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Multicenter, Randomized, Comparative Cost-effectiveness Study Comparing 0, 1, and 2 Diagnostic Medial Branch (Facet Joint Nerve) Block Treatment Paradigms before Lumbar Facet Radiofrequency Denervation

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ABSTRACT

Background: Among patients presenting with axial low back pain, facet arthropathy accounts for approximately 10–15% of cases. Facet interventions are the second most frequently performed procedures in pain clinics across the United States. Currently, there are no uniformly accepted criteria regarding how best to select patients for radiofrequency denervation.

Methods: A randomized, multicenter study was performed in 151 subjects with suspected lumbar facetogenic pain comparing three treatment paradigms. Group 0 received radiofrequency denervation based solely on clinical findings; group 1 underwent denervation contingent on a positive response to a single diagnostic block; and group 2 proceeded to denervation only if they obtained a positive response to comparative blocks done with lidocaine and bupivacaine. A positive outcome was predesignated as ≥50% pain relief coupled with a positive global perceived effect persisting for 3 months.

Results: In group 0, 17 patients (33%) obtained a successful outcome at 3 months *versus* eight patients (16%) in group 1 and 11 (22%) patients in group 2. Denervation success rates in groups 0, 1, and 2 were 33, 39, and 64%, respectively. Pain scores and functional capacity were significantly lower at 3 months but not at 1 month in group 2 subjects who proceeded to denervation compared with patients in groups 0 and 1. The costs per successful treatment in groups 0, 1, and 2 were $6,286, $17,142, and $15,241, respectively.

Conclusions: Using current reimbursement scales, these findings suggest that proceeding to radiofrequency denervation without a diagnostic block is the most cost-effective treatment paradigm.

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◆ This article is accompanied by an Editorial View. Please see: Van Zundert J, Mekhail N, Vanelderen P, van Kleef M: Diagnostic medial branch blocks before lumbar radiofrequency zygapophysial (facet) joint denervation: Benefit or burden? ANESTHESIOLOGY 2010; 113:276–8.

What We Already Know about This Topic

- Facet denervations are commonly performed in pain clinics, but the ideal number of diagnostic blocks that should guide patient selection is unknown

What This Article Tells Us That Is New

- In 151 patients with suspected lumbar facetogenic pain, performing diagnostic local anesthetic blocks before radiofrequency denervation increased costs and decreased the overall success rate

LUMBAR facet arthropathy represents a significant cause of chronic axial low back pain, accounting for approximately 10–15% of cases.[1–4] Numerous studies, reviews, and guidelines have determined that diagnostic blocks of either the facet joints themselves, or more commonly the medial branch nerves that innervate them, are the only valid method to identify the zygapophysial joints (z-joints) as pain generators.[1,5–7] But diagnostic spinal injections can be notoriously inaccurate and unreliable, and facet blocks are no exception.[8] Multiple investigators have found uncontrolled z-joint blocks to be associated with high false-positive rates, ranging between 20 and 40%.[2,3,9] These findings have led numerous organizations to advocate controlled or confirmatory blocks as the only true indicator of a painful facet joint.[7,10,11] Perhaps more concerning is that false-positive responses can be commonplace even in people whose symptoms are concentrated in their extremities. In a prospective study by North *et al.*,[12] the authors found that a majority of patients with radiologically confirmed radiculopathy from a herniated disc experienced ≥50% pain relief not only with nerve root blocks but also with sciatic and medial branch (facet joint nerve) blocks (MBB).

However, these organizations may be operating under idealistic premises that fail to consider several factors. First, an unavoidable by-product of confirmatory blocks is that they will indubitably fail to diagnose a significant percentage of true disease sufferers.[13] Among the myriad reasons for false-negative responses are the failure of patients to discern procedure-related pain from baseline symptoms accurately, the failure of the injectate to bathe the target nerve, and normal diurnal variation in symptoms. Second, the use of any diagnostic injection can be hard to justify when the definitive procedure, radiofrequency denervation, carries comparable risk to the diagnostic block. Among serious complications (*i.e.*, neuraxial infection), the risk of radiofrequency lesioning may even be lower than that for diagnostic blocks because of the protective effect of heat.[14] Third, there is a growing body of evidence, based entirely on theoretical computations in the absence of hard data, that the "double-block" paradigm is not cost-effective.[15,16] This is particularly concerning in the context of a "zero-sum" healthcare reimbursement paradigm. Fourth, the use of double-blocks to screen patients for a minimally invasive treatment is inconsistent with much more invasive spine interventions, in which even single diagnostic procedures are not always used. For example, many patients undergo laminectomies,[17] disc replacements,[18] and fusions[19] without the benefit of available diagnostic injections (*e.g.*, selective nerve root blocks and discography), and there is no conclusive evidence that diagnostic discography improves surgical outcomes.[8,20,21] Finally, in the absence of a "gold standard," the true accuracy rate of any injection is impossible to know, and controlled studies have shown that a significant percent of patients who either fail to respond or do not undergo diagnostic blocks will still obtain good relief from radiofrequency denervation.[22,23]

