Clinical Predictors of Success and Failure for Lumbar Facet Radiofrequency Denervation

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Objective: To determine the clinical factors associated with the success and failure of radiofrequency denervation of the lumbar facet joints.

Methods: Clinical data were garnered from 3 academic medical centers on 192 patients with low back pain who underwent radiofrequency denervation after a positive response to diagnostic blocks. Success was defined as $\geq 50\%$ pain relief lasting at least 6 months. Factors evaluated for their association with outcome included duration of pain, opioid use, symptom location, paraspinal tenderness, pain exacerbated by extension/rotation (ie, facet loading), MRI abnormalities, diabetes, smoking, scoliosis, obesity, prior surgery and levels treated.

Results: The only factor associated with a successful outcome was paraspinal tenderness. Variables that correlated with treatment failure were 'facet loading,' long duration of pain, and previous back surgery.

Conclusions: It is counterproductive to use 'facet loading' as the sole basis for choosing patients for facet interventions. In patients at high risk for treatment failure, taking additional steps to reduce the rate of false-positive screening blocks may improve outcomes.

Key Words: facet joint, low back pain, medial branch block, predictive value, radiofrequency, zygapophysial joint

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Lumbar zygapophysial joint (z-joint) pain is a common cause of axial low back pain (LBP), with an estimated prevalence ranging between 15% and 40% in patients with chronic low back complaints.[1,2] Whereas previous small, uncontrolled studies proposed a "lumbar facet syndrome" based on a scoring system composed of historical and physical exam findings,[3] larger, better designed studies failed to identify a set of clinical features predictive of response to controlled blocks.[4,5] It is now widely accepted that the only valid method to diagnose the lumbar facet joints as definitive pain generators is through the use of either diagnostic intra-articular z-joint injections or blockade of the medial branches and L5 primary dorsal rami (MBB) that innervate the joints.[6] Whereas these 2 techniques are widely believed to provide comparable diagnostic utility, the evidence supporting this notion is based on only 2 randomized studies, neither of which used a crossover design or prescreened patients for lumbar z-joint pain.[7,8] Because the medial branches innervate not only the lumbar z-joints but also the multifidus muscle, the interspinous ligament and muscle, and the periosteum of the neural arch,[9] one might infer that diagnostic MBB are inherently less specific than low-volume intra-articular injections. However, in the absence of any definitive treatment or gold standard for diagnosis, this supposition is impossible to prove. Two reasons many practitioners cite as the rationale for performing MBB in lieu of intra-articular injections are that they are easier to perform and serve as a trial run before medial branch radiofrequency (RF) denervation. In any case, the utility of both types of blocks is limited by the high rate of false-positive results, estimated to be between 25% and 38%.[1,10]

Until recently, the assertion that RF denervation of the medial branches and L5 dorsal rami provided intermediate to long-term pain relief for lumbar facet pain went largely unchallenged, as 2 controlled and numerous uncontrolled studies supported its efficacy.[11–13] Yet in the past 6 years, 2 double-blind, placebo-controlled studies have been published showing no or minimal benefit for RF denervation compared to sham lesioning.[14,15] There are several possible explanations for this discrepancy, with the 2 most likely ones being methodological flaws in the earlier studies leading to invalid conclusions, and the failure of later studies to properly identify the best candidates for RF denervation. In the United States, facet joint interventions are the second most commonly performed pain management procedures, ranking just behind epidural steroid injections.[16] It is thus surprising that among the plethora of research conducted

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on facet arthropathy, no studies have sought to identify what factors predict a successful outcome for facet joint RF denervation, and which characteristics predispose patients to failure. The purpose of this study is to identify which demographic and clinical variables are associated with a positive outcome after lumbar medial branch and L5 dorsal ramus RF lesioning.

PATIENTS AND METHODS

After obtaining permission to conduct this study from the Internal Review Boards at 3 different institutions, Walter Reed Army Medical Center (WRAMC), The Johns Hopkins Medical Institutions (JHMI), and Massachusetts General Hospital (MGH), the medical records of 216 consecutive patients who underwent medial branch and L5 dorsal rami RF denervation between January 2004 and May 2005 for suspected lumbar facet joint pain were reviewed. Twenty-four patients with ambiguous or missing medical records were excluded, leaving 192 patients eligible for inclusion.

