitor their response. They were able to request an earlier appointment if complications arose. Independent of the number of levels ablated per procedure, each patient provided a total of 2 data samples. If patients developed neuropathic pain, they were either monitored without intervention or initiated on gabapentin/oral corticosteroids, depending on symptom severity. Considering the potential for referred pain patterns to confound accurate spinal level estimation, the incidence of PNN was recorded by laterality (right or left) (13). A questionnaire (Fig. 1) was developed to monitor for PNN at 4- and 8- weeks post-neurotomy, and an Oswestry Disability Index (ODI) (14) or Neck Disability Index (NDI) (15) was administered at baseline, 4-weeks, and 8-weeks post-neurotomy to monitor functional outcomes. Patient demographics (gender, age, and race) and parameters of the neurotomy (needle gauge size, duration of neurotomy, and temperature of neurotomy) were also collected for potential subanalysis. At the time

of data analysis, 63 patients had been enrolled, and 35 patients had completed the study protocol (Fig. 2).

Post-ablation Neuropathic Pain Questionnaire

1. Do you/Did you have pain described as a burning or painful dysesthesia that is new since the procedure?
   a. If yes, when did it start?
   b. How long did it last?
   c. Did it prevent you from completing normal acts of daily living?

Fig. 1. *Post-ablation neuropathic pain questionnaire.*

Inclusion/Exclusion Criteria

Inclusion criteria included patients greater than 18 years old and English-speaking seen in the pain management clinic in the Department of Physical Medicine and Rehabilitation with a diagnosis of either cervical, thoracic, lumbar facet, or sacroiliac joint pain who responded to concordant medial (or lateral for sacral level) branch blocks with lidocaine or similar anesthetic agent, and were scheduled for bilateral RFN. Patients who experienced less than 50% pain relief in one or both medial (or lateral for sacral level) branch blocks did not progress to RFN and, therefore, were not considered for inclusion in the study (4).

Exclusion criteria included patients previously scheduled (within the last year) for RFN of the cervical, thoracic, or lumbar facet joints, or sacroiliac joints at the same levels as those examined in this study. Patients who had received any corticosteroid injection within 3 months leading up to the first RFN procedure, were on anticoagulation medication, had a pacemaker, were less than 18 years old, or non-English speaking were also excluded (Fig. 3).

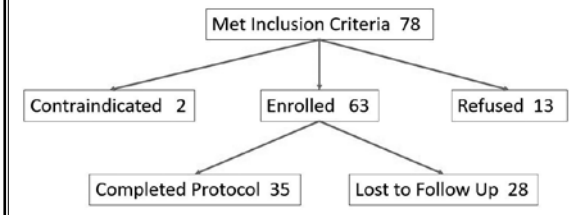

Fig. 2. *Pilot study protocol.*
Both contraindications were due to allergies to corticosteroids. Thirteen patients lost to follow-up were recruited in early 2020 and did not complete protocols due to COVID-19 pandemic restrictions. One patient was not able to complete a second ablation due to illness. The remaining 14 patients were not reachable for follow-up in the protocol window (8 weeks) or decided to receive corticosteroids for different pain etiologies.

Inclusion Criteria:

- Diagnosis of either cervical, thoracic, lumbar facet or sacroiliac joint pain who responded to concordant medial (or lateral for sacral level) branch blocks, and thus were scheduled for bilateral radiofrequency ablations.
- Greater than 18 years old
- English speaking.

Exclusion Criteria:

- Patients previously scheduled (within the last year) for radiofrequency ablation of the cervical, thoracic, lumbar facet joints, or sacroiliac joints at the same levels as those examined in this study
- Received any corticosteroid injection within three months leading up to the first RFA procedure.
- Anticoagulation
- Pacemaker
- Less than 18 years old
- Non-English speaking

Fig. 3. *Inclusion/exclusion criteria.*

Definition of Treatment Failure or Patient Removal Criteria

Treatment failure was defined as the development of PNN within 2 months (length of follow-up for study) of post-neurotomy steroid administration. Patient removal criteria included: patient request for removal, lack of post-procedure follow-up, receiving steroid injection while still enrolled in the study, and rapid development of weakness or sensory loss post-injection. In this event, the patient would not have been given further study protocol injections, and data would have been used to report an adverse event. Once the study was complete, or if participation in the study ended prematurely, patients continued with the standard of care.