In an attempt to determine which treatment strategy is most beneficial, we conducted the first randomized study evaluating lumbar z-joint denervation costs and outcomes using three paradigms: (1) radiofrequency denervation without the use of a screening block; (2) radiofrequency denervation if the patient obtains significant relief after a single diagnostic block; and (3) radiofrequency denervation only if an appropriate patient has a positive response to two confirmatory MBB in random order. Our objectives were twofold: (1) to determine which treatment paradigm was associated with the highest overall and radiofrequency denervation success rates and (2) to evaluate the relative costs per successful treatment for each of the three groups.

Materials and Methods

Permission to conduct this multicenter randomized study was granted by the Internal Review Boards at Walter Reed Army Medical Center and Johns Hopkins Medical Institutions, as well as all participants who provided informed consent. The standardized protocol was performed at both parent institutions and two nonteaching affiliates, with all procedures and follow-up visits occurring between January 2007 and April 2009.

All subjects were recruited from the pain clinics at the participating institutions, which received referrals from primary care and spine clinics at more than a dozen affiliated treatment centers. All procedures were performed in outpatient facilities using superficial local anesthesia for diagnostic blocks and local anesthesia and light sedation as needed for radiofrequency denervation. Inclusion criteria were age ≥18 yr, predominantly axial low back pain ≥3 months in duration, failure to respond to more conservative therapy, paraspinal tenderness, and absence of focal neurologic signs or symptoms. Excluded from participation were patients with a known, specific etiology for low back pain (*e.g.*, significant spinal stenosis or grade II or III spondylolisthesis), a positive response to previous spine interventions such as epidural steroids or sacroiliac joint blocks, previous facet interventions, lumbar spine fusion, untreated coagulopathy, and concomitant medical (*e.g.*, unstable angina) or psychiatric condition likely to undermine the diagnostic work-up or treatment response.

Before commencement, a review of the medical records of 120 radiofrequency denervation patients (C.S.), and inter-

views with 15 radiofrequency denervation patients and five board-certified interventional pain physicians suggested that 3 months of significant pain relief constituted a realistic goal for a procedure to be considered "clinically successful." A power analysis was then conducted using the following assumptions: the cost for a diagnostic facet joint block would average $350 for the first level and $170 for each subsequent level; the cost for a radiofrequency denervation would average $650 for the first joint and $325 for each additional joint; the overall group success rates would range between 17 and 32% and the mean cost for a successful treatment in the single-block group would be $5,172 (SD $860).[23–26] Using a three-group comparison-wise α level set at 0.016 and an anticipated dropout rate of 9%, we determined that recruiting 50 patients per group would have an 85% likelihood of detecting a between-group difference in cost of $600.

Randomization and Treatment Groups

One hundred fifty-one study subjects were randomized in a 1:1:1 ratio to one of the three treatment groups by a research nurse (C.K.) at the coordinating institution *via* presealed envelopes. Group 0 patients were randomized to receive radiofrequency denervation without undergoing diagnostic blocks. Group 1 patients underwent denervation if they obtained ≥50% pain relief that was maintained for at least 3 h after diagnostic MBB done with 0.5 ml 0.5% bupivacaine. Group 2 patients proceeded to denervation only if they experienced ≥50% concordant pain relief after comparative local anesthetic done with both 0.5 ml lidocaine, 2% (≥1 h) and 0.5% bupivacaine (≥3 h). The 50 patients in this group were suballocated to receive their MBB in random order *via* the same randomization scheme, with one half receiving the lidocaine blocks first and the other half receiving the bupivacaine injections. Only patients who obtained a positive response to the initial block underwent the second block, and only patients who obtained concordant analgesia from both blocks proceeded to facet joint denervation. In group 2, the two diagnostic blocks were done within a 2-week interval, and patients were unaware of their suballocation group (*i.e.*, which local anesthetic they received first).