Inclusion criteria for RF denervation were age ≥ 18 years, chronic LBP ≥ 3 months duration, absence of focal neurologic signs or symptoms, and $\geq 50\%$ pain relief after diagnostic MBB. Excluded from the study were patients with a known, specific cause of LBP (eg, spondylolisthesis or significant spinal stenosis), untreated coagulopathy, or concomitant medical (eg, poorly controlled cardiac condition) or psychiatric illness (as determined historical findings, and prescreening Beck Depression Inventory) likely to compromise evaluation or treatment.

Lumbar Medial Branch and L5 Dorsal Ramus Blocks

Diagnostic MBB were performed using our previously described single[17,18] and multiple needle[19] techniques. Before needle placement, the skin at each entry point was anesthetized using ≤ 1 mL of lidocaine 1%. Patient with unilateral pain underwent unilateral blocks; those with bilateral or central pain received bilateral blocks. The number of levels blocked varied according to the patient's symptoms. Correct needle placement was confirmed in both antero-posterior and oblique fluoroscopic views after the administration of 0.5 mL of radiopaque contrast. At each level, 0.5 mL of bupivacaine or ropivacaine was injected. No patient received intravenous sedation.

In the recovery area, patients were instructed to engage in their normal daily activities and to maintain a written pain diary every 30 minutes for 8 hours. In addition to pain scores, diaries were used to monitor postblock activities. To control for the presence of other spinal pathology, $\geq 50\%$ pain relief during normal activities was used as the criterion for a positive response. All patients who obtained significant pain relief after MBB proceeded to RF denervation at their next visit.

RF Denervation

RF denervation was performed as an ambulatory procedure using superficial local anesthesia and if necessary, intravenous sedation. With the C-arm intensifier positioned to confer a slightly oblique or antero-posterior view, 22-gauge SMK-C10 (Radionics, Burlington, MA) cannulas with 5-mm active tips were inserted parallel to the course of the nerve until the bone was contacted at the junction between the superior border of the transverse process and the superior articular process for all medial branch lesions, and at the junction of the ala and articular process of the sacrum for all L5 dorsal ramus lesions. For each lesion, correct placement was confirmed using electrostimulation at 50 Hz, with concordant sensation achieved at ≤ 0.5 V. Before lesioning, multifidus stimulation and the absence of leg contractions was verified with electrostimulation at 2 Hz. After satisfactory electrode placement, 0.5 mL of lidocaine 1% was injected through each cannulae to reduce thermal pain. The RF probe was then reinserted and a 90-second, 80°C lesion was made using an RF generator (Electrothermal 20S Spine System, Smith and Nephew, Andover, MA or Radionics RF Lesion Generator System, Model RFG-3C, Radionics, Valleylab, Boulder, CO).

Outcome Measures and Statistical Analysis

All pain scores were measured using 0-10 visual analog scale (VAS) pain scores. A successful treatment was defined as a $\geq 50\%$ average (proportioning rest and activity scores) reduction in preprocedure VAS pain score that persisted at least 6 months after the procedure. In addition to treatment outcome, the other demographic and clinical variables recorded for analysis were age, sex, duration of pain, opioid usage, location of symptoms, presence of paraspinal tenderness (pain overlying the facet joints with an estimated 4 kg of applied force), presence of pain exacerbation with extension and/or axial rotation (facet loading), MRI evidence of lumbar facet joint hypertrophy or degeneration, history of diabetes, smoking history, scoliosis, obesity (body mass index ≥ 30), prior back surgery, number of levels denervated, and for procedures done at WRAMC, active duty status.

For the WRAMC patient subset, a secondary outcome measure, global perceived effect (GPE), was recorded based on the response to 3 questions routinely administered to all patients in the pain clinic. These questions were:

1. My pain is better now than before treatment;
2. The treatment I received improved my ability to perform daily activities;
3. I am satisfied with the treatment I received and would recommend it to others.

An affirmative response to all 3 of these questions at the 6-month follow-up visit was considered a positive GPE. A negative response to any of these questions constituted a negative GPE outcome.