Drug Rationale

Injectable corticosteroids can be categorized into particulate and nonparticulate compounds. Current commercially available particulate agents include triamcinolone, betamethasone, and methylprednisolone. Injecting particulate steroids near the spinal cord's vas-

culature, such as the radiculomedullary arteries during transforaminal epidural steroid injections (TFESI) (16,17), poses an increased risk of paralysis. Dexamethasone is the most used nonparticulate compound and has a well-known safety profile as an anti-inflammatory medication. It is the recommended agent by the Multisociety Pain Workgroup for all cervical TFESIs and/or initial lumbar TFESIs (18-21). Although vascular injury risk is reduced with dexamethasone use (22), it is not completely eliminated. This type of injury has not been reported when targeting facet joints, but the authors considered this theoretical risk in the setting of reported intravascular penetration, especially with cervical facet nerve blocks (23). Additionally, intraarticular steroid injections have been associated with higher risks of influenza (24) and considering the current COVID-19 pandemic, there theoretically may be an increased risk of COVID infection after steroid administration. However, the duration of immune suppression could be less with dexamethasone (25). Thus, dexamethasone is considered the safest injectate across all spinal segments. It was chosen for this study due to safety (nonparticulate) and ease of blinding (dexamethasone in solution is clear like normal saline). The interventionalist used dexamethasone 4 mg/mL, with 1 mL given at each level to potentially blunt the inflammatory response causing PNN (24).

Procedure

All neurotomies were completed using the Stryker Multigen 2 RF generator and 18-gauge 150 mm RF Venom cannulas (Stryker, United States). Neurotomy technique followed currently recommended protocols for cervical, thoracic, and lumbar spinal levels with cannulas placed under fluoroscopic guidance parallel to the medial branches and sacral sulci for the L5 dorsal rami (20). For all sacroiliac neurotomies, 18-gauge 150 mm RF Venom cannulas were placed under fluoroscopic guidance adjacent to the lateral portion of the S1, S2, and S3 foramina in the region of the lateral branches and at the sacral sulci for the L5 dorsal rami. Once placement was confirmed by lateral and AP fluoroscopic imaging, motor testing was performed to demonstrate twitching of the back only (multifidi stimulation) and neurotomies were then completed for 90 seconds at 80 °C.

Study Statistics

Our primary outcome measure was the incidence of PNN after neurotomy. We used a chi-squared test of proportions to compare the proportions of incidence of PNN following saline or steroid injections on each side. We also performed several secondary analyses. To assess whether the spinal level of neurotomy affected ODI/NDI scores over time, we used a 3 x 3 mixed model repeated measures analysis of variance (ANOVA) with the spinal levels (i.e., cervical, lumbar, sacral) as the between-patients factor and time (i.e., baseline, 4-week follow-up, 8-week follow-up) as the within-patients factor. To assess whether the incidence of PNN differed across patients with different spinal levels of neurotomy, we used a chi-squared test. We also performed a chi-squared test of proportions to assess whether there was an order effect of the injections (i.e., whether receiving steroid injection first may have some protective effect over the contralateral side). Finally, to assess whether patients who developed PNN differed in ODI/NDI scores from those who did not develop PNN, we used a 2 x 3 mixed model repeated measures ANOVA with PNN (yes or no) as the between-patients factor and time (i.e., baseline, 4-week follow-up, 8-week follow-up) as the within-patients factor. All analyses were performed using SPSS (Version 26.0, (IBM Corporation, Armonk, NY) with $\alpha \leq 0.05$. Bonferroni post hoc corrections for multiple comparisons were applied when appropriate.