Diagnostic Medial Branch and L5 Dorsal Ramus Blocks

Diagnostic MBB were performed in accordance with previous published standards and techniques.[24,27] Target levels were selected based on tenderness to palpation using fluoroscopic localization and the recognized innervation of the affected joints.[28–30] Patients with unilateral pain underwent unilateral blocks, whereas those with bilateral or central pain received bilateral blocks. Correct needle placement at the junction of the superior articular and transverse processes for MBB, and the sacral ala and articular process for L5 dorsal rami were confirmed *via* oblique, anteroposterior, and lateral fluoroscopy. Before the administration of the 0.5 ml local anesthetic, 0.5 ml radiopaque contrast was injected under real-time fluoroscopy to ensure the absence of vascular uptake.[31]

In the recovery area, patients were instructed to engage in their normal activities, discount procedure-related pain, and maintain a written pain diary every 30 min for the ensuing 8 h after discharge. In addition to 0–10 numerical rating scale pain scores, diaries were used to monitor postblock activities. To control for the presence of concomitant spinal pathology, ≥50% pain relief was predesignated to be a positive result. In blocks performed with bupivacaine, pain relief lasting ≥3 h was necessary for a block to be deemed positive. For blocks done with lidocaine, the threshold criterion was ≥1 h.

Radiofrequency Denervation

All radiofrequency procedures were done within 4 weeks of the final diagnostic block unless extenuating circumstances dictated otherwise. In subjects who experienced prolonged relief from a diagnostic block, the definitive procedure was done after the pain returned to baseline. If the analgesia lasted more than 3 months, the outcome was classified as positive.

With the C-arm intensifier positioned in an ipsilateral oblique and sharp, caudad-cephalad direction to maximize the lesion size in an orientation parallel to the course of the target nerve, 20-gauge curved radiofrequency needles with 10-mm active tips (BMC RF Cannula; Baylis Medical, Montreal, Quebec, Canada) were inserted in coaxial views until bone was contacted between the superomedial border of the transverse and superior articular processes, and the inferior portion of the lateral neck of the superior articular process. For L5 dorsal rami lesioning, the cannula was positioned in the groove between the lower part of the lateral aspect of the S1 articular process and the upper surface of the sacral ala. At each level, needles were adjusted to optimize sensory and motor stimulation. For each nerve lesion, correct placement was confirmed using electrostimulation at 50 Hz, with concordant sensation achieved at ≤0.5 V. Before denervation, multifidus stimulation and the absence of leg contractions was verified with electrostimulation at 2 Hz. After satisfactory electrode placement, 0.5 ml lidocaine, 2%, mixed with 5 mg depomethylprednisolone was injected through each cannulae in an attempt to minimize procedure-related pain and enhance lesion size and to prevent postprocedure neuritis.[32,33] The radiofrequency probe was then reinserted, and a 90-s, 80°C lesion was made using a radiofrequency generator (Electrothermal 20S Spine System; Smith and Nephew, Andover, MA; Baylis Medical Pain Management Generator 115V; Baylis Medical; or Radionics RF Lesion Generator System, Model RFG-3C; Radionics, Valleylab, Boulder, CO).

Outcome Measures and Follow-up

Baseline data recorded before treatment included age, gender, active duty status for Department of Defense beneficiaries, opioid use, analgesic medications, previous decompression surgery, 0–10 numerical rating scale pain scores at rest and with activity for the week preceding the first block, and Oswestry Disability Index score (version 2.0; MODEMS, Des Plaines, IL). In the interval between the radiofrequency

Table 1. Demographic and Clinical Characteristics of Study Subjects

	0 Block (Radiofrequency) Paradigm (n = 51)	Single-block Paradigm (n = 50)	Double-block Paradigm (n = 50)	*P* Value
Age, yrs, median (IQR)	41.0 (22.0–72.0)	44.0 (23.0–66.0)	41.0 (26.0–73.0)	0.754
Gender				0.647
Male (%)	31 (60.8)	26 (52.0)	27 (54.0)	
Female (%)	20 (39.2)	24 (48.0)	23 (46.0)	
Duration of symptoms, yr, median (IQR)	3.0 (1.0–14.0)	3.0 (0.5–13.0)	4.0 (0.5–20.0)	0.861
Opioid use (%)	13 (25.5)	12 (24.0)	17 (34.0)	0.484
Number of levels treated, median (IQR)	3.0 (3.0–4.0)	3.0 (3.0–4.0)	3.0 (2.0–4.0)	0.049
Laterality				0.250
Unilateral	20 (39.2)	12 (24.0)	15 (30.0)	
Bilateral	31 (60.8)	38 (76.0)	35 (70.0)	
Active duty (%)	27 (67.5)	27 (67.5)	22 (59.5)	0.698
Previous decompression surgery (%)	5 (9.8)	2 (4.0)	2 (4.0)	0.510
Baseline NRS pain score at rest, median (IQR)	4.5 (1.0–8.0)	4.3 (2.0–8.0)	4.8 (2.0–8.0)	>0.999
Baseline NRS pain score with activity, median (IQR)	8.0 (4.0–10.0)	8.0 (5.0–10.0)	8.0 (4.0–10.0)	0.979
Baseline ODI Score, median (IQR)	34.0 (14.0–54.0)	36.0 (18.0–56.0)	30.0 (14.0–56.0)	0.394

IQR = interquartile range; NRS = numerical rating scale; ODI = Oswestry Disability index.

procedure and 1-month follow-up, no contact was permitted between any patient and investigator. A physician or nurse unaware of study group assignment collected all outcome data at each of the 1- and 3-month follow-up visits. It is important to emphasize that only patients who underwent denervation or who experienced sustained relief from a diagnostic MBB and remained in the study had outcomes recorded at 1 month. For 3-month follow-up, only patients with a positive outcome at 1 month who remained in the study and elected to forego treatment had outcomes recorded.