Statistical analyses were performed using STATA version 9.1 (Statcorp, College Station, TX). The distribution of categoric variables in each group was compared using Fisher exact test for parametric data. Continuous variables were compared with analysis of variance. Categoric data are reported both by number of patients and percentage. Continuous data are reported as mean and standard deviation unless otherwise indicated. A "P" value < 0.05 was considered statistically significant. Data were combined across institutions except for the variables "active duty" and GPE. Regression analysis was used to quantify the association between the many possible predictive variables and clinical outcome. As the outcome variable was binary (either positive or negative), a logistic statistical model was chosen. Unadjusted univariate analyses were performed, followed by multivariate logistic regression. Those variables with $P < 0.25$ in univariate analysis were included in multivariate logistic regression.

RESULTS

Data were analyzed on 192 patients. Morphometric, demographic, and clinical characteristics were similar among the 3 treatment centers except that there were fewer smokers and less patients on opioids at WRAMC, a higher incidence of paraspinal tenderness in patients from MGH, and a greater number of levels treated at JHMI (Table 1). There was no statistically significant difference found for either univariate or multivariate analyses with regard to treatment outcome between study centers, therefore all data were combined.

Age, sex, and the medical center at which patients received treatment were not associated with patient-reported outcome in either univariate analysis, or when all covariates were controlled for using multivariate logistic regression (Tables 2, 3). Patients at WRAMC, JHMI, and MGH had success rates of 58%, 55%, and 43%, respectively. The mean age of those with a successful outcome was 54.3 (SD 14.2) versus 55.3 (SD 16.9) in those with a negative outcome. Forty-seven percent of males and 53% of females had a successful outcome. Obesity, diabetes, and smoking did not affect patient outcomes.

Symptom location was unrelated to procedure outcome in multivariate analysis. Axial pain was the most common presentation, with outcomes being proportionately distributed between success (n = 59; 56%) and failure (n = 47; 44%). However, when pain location was restricted to "above" and "below knee" symptomatology, a significant difference in outcomes was found with multivariate analysis ($P = 0.05$). Sixty-five percent (n = 28) of patients who had symptoms extending into their upper leg or groin had a positive outcome, with 35% (n = 15) reporting a negative outcome. In patients whose symptoms were referred below their knee, 17 (40%) and 26 (61%) had positive and negative outcomes, respectively.

There was a negative correlation between duration of pain and treatment outcome that fell shy of statistical significance. The longer a given patient suffered from pain symptoms, the less likely he or she was to report treatment success ($P = 0.1$). The mean duration of those with a negative outcome was 6.6 years (SD 6.6) vs. 4.9 (SD 5.1) in those with a positive outcome.

A substantial number of patients underwent previous treatments for LBP including opioid and surgical therapy. Although opioid usage was found to predict

TABLE 1. Patient Characteristics by Study Center

	WRAMC (n = 110)	JHMI (n = 42)	MGH (n = 40)	P*
Age in years, mean (SD)	51.2 (15.7)	57.9 (14.3)	61.2 (14.5)	0.001
Sex				0.13
Male	58 (53%)	16 (39%)	15 (37%)	—
Female	52 (47%)	26 (61%)	25 (63%)	—
Success	64 (58%)	23 (55%)	17 (43%)	0.22
Smoking	23 (21%)	15 (38%)	15 (38%)	0.04
Diabetes	12 (11%)	10 (24%)	3 (8%)	0.078
Scoliosis	14 (13%)	9 (26%)	11 (28%)	0.061
Location of symptoms				0.24
Axial	64 (58%)	24 (57%)	18 (45%)	—
Above knee/groin	27 (25%)	8 (19%)	8 (20%)	—
Below knee	19 (17%)	10 (24%)	14 (20%)	—
Obesity	43 (39%)	19 (45%)	17 (50%)	0.49
Opioid use	19 (17%)	19 (45%)	15 (38%)	0.001
Failed back surgery syndrome	23 (21%)	5 (12%)	13 (33%)	0.08
Duration of symptoms in years, mean (SD)	6.12 (6.2)	5.33 (6.7)	4.78 (4.4)	0.43
Facet pathology on MRI	65 (66%)	25 (68%)	27 (68%)	1.0
Facet loading	72 (67%)	26 (70%)	31 (79%)	0.35
Paraspinal tenderness	50 (51%)	25 (68%)	35 (88%)	0.001
Number of levels treated, mean (SD)	3.11 (0.3)	3.24 (0.5)	3.0 (0.3)	0.03

*Age, duration of symptoms, and number of levels treated were compared with analysis of variance; categoric data were compared with Fisher exact test.