Results

Out of the 63 enrolled patients, 35/63 patients completed the study protocol at the time of data analysis. Average age of patients was 58.83 years of age. Fifteen men and 20 women completed the protocol. There were 15 patients in the cervical subgroup, 1 patient in the thoracic subgroup, 14 patients in the lumbar subgroup, and 5 patients in the sacral subgroup (Table 1).

The Incidence of PNN was Significantly Higher Following Saline Injection vs Steroid Injection

The incidence of PNN following saline (control) injection was significantly higher than following steroid injection (χ^2[1, n = 70] = 18.7, $P < 0.01$). Specifically, we observed that PNN occurred in 20/35 patients (57.1%) following saline (control) injection, but only in 3/35 patients (8.6%) following steroid injection (Fig. 4).

ODI/NDI Scores Changed Over Time Depending on the Spinal Level of Neurotomy

We observed a significant main effect of spinal level (F[2,24] = 4.39, $P = 0.02$) and a significant level x time interaction (F[4,48] = 5.12, $P < 0.01$) but no signifi-

cant main effect of time (F[2,48] = 0.032, $P = 0.97$). Post hoc analyses revealed no significant differences among ODI/NDI scores among patients of different spinal levels at baseline (all $P = 1.00$). However, patients with neurotomy at the sacral level showed significantly higher scores than patients with neurotomy at the cervical or lumbar levels at both the 4- and 8-week follow-up assessments (all $P < 0.03$). Furthermore, when comparing across time, patients with neurotomy at the cervical level showed a significant decrease in ODI/NDI scores from baseline to the 4-week follow-up ($P = 0.05$), and patients with neurotomy at the lumbar level showed a significant decrease from baseline to the 8-week follow-up ($P < 0.01$). In contrast, patients with neurotomy at the sacral level did not show significant changes from baseline to either follow-up ($P = 0.25$ at 4-week follow-up, $P = 0.09$ at 8-week follow-up) (Fig. 5).

The Incidence of PNN was Not Significantly Different Among Patients with Different Spinal Levels of Neurotomy

We did not observe a statistically significant difference in the proportions of patients who developed PNN among different spinal levels of neurotomy (χ^2[3, n = 34] = 1.33, $P = 0.51$)

Patients Who Developed PNN Did Not Differ in ODI/NDI Scores at Any Time Point

We did not observe significant main effects of PNN (F[1,25] = 2.48, $P = 0.13$) or a significant PNN x time interaction (F[2,50] = 0.92, $P = 0.41$) on ODI/NDI scores, demonstrating patients who developed PNN did not differ in ODI/NDI scores at any time point.

The Order of Injection Had No Effect on Incidence of PNN

Of the patients who received dexamethasone first, 7 had PNN on the saline side, and 5 did not. Of the patients who received saline first, 13 had PNN on the saline side, and 10 did not. We did not observe any statistically significant difference between the proportions of patients in each group (χ^2[2, n = 34] = 0.01, $P = 0.92$).

Analysis of RF needle gauge and neurotomy temperatures was not completed as these parameters remained constant in the pilot cohort (18-gauge cannulas and 80°C, respectively).

Discussion

Administration of concomitant corticosteroids with RFN remains controversial, with some data advocating for its use and others recommending anesthetic only (9,20,26). This pilot study favors administration of corticosteroids post-lesion to prevent the incidence of PNN (8.6% in the steroid group compared to 57.1% in the control group [$P < 0.001$]). Additionally, there was