The categorical outcome measure "medication reduction" was predefined as either a ≥20% reduction in opioid use or complete cessation of a nonopioid analgesic.[34] In addition to the aforementioned clinical outcome measures, the variable global perceived effect was also annotated at each follow-up. A positive global perceived effect was predefined as an affirmative response to the following two questions:

1. My pain has improved/worsened/stayed the same since my last visit;
2. I am satisfied/not satisfied with the treatment I received and would recommend it to others.

The composite binary variable "successful outcome" was predefined before initiation of the study as a ≥50% reduction in either rest or activity numerical rating scale pain score, coupled with a positive global perceived such that the patient did not require an additional procedural intervention that persisted ≥3 months. All patients with an interval successful outcome at their 1-month follow-up were evaluated at 3 months. Any patient with an unsuccessful 1-month outcome, or whose pain relief dissipated between their 1- and 3-month visits exited the study per protocol. The primary question we sought to answer was which treatment paradigm was associated with the lowest cost per successful outcome.

Statistical Analysis

Continuous variables are presented as medians and interquartile ranges. Statistical significance was evaluated using Wilcoxon rank sum and Kruskal-Wallis tests for continuous data, and Pearson chi-square and Fisher exact tests for categorical data using Stata software (StataCorp. 2007, Stata Statistical Software, Release 10; StataCorp LP, College Station, TX). For the cost-effectiveness analysis, 2007 Medicare reimbursement was used for diagnostic blocks, radiofrequency denervation, and facility fees.[35] Analysis of outcomes stratified by demographic and clinical data was conceived of *post hoc*, with all others being preplanned. To minimize the chance of a type I error due to multiple comparisons, a $P < 0.016$ (calculated by dividing the α of 0.05 by three comparisons for each variable) was considered to be statistically significant.

Results

Demographic and clinical characteristics of the study participants are presented in table 1. Median age was in the 40s for each of the three treatment groups, and males accounted for more than half of the people overall and in each group. Median duration of symptoms ranged from 3 to 4 yr across groups, and 24–34% of participants used opioids. Baseline low back pain was moderate at rest and severe with activity. In groups 0, 1, and 2, the median pain scores at rest were 4.5,

Table 2. Clinical Data and Treatment Results Stratified by Treatment Group

	0 Block (Radiofrequency) Paradigm (n = 51)	Single-block Paradigm (n = 50)	Double-block Paradigm (n = 50)	*P* Value
1st MBB positive, n (%)	NA	20 (40.0)	29 (58.0)	0.072
Percent relief after 1st MBB, median (IQR)	NA	77.5 (67.0–100.0, n = 20)	75.0 (50.0–100.0, n = 29)	0.375
2nd MBB positive, n (%)	NA	NA	14 (53.8)	NA
Percent relief among persons with positive 2nd MBB, median (IQR)	NA	NA	77.5 (60.0–100.0, n = 14)	NA
Prolonged pain relief from MBB, n (%)	NA	1 (2.0)	2 (4.0)	>0.999
NRS pain score at 1-month on rest, median (IQR)	2.0 (0.0–7.0, n=51)	2.3 (0.0–4.0, n = 20)	1.5 (0.0–3.0, n = 16)	0.504
NRS pain score at 1-month on activity, median (IQR)	4.5 (1.0–8.5, n=51)	4.3 (2.0–6.0, n = 20)	2.8 (2.0–5.0, n=16)	0.370
ODI score at 1 month, median (IQR)	24.0 (2.0–46.0, n=51)	19.0 (12.0–38.0, n=20)	14.0 (6.0–26.0, n=16)	0.178
Medication reduction at 1 month, %	19 (44.2, n = 43)	11 (61.1, n = 18)	9 (69.2, n = 13)	0.203
Positive global perceived effect at 1 month, %	35 (70.0, n=51)	16 (80.0, n=20)	12 (75.0, n=16)	0.677
NRS pain score at 3 months at rest, median (IQR)	2.0 (0.0–6.0, n = 30)	2.0 (1.5–3.0, n = 12)	1.0 (0.0–1.5, n = 11)	0.097
NRS pain score at 3 months with activity, median (IQR)	6.3 (1.0–9.0, n = 30)	4.5 (2.0–7.0, n = 12)	2.0 (1.0–3.0, n = 11)	0.015
ODI score at 3 months, median (IQR)	21.0 (3.0–41.0, n = 30)	15.5 (11.0–22.0, n = 12)	10.0 (4.0–12.0, n = 11)	0.008
Medication reduction at 3 months, %	9 (36.0, n = 25)	9 (81.8, n = 11)	7 (87.5, n = 8)	0.006
Positive GPE at 3 months, %	23 (74.2, n = 31)	11 (91.7, n = 12)	11 (100.0, n = 11)	0.109