"Facet loading" is defined as pain exacerbated by lumbar extension and/or rotation.

Data are presented as number (percent) unless otherwise specified.

TABLE 2. Patient Characteristics by Outcome

	Positive Outcome (n = 104)	Negative Outcome (n = 88)	P
Age in years, mean (SD)	54.3 (14.2)	55.3 (16.9)	0.66
Sex			0.89
Male (n = 89)	49 (55.1%)	40 (44.9%)	—
Female (n = 103)	55 (53.4%)	48 (46.6%)	—
Smoking (n = 53)	29 (54.7%)	24 (45.3%)	0.87
Diabetes (n = 25)	13 (52.0%)	12 (48.0%)	0.83
Scoliosis (n = 34)	14 (41.1%)	20 (58.9%)	0.09
Location of symptoms			0.05
Axial back pain only (n = 106)	59 (55.7%)	47 (44.3%)	—
Above knee/groin (n = 43)	28 (65%)	15 (35%)	—
Below knee (n = 43)	17 (39.5%)	26 (60.5%)	—
Obesity (n = 79)	39 (49.4%)	40 (50.6%)	0.24
Opioid use (n = 53)	21 (39.6%)	32 (60.4%)	0.02
Failed back surgery syndrome (n = 41)	18 (43.9%)	23 (56.1%)	0.16
Duration of symptoms, mean (SD)	4.9 (5.1)	6.6 (6.6)	0.05
Facet pathology seen on MRI (n = 117)	61 (52%)	56 (48%)	0.75
Facet loading (n = 129)	63 (48.8%)	66 (51.2%)	0.02
Paraspinal tenderness (n = 110)	69 (62.7%)	41 (37.3%)	0.01
Number of levels treated, mean (SD)	3.1 (0.1)	3.1 (0.1)	0.37

Positive outcome defined as ≥ 50% pain relief 6-month postprocedure.
"Facet loading" is defined as pain exacerbated by lumbar extension and/or rotation.
Data are presented as number (percent) unless otherwise specified.
Age, duration of symptoms, and number of levels treated were analyzed with analysis of variance; categoric data were compared with Fisher exact test.

procedure outcome using univariate analysis and Fisher exact test, when confounding variables were controlled for, this association was no longer statistically significant. Forty percent (n = 21) of patients who were on opioids had a positive treatment outcome versus 60% (n = 32) who reported negative results. However, previous surgical treatment did predict outcome. Those patients with previous back surgery had an increased likelihood of treatment failure (56%) compared with those patients who did not undergo prior back surgery (44%; $P = 0.1$ in multivariate analysis).

Strong correlations with treatment outcome were found for 2 of the 4 physical and diagnostic findings. "Facet loading" and paraspinal tenderness were highly predictive of outcome failure and success, respectively. Forty-nine percent of the 129 patients with pain aggravated by lumbar extension and/or rotation reported significant pain relief at their 6-month follow-up visit, versus 69% of the 56 patients with negative facet loading. Paraspinal tenderness was the only clinical variable associated with a successful outcome. Sixty-three percent of the 110 patients with tenderness had a successful