Table 1. *Cohort demographics.*

	Men	Women
Cervical	4	11
Thoracic	1	--
Lumbar	9	5
Sacral	1	4
Total	15	20

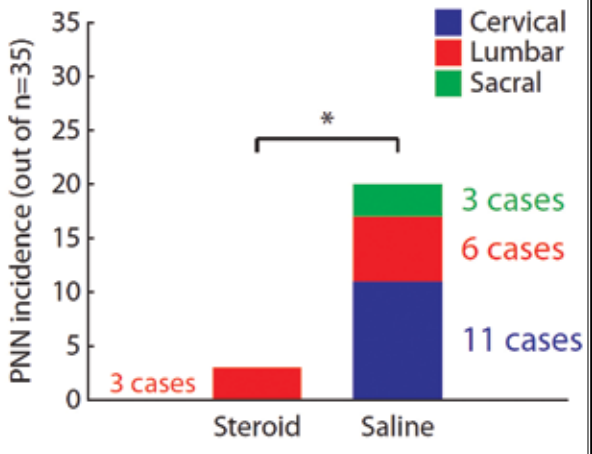

Fig. 4. *Comparison of PNN incidence among different spinal levels.*

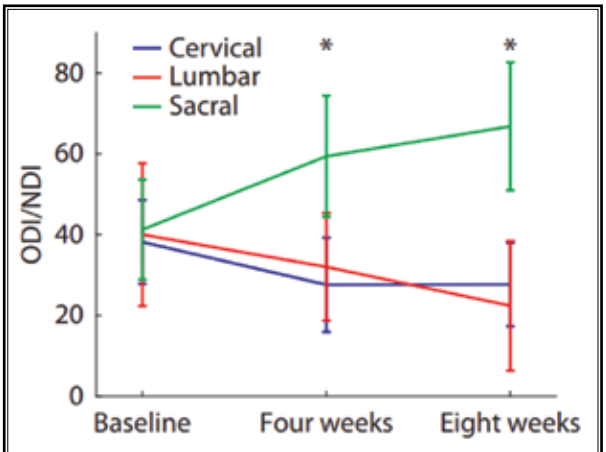

Fig. 5. *ODI/NDI change over time.*

a statistically significant improvement in the ODI/NDI scores in the cervical and lumbar groups at 4-week ($P = 0.05$) and 8-week time points ($P < 0.01$), respectively. A possible explanation for the lack of improvement in ODI scores (Fig. 5) in the sacral group is the variability in the targeted lateral sacral branches' anatomical locations, and successful neurotomy may be limited by the technique used (6,27,28). Surprisingly, the incidence of PNN was not significantly different among patients with different spinal levels of neurotomy, and patients who developed PNN did not differ in ODI/NDI scores at any time point. However, the absolute PNN incidence was much higher in the cervical subgroup, congruent to the reported incidence in Gazelka et al (8). Finally, these results demonstrate that this protocol can be completed through resource-efficient collaboration between the attending fellows, residents, and support staff without institutional or industry funding.

One other prospective study by Dobrogowski et al (11) assessed the Visual Analog Scale (VAS) at 4 time points after RFN. Patients were randomized into 3 groups: pentoxifylline, methylprednisolone, and saline (control) and all groups showed reduced pain after the procedure. However, when analyzing difference in post-ablation pain, the pentoxifylline and methylprednisolone groups (11) had reduced VAS scores, although not statistically significant. This reduction should be interpreted with caution as post-procedure pain was determined by tenderness on palpation compared to the contralateral side and did not consider neuropathic characteristics of the reported discomfort. In the current pilot study, patients served as their own control with the intention to reduce reporting bias (30). Similarly, the PNN questionnaire was designed to tease out PNN vs nonresolved pre-RFN facetogenic pain (Fig. 1). Tenderness to palpation was not a primary characteristic to quantify PNN as tenderness post-neurotomy can be common in the setting of larger (18-gauge) needle gauge use.

Singh et al (9) performed a retrospective review on 164 patients categorized into nonsteroid (n = 87) and steroid (n = 77) groups. PNN was determined if patients self-reported transient burning/neuropathic pain within 6-weeks post-RFN. The review revealed no statistically significant difference in PNN incidence between the 2 groups. This study's limitations included examining mostly unilateral lesions, relying on self-reporting where patients were not specifically asked about PNN symptoms, and a lack of control for certain confounding factors, such as technique, radiofrequency parameters, and needle gauge. In contrast, this pilot study was prospective, examined patients receiving bilateral neurotomies, and used a questionnaire specifically asking about PNN symptoms, duration, and effects on activities of daily living (Fig. 1). Additionally, although RF parameters (temperatures and needle gauge used) were collected, sub-analysis was not completed as these variables were constant across the pilot cohort.