Positive block defined as ≥50% pain relief from baseline in concordance with duration of action of local anesthetic. Positive radiofrequency defined as ≥50% pain relief from baseline at rest or with activity plus positive global perceived effect. Prolonged pain relief from medial branch block (MBB) defined as ≥6 weeks. These subjects received repeat MBB and did not undergo radiofrequency denervation. Patients who received <6 weeks of relief underwent radiofrequency when their pain returned. Medication reduction defined as >20% reduction in opioid dose from baseline or complete cessation of a nonopioid analgesic. Category not graded for patients on no analgesics.

GPE = global perceived effect; IQR = interquartile range; NA = not applicable; NRS= numerical rating scale; ODI = Oswestry Disability Index score.

4.25, and 4.8, respectively. With activity, the median pain score in each group was 8.0. None of the differences observed was statistically significant.

There were two dropouts during the course of the study. One was a soldier in group 1 who had a positive outcome after denervation at 1 month but exited the service and was lost to follow-up before his 3-month visit. He was counted as a "success" at 1 month, but removed from calculations for 3-month outcomes. The second patient was a female dependent (*i.e.*, spouse of a service member) allocated to receive two blocks, who failed to show up for her second block after a positive response to the first injection. She was excluded from all analyses of success rates.

Treatment results are shown in table 2. The first diagnostic facet block was positive for 40% of persons in the single-block group and 58% of individuals in the double-block group. Among these 49 responders, three patients experienced sustained pain relief, all after the first block (two in group 2 and one in group 1), obviating the need for radiofrequency denervation. Pain relief after the first block was substantial in responders, with the median being 77.5% in group 1 and 75% in group 2. In group 2 patients with a positive initial block (n = 29), 48% had a positive "confirmatory" second block, representing 28% of the total study group. The median percent relief in those patients who responded to the second block was 77.5% (see fig. 1 for Consolidated Standards of Reporting Trials flowchart).

At 1 month, patients in the double-block group who proceeded to radiofrequency had lower pain scores at rest and