TABLE 3. Factors Associated With Successful Outcome

	Univariate Data Analysis	Adjusted Multivariate Analysis*	P**
Age	0.99 (0.98-1.0)	—	—
Center	0.75 (0.52-1.1)	0.75 (0.46-1.21)	0.25
Sex	0.93 (0.53-1.7)	—	—
Smoking	1.1 (0.56-2.0)	—	—
Diabetes	0.90 (0.39-2.1)	—	—
Scoliosis	0.5 (0.24-1.09)	0.57 (0.22-1.50)	0.26
Location of symptoms	0.78 (0.55-1.1)	0.89 (0.56-1.42)	0.63
Obesity	0.69 (0.38-1.24)	0.74 (0.35-1.56)	0.42
Opioid use	0.44 (0.23-0.85)	0.77 (0.33-1.79)	0.55
Failed back surgery syndrome	0.59 (0.29-1.19)	0.46 (0.18-1.16)	0.10
Duration of symptoms	0.95 (0.9-1.01)	0.94 (0.89-1.01)	0.10
Facet pathology seen on MRI	0.89 (0.47-1.7)	—	—
Facet loading	0.43 (0.22-0.83)	0.21 (0.08-0.50)	0.001
Paraspinal tenderness	2.4 (1.3-4.4)	4.47 (1.9-10.3)	0.0001
Number of levels treated	1.4 (0.68-2.8)	—	—

*See methods for the list of variables included in multivariate analysis.
**P values are based on adjusted multivariate logistic regression analysis.
Positive outcome defined as ≥ 50% pain relief 6-month postprocedure.
"Facet loading" is defined as pain exacerbated by lumbar extension and/or rotation.
Data are presented as odds ratio (95% confidence intervals).

TABLE 4. Factors Associated With Successful Global Perceived Effect Outcome

	Univariate Data Analysis	Adjusted Multivariate Analysis	P*
Success assessed by VAS	59 (15.4-226.6)	—	0.0001
Age	0.99 (0.96-1.02)	—	—
Sex	1.19 (0.53-2.66)	—	—
Smoking	1.04 (0.38-2.84)	—	—
Diabetes	0.38 (0.11-1.36)	0.31 (0.05-1.77)	0.19
Scoliosis	0.48 (0.15-1.51)	0.35 (0.08-1.49)	0.15
Location of symptoms	0.65 (0.38-1.09)	0.62 (0.31-1.25)	0.18
Obesity	0.47 (0.20-1.07)	0.36 (0.12-1.10)	0.07
Opioid use	0.58 (0.21-1.63)	—	—
Failed back surgery syndrome	0.47 (0.18-1.21)	0.29 (0.08-1.05)	0.06
Duration of symptoms	0.92 (0.86-0.98)	0.95 (0.88-1.02)	0.22
Facet pathology seen on MRI	1.12 (0.46-2.69)	—	—
Facet loading	0.62 (0.25-1.45)	0.31 (0.09-1.0)	0.05
Paraspinal tenderness	1.99 (0.84-4.71)	2.49 (0.85-7.23)	0.09
Number of levels treated	8.65 (1.09-68.2)	12.4 (1.04-147)	0.05

*P values are based on adjusted multivariate logistic regression analysis.
"Facet loading" is defined as pain exacerbated by lumbar extension and/or rotation.
Data are presented as odds ratio (95% confidence intervals).

outcome, which compared favorably with 42% of the 65 patients without tenderness who obtained significant postprocedure pain relief. The presence of scoliosis or facet pathology on MRI was unrelated to outcome. In the only treatment variable reported, there was no relation between procedure outcome and the number of levels treated.

Subgroup analysis was performed on variables exclusive to WRAMC patients. A patients' duty status had no relation to treatment success or failure ($P = 0.6$) when analyzed in isolation or in multivariate models controlling for possible confounding factors. Seventeen (43%) active duty soldiers obtained significant pain relief from the facet joint denervation at 6-month follow-up versus 23 (57%) who had an unsuccessful outcome. The outcome GPE was available for 106 out of the 110 patients treated at WRAMC. There was a highly significant association between GPE and $\geq 50\%$ VAS pain reduction (Table 4). Among the 62 patients obtaining $\geq 50\%$ pain relief for whom data were available, 59 (95%) had a positive GPE outcome versus only 11 of 44 who had $< 50\%$ pain reduction. Similar to VAS outcome, the GPE was negatively correlated with facet loading, suggesting its presence on physical exam is a predictor of treatment failure ($P = 0.05$). Unlike the results using VAS scores, those patients who had more levels treated had a significantly higher level of global satisfaction ($P = 0.05$), and those with paraspinal tenderness only tended to have a higher probability of success as assessed by GPE ($P = 0.09$). Patients who were obese or had prior back surgery had a trend toward lower perceived success that fell shy of statistical significance.