Current literature supports that pre-ablation injection of fluid and increasing sodium chloride (NaCl) concentration consistently increases lesion size with monopolar RF. However, injection with an anesthetic minimizes procedural discomfort and lowers impedance but does not significantly affect NaCl concentration (29). A narrative review by Odonkor et al (10) investigating therapeutic value, affect lesion size, and PNN prevention concluded that steroids administered immediately after RFN may play a role in preventing PNN and providing long-term therapeutic pain relief in some patients, but may have a negative impact on lesion size if given before denervation as seen in an ex vivo study (29). The results of this pilot study support a reduced PNN incidence with post-lesion administration of corticosteroids. Although we did not explicitly monitor VAS scores, improvements in ODI/NDI scores were observed in the cervical and lumbar groups.

Our study has several limitations, most notably the large percentage of patients lost to follow-up (44%). Patient enrollment started prior to the COVID-19 pandemic, and patients enrolled in early 2020 were excluded from data analysis due to failure to complete the study protocol (Fig. 2). We plan to mitigate this issue by adding a 2-week follow-up in the main trial to reduce both reporting bias and loss to follow-up with an earlier time point to monitor the primary outcome of PNN incidence. Another limitation of this protocol is analyzing the efficacy of only one corticosteroid. Many interventionalists use particulate corticosteroids to reduce PNN incidence as facet joints are anatomically removed from radiculomedullary vessels (16,17). Therefore, it may be challenging to generalize future data analysis, and future research comparing different injectates would be necessary to demonstrate the superiority (or inferiority) of particulate vs nonparticulate corticosteroids. Yet, dexamethasone is the safest injectate across all spinal levels, which is especially relevant during the current COVID-19 pandemic (18-21,24,25). Furthermore, the current pilot data is composed of a patient pool from only one interventionalist using a single RFN system (Stryker Vector System). To improve

the generalization of results, the main trial will incorporate multi-institutional collaboration and consider factors, such as technique, RF parameters, and needle gauge (9).

It is also essential to address the significant percentage of reported PNN (57.1%) in the control group. This is likely associated with many factors, including patients reporting bias, loss to follow-up, small sample size, increased tendency of patients to report adverse effects, and identifying PNN by laterality (not per lesion) (30).

Previous literature has cited PNN incidence at an average of 5% per RFN lesion; however, our patients reported PNN based on laterality which can include up to 4 lesions per side. Therefore, the potential incidence of PNN per patient (6,8) could be higher than incidence per lesion. The time the patients remain enrolled in the study may also be considered a limitation as patients were off-study after their 8-week follow-up. This period was set based on the 6-week average time of PNN incidence, but prolonged discomfort has also been identified in the literature (6,7). Finally, the patient serving as their own control may theoretically introduce a "protective" effect if the patient received dexamethasone during their initial RFN. This effect is an inherent limitation of the study design, and sub-analysis demonstrated no statistical significance between the proportions of patients who experienced PNN and who received dexamethasone on their initial RFN. Thus, future data analysis may continue to favor post-ablative administration of corticosteroids to reduce PNN incidence. This protocol will be continued to answer an essential question in the interventional pain community.

Conclusions

Data analysis demonstrates that post-neurotomy administration of corticosteroids reduces the incidence of PNN in this cohort. This pilot study also shows that this protocol can be feasibly conducted in an effective and resource-efficient manner. Surprisingly, the incidence of PNN was not associated with higher ODI/NDI scores, but improvements in function/disability were demonstrated in the cervical and lumbar subgroups. Continued research is required to increase this protocol's power, and with multi-institutional collaboration, other possible confounding variables (e.g., RF needle gauge, RF temperatures, RF system) can be evaluated.

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