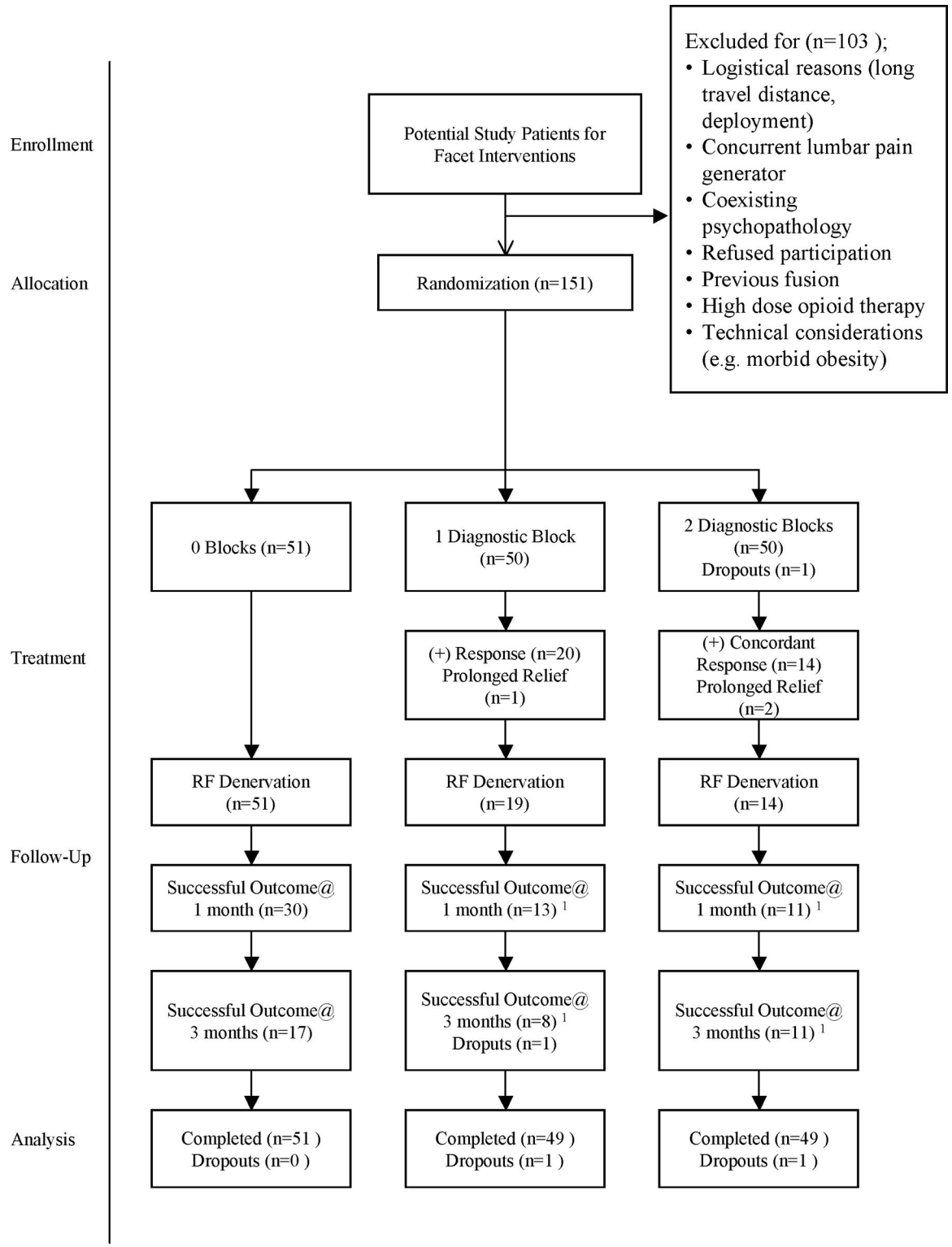

Fig. 1. Consolidated Standards of Reporting Trials flowchart showing progression of subjects in study arms. * Successful outcomes at 1 and 3 months include patients (n = 3) who obtained prolonged relief from their diagnostic block. RF = radiofrequency.

with activity than patients in the 0 and 1 block groups, but these differences failed to reach statistical significance. Three months after the procedure, median pain scores at rest in patients with a positive outcome at 1 month who remained in the study were 2.0 in groups 0 (interquartile range [IQR] 0–6.0) and 1 (IQR 1.5–3.0), and 1.0 (IQR 0–1.5) in group 2 ($P = 0.097$). With activity, the 3-month median pain scores were 6.3 (IQR 1.0–9.0) in group 0, 4.5 (IQR 2.0–

Table 3. Successful Outcomes Stratified by Treatment Group

	0 Block (RF) Paradigm (n = 51)	Single-block Paradigm (n = 49)*	Double-block Paradigm (n = 49)†	*P* Value
Successful outcome at 1 month (%)‡	30 (58.8)	13 (26.0)	11 (22.5)	<0.001
Success at 1 month among persons with RF denervation§	30 (58.8, n = 51)	12 (63.2, n = 19)	9 (64.3, n = 14)	0.905
Successful outcome at 3 months (%)‡‖	17 (33.3)	8 (16.0)	11 (22.0)	0.115
Success at 3 months among persons with RF denervation§‖	17 (33.3, n = 51)	7 (38.9, n = 18)	9 (64.3, n = 14)	0.111

Successful outcome defined as ≥50% pain relief either at rest or with activity plus a positive global perceived effect.

* One subject in the one-block group was excluded from the denominator at 3 months because there was no follow-up after 1 month (this person left the Army). † One subject in the two-block group excluded from the denominator at 1 and 3 months because of a failure to show up for the second block. ‡ Includes subjects who obtained prolonged pain relief from diagnostic medial branch blocks. § Excludes subjects who did not undergo radiofrequency (RF) denervation secondary to prolonged pain relief from medial branch blocks. ‖ Failed treatments at 1 month carried over to 3 months.

7.0) in group 1, and 2.0 (IQR 1.0–3.0) in group 2 (P = 0.015). Median disability ratings among radiofrequency patients were highest in the zero-block group and lowest in the double-block group at 1 (24.0, IQR 2.0–46.0 *vs.* 14.0, IQR 6.0–26.0; P = 0.178) and 3 months (21.0, IQR 3.0–41.0 *vs.* 10.0, IQR 4.0–12.0; P = 0.008). The percentage of radiofrequency subjects in each group who were able to reduce or discontinue medications was highest in the double-block group at each time point (69% at 1 month and 87.5% at 3 months) but was statistically significant only at 3 months (P = 0.006).

The proportion of successful outcomes for each individual group cohort was highest in group 0 throughout the study (table 3). Overall, 33% (n = 17) of the total enrolled patients had a positive 3-month outcome in the 0-block group *versus* 16% (n = 8) in the single-block group and 22% (n = 11) in the double-block group (P < 0.001). Not surprisingly, success rates in only those patients who proceeded to denervation (*i.e.*, radiofrequency success rate) was reversed from the overall success rate: 33% in the 0-block group, 39% in the single-block group, and 64% in the double-block group. When patients with postlaminectomy syndrome, who may be more likely to experience false-positive blocks and fail denervation,[1,24,36,37] were removed from analysis, the overall success rates in groups 0, 1, and 2 were 37, 17, and 21%, whereas the radiofrequency success rates were 37, 39, and 67%, respectively.

Outcomes by clinical and demographic characteristics are given in table 4. The distribution of age, sex, duration of symptoms, and treatment received was similar across groups. A negative outcome was slightly more prevalent in persons who received at least one block, whereas a positive outcome was much more common in the zero-block group. In addition, opioid use was more common (34.5 *vs.* 5.6%, P = 0.001), median baseline pain scores at rest (5.0, IQR 1.0–9.0 *vs.* 4.0, IQR 2.0–6.0, P = 0.016) and with activity (8.0, IQR 4.0–10.0 *vs.* 7.0 IQR 4.0–9.0, P = 0.044) were higher, and disability was more severe (median Oswestry Disability Index score 36.0, IQR 12.0–60.0 *vs.* 28.5, IQR 14.0–46.0, P = 0.018) among persons with a negative outcome. Considering the multiple comparisons made, these differences may not be statistically significant.

The cost per successful treatment and the assumptions used to make these calculations are given in table 5. Excluding corrections for medication reduction and missed work days, these costs ranged from a low of $6,053.68 in the 0-block group to $16,236.12 in the single-block group. When estimated costs for missed work days were added and those for medication reductions were subtracted from the total, these costs ranged $6,286.03 in the 0-block group to $17,129.87 in the single-block group (P < 0.001).

Few complications were noted. Two patients, one each in group 0 and 2, experienced significant worsening (≥2-point increase in numerical rating scale pain score at rest and ≥4 point increase in Oswestry Disability Index score) back pain 1 month after denervation. One patient experienced the new development of radiating pain into the lower leg at the first follow-up visit, which was not accompanied by corresponding magnetic resonance imaging pathology. These symptoms were all resolved by 3 months.

Discussion

Lumbar facet interventions are the second most frequently performed procedures in pain clinics across the United States.[38] A major source of controversy is whether to perform confirmatory blocks before lumbar z-joint denervation. Although virtually all guidelines and commissioned position papers endorsed by major spine and interventional pain societies recommend using double blocks to screen patients for facet denervation,[7,10,11] four of the five randomized controlled studies evaluating lumbar facet radiofrequency lesioning used single blocks as prognostic tools.[22,26,39,40] Our results suggest that the current controversy surrounding

Table 4. Subject Characteristics by Outcome at 3 Months

	Negative Outcome (n = 113)	Positive Outcome (n = 36)	*P* Value
Age, yrs, median (IQR)	40.0 (21.0–77.0)	43.5 (24.0–64.0)	0.366
Gender			0.128
Male (%)	59 (52.2)	24 (66.7)	
Female (%)	54 (47.9)	12 (33.3)	
Duration of symptoms, yrs, median (IQR)	4.0 (0.3–20.0)	3.5 (1.0–15.0)	0.409
Opioid use (%)	39 (34.5)	2 (5.6)	0.001
No. of levels treated, median (IQR)	3.2 (0.6)	3.1 (0.5)	0.397
Laterality			0.133
Unilateral	32 (28.3)	15 (41.7)	
Bilateral	81 (71.7)	21 (58.3)	
Active duty (%)	57 (50.4)	18 (50.0)	0.963
Previous decompression surgery (%)	8 (7.1)	1 (2.8)	0.688
Baseline NRS pain score at rest, median (IQR)	5.0 (1.0–9.0)	4.0 (2.0–6.0)	0.016
Baseline NRS pain score with activity, median (IQR)	8.0 (4.0–10.0)	7.0 (4.0–9.0)	0.044
Baseline ODI score, mean (SD)	36.0 (12.0–60.0)	28.5 (14.0–46.0)	0.018
Treatment group			0.131
No blocks	34 (30.1)	17 (47.2)	
Single block	41 (36.3)	8 (22.2)	
Double block	38 (33.6)	11 (30.6)	

Positive outcome defined as ≥50% pain relief at 3 months plus positive global perceived effect.
IQR = interquartile range; NRS = numerical rating scale; ODI = Oswestry Disability Index.

whether single or double blocks are superior may be misguided. Instead, the operative question may be whether any blocks should be done before lumbar z-joint denervation.

The principal finding in this study is that based on this simple model of cost-effectiveness, proceeding straight to radiofrequency denervation without any diagnostic blocks is associated with both the lowest cost per successful procedure and the highest number of total successful procedures. Although this might be construed by some as compelling evidence to abandon the practice of diagnostic blocks altogether, we would caution against this interpretation for two reasons. First, the current reimbursement paradigm for facet interventions is an artificial construct incommensurable with that for other spinal interventions (*e.g.*, spinal fusions, decompression surgeries), wherein the diagnostic procedure generally is reimbursed only a small fraction of the "defini-

Table 5. Cost-effectiveness Analysis for Different Treatment Paradigms*†‡

	0 Block (RF) Paradigm (n = 51)	Single-block Paradigm (n = 49)§	Double-block Paradigm (n = 49)§
Cost per successful treatment‖#	$6,286.03	$17,142.11	$15,241.31
Cost per successful treatment excluding medication costs and missed work days	$6,053.68	$16,236.12	$14,237.76
Total cumulative costs for facility fees	$63,936	$86,247	$103,563
Total cumulative costs for diagnostic blocks	$0	$29,294.38	$42,718.26
Total cumulative costs for RF denervation	$38,976.51	$14,345.46	$10,323.10
Estimated cost of missed work days‖	$7,650	$10,050	$13,350
Estimated savings on medications#	$3,700	$2,800	$2,300

P = 0.0001 between groups for both cost calculations.

* Based on 2007 Medicare reimbursement payments to include facility and professional fees.[35] † Successful treatment predefined as ≥50% decrease in back pain at rest or with activity coupled with a possible global perceived effect at 3 months. ‡ Cost per successful treatment estimated by adding the individual costs per treatment for each treatment group and dividing by the total number of successful treatments in that group. § Excludes one dropout per group. ‖ For each procedure performed, $150 was added to the total cost of treatment in each group as the cost per missed work day. # Medication reduction was predefined as $100/month, which was subtracted from the total cost of treatment in each group. In patients with medication reduction at 1 and 3 months after treatment, $300 was subtracted. For patients with medication reduction at 1 month only, $100 was subtracted.

RF = radiofrequency.

tive" treatment. If the costs for radiofrequency denervation were increased, or alternatively that for MBB were decreased, our findings would be correspondingly altered. Second, because the prevalence rate for lumbar facetogenic pain is probably considerably lower than the 33% success rate obtained in this study in the 0-block group,[1–4] many of these patients were indubitably placebo responders. Although some might argue that trying to discern placebo responders from true disease sufferers is a pointless and irrelevant exercise, one cannot conclude this without knowing whether the positive response for the 0-block successes (including placebo responders) is as enduring and reproducible as it is for patients with real facet arthropathy. The placebo effect is particularly strong for pain conditions, can last for many months or years, and could be repeated many times with similar "efficacy"[41,42]; however, this latter assertion has never been evaluated for z-joint pain. In contrast, we know from previous studies that a successful radiofrequency denervation procedure often lasts for more than 8 months[25,26,34,43] and can be reproduced with an equal likelihood of success after the beneficial effects wear off.[44,45]

Although this "comparative-effectiveness" trial was not designed to determine efficacy for radiofrequency denervation or reevaluate the incidence of false-positive blocks, people will inevitably draw their own conclusions. Clearly, the small difference between 3-month outcomes between subjects allocated to groups 0 and 1 is consistent with earlier findings showing a high incidence of false-positive rates associated with uncontrolled MBB.[2,7,9] The vastly superior radiofrequency outcomes in the double-block group might also be construed as indirect evidence supporting the efficacy of denervation in patient with painful lumbar z-joints. However, an alternative explanation is that these patients had higher expectations for a positive outcome than those in groups 0 and 1 and hence were more likely to experience a placebo effect.

One consideration that should be made when interpreting the results in this study is that the framework may not lend itself to widespread generalizability. Specifically, patients were screened in such a way as to maximize compliance (*i.e.*, subjects with professional and geographical limitations that could preclude multiple clinic visits were excluded) and minimize encumbrances. If a greater lag time between procedures had been permitted or if subjects were not preselected to minimize dropouts, it is probable that more dropouts might have occurred in groups 2 and 1.

The dilemma posed by our findings parallels those surrounding other interventional spine treatments. For example, the ongoing controversy about discography is not whether one or two procedures are warranted, but whether any disc provocation procedure is necessary before spinal fusion or disc replacement, both of which carry much greater risks than radiofrequency lesioning.[20] With regard to intrathecal pump replacement, the most recent guidelines condone pump implantation, a procedure associated with significant risks that has never been evaluated in double-blind studies, without trials in cancer patients otherwise deemed to be good candidates.[46] Although the results of this study may serve as an additional piece to a rather complex, evolving puzzle, we do not expect it to provide a definitive answer.

There are several flaws to this study which need to be addressed. First, is the lack of blinding. Whereas blinding patients and treating physicians was not possible using this study design, this effect may have been somewhat