DISCUSSION

It would be difficult to overestimate the impact LBP has in industrialized countries. Over the past half century, the incidence of LBP has exploded in the Western world. The economic costs of this epidemic are astounding, exceeding by some estimates 50 billion dollars in the United States alone.[20] Among the various causes of LBP, facet arthropathy is estimated to account for approximately 15% of cases.[1]

In pain treatment centers across the United States, lumbar facet interventions are the second most commonly performed procedure.[16] Considering the cost and frequency of these interventions, it is somewhat surprising that no study has examined which factors predict success and which predispose to failure in patients who receive RF denervation. For almost all other commonly performed back pain interventions including spine surgery, intradiscal electrothermal therapy, and lumbar and cervical epidural steroid injections,[21–25] the variables associated with failure and success have been critically examined.

Based on multivariate analysis, the factor most associated with facet denervation outcome in this study was exacerbation of pain with extension and/or rotation of the lumbar spine (a.k.a "facet loading"), which strongly correlated with failure. Although early studies found an association between facet loading and a positive response to a single, diagnostic intra-articular facet injection,[3,26] more recent studies conducted using placebo-controlled,[5] and confirmatory blocks[4,27] failed to support the concept of facet loading. In the Schwarzer et al[4] study, pain worsened by lumbar extension was the least correlated with lumbar facet pain among 16 variables evaluated with double, diagnostic lumbar z-joint injections. In the double-blind, placebo-controlled study by Revel et al,[5] increased pain with extension negatively correlated with facet joint pain. One possible explanation for this negative association is that clinicians may inappropriately choose patients for facet interventions based on old, refuted clinical data. Pain stemming from many pathologic spine conditions can be exacerbated with back extension such as spinal stenosis,

ligamentous injury, and spondylolisthesis. Combined with the high rate of false-positive MBB,[1,6,10] selecting patients for diagnostic injections based on "facet loading" can inadvertently increase the chances for failure.

A significant positive association was found between paraspinal tenderness and a successful RF denervation outcome. Some,[3,28] but not all[26,27] studies have shown paraspinal tenderness to predict pain relief after diagnostic facet joint injections. Tenderness to palpation is often elicited with other types of arthralgias such as knee osteoarthritis and to a lesser extent, sacroiliac joint pain,[29,30] but these joints may be more palpable in nonobese patients and have less surrounding, potential pain generators (ie, muscles, ligaments, discs) than facet joints. However, even when obesity was controlled for, paraspinal tenderness was still predictive of a positive outcome.

A strong trend was found between previous back surgery and failed RF denervation. Under the blanket term "failed back surgery syndrome" fall many different causes of persistent back and leg pain, with the z-joints being only one of many possible pain generators. Spinal fusion is sometimes advocated as a treatment for facetogenic pain,[31,32] and many surgeons consciously or inadvertently perform medial branch rhizotomies when placing pedicle screws. In a previous study by Cohen et al[19] conducted in the military community, the authors found a similar propensity for failed back surgery patients to fail lumbar facet RF denervation that also fell just shy of statistical significance. These findings are in contrast with those of North et al,[33] who found no difference in success rates between patients who underwent previous lumbosacral spine surgery and those who had not. They are consistent with the work of Carragee et al,[34] who found patients with prior back surgery to be at higher risk for false-positive discography results.

Perhaps the least surprising finding was the inverse relationship between duration of pain and treatment success. A negative correlation between treatment success and duration of symptoms has been found not only for lumbar disc surgery [35,36] and epidural steroid injections,[24] but for a host of nonspinal pain conditions as well.[37,38] There are a myriad of different reasons why patients with prolonged pain complaints are predisposed to treatment failure, including neuroplasticity, catastrophizing, and other psychopathology, and a greater degree of concomitant spinal pathology.[39,40]

Finally, opioid therapy was found to be associated with treatment failure in univariate, but not in multivariate, analysis. There are several possible reasons why opioids may predispose patients to treatment failure, including nociceptor sensitization, diminished pain tolerance and coping mechanisms, more significant baseline pathology, and secondary gain issues.[41] In the present study, the attenuation of this effect with multivariate logistic regression suggests that opioids tend to be reserved for the most challenging and refractory patients, who are likely to have already failed multiple attempts at treatment.

There are several flaws in this study that need to be addressed. First, double, confirmatory blocks were not used in this study as recommended by some experts,[6] and our success rates were lower than those reported in many uncontrolled studies.[42] With regard to the first point, a previous clinical study showed comparative blocks to have only marginal (54%) sensitivity,[43] and an economic analysis revealed double-blocks to lack cost effectiveness.[44] In a busy academic practice where appointment lag times are measured in months, it is difficult to justify performing confirmatory, MBB when the definitive treatment, RF denervation, takes only slightly longer to perform and has a similar complication rate. A study evaluating the utility of comparative local anesthetic blocks for cervical z-joint pain also found a substantial false-negative rate, which means that when double-blocks are employed, an accurate diagnosis and effective treatment will be withheld from some patients.[43] In the 4 controlled studies evaluating the efficacy of lumbar medial branch RF denervation, none used confirmatory blocks.[12–15] In addition to performing placebo-controlled or comparative blocks, other technical steps that may improve outcome measures include increasing the size of the electrode, performing multiple lesions, and increasing the length of the active tip.[42,45]

Second, because this was a retrospective study, data were missing from some patients, and the clinical variables analyzed were selected post hoc. Although the percentage of missing data was small (approximately 2%), the inclusion of these data (had they been available) could conceivably have influenced our findings. Third, the clinical variables we did examine were not standardized. For example, what constituted "paraspinal tenderness" for one clinician may have been recorded as "normal" by another. In this study, more patients at MGH had paraspinal tenderness than at WRAMC. This difference may have been secondary to a number of factors including demographic differences between the 2 institutions (patients at MGH were more likely to be older, female, and have more concomitant medical illnesses than those treated at the military hospital), more force being applied by practitioners at MGH during physical examination (the 4 kg force estimate, similar to what is used to examine fibromyalgia patients, was calculated in hindsight), and a greater propensity for patients at MGH to be selected for facet interventions based on paraspinal tenderness. In previous studies examining the ability of physical exam findings to predict response to facet blocks, none used dolorimetry as an aid to assess tenderness.[3,27,28] Even if pressure algometry had been used, there is no set standard as to what force should be applied to most accurately elicit "tenderness." Regardless, the sheer size of this study, which is one of the largest to date assessing lumbar facet RF outcomes, should have mitigated any outlying variance.

Last and most important, the only outcome measure assessed in all study patients was pain relief. In the 21st century, the field of pain management extends beyond just pain control to include a plethora of variables

affecting a patient's general well-being. In a recent consensus conference comprised of representatives from academia, governmental agencies, and pharmaceutical companies, experts concluded that clinical trials designed to assess the effectiveness of treatments for chronic pain should consider outcomes in 6 core domains: pain, physical functioning, emotional functioning, global satisfaction ratings, adverse events (to include medication reduction), and disposition.[46] In this study, GPE was tabulated by a patient's response to 3 questions assessing pain reduction, functional improvement, and satisfaction with treatment. Although a very strong correlation was found between our main outcome measure and GPE, these questions were only asked at one institution, and have not been validated in formal studies. Although some studies demonstrated a strong correlation between significant pain relief and improvement in secondary outcome measures, other studies have shown pain and functioning to be only modestly related.[46]

In conclusion, this large, multicenter clinical data analysis found symptom duration and exacerbation of pain during extension and/or axial rotation to be significantly associated with lumbar facet RF denervation treatment failure. A trend toward failed back surgery patients to have negative outcomes was also noted. The only clinical variable associated with success was paraspinal tenderness. Prospective studies evaluating not only pain but secondary outcome measures as well, are needed to confirm our findings and determine what measures can be taken in high-risk patients to reduce the likelihood of treatment failure. Possible solutions include using placebo-controlled or comparative local anesthetic blocks, using smaller volumes of local anesthetic, using a different technique that might reduce the risk of false-positive blocks such as the single-needle approach, or employing better screening methods for patients.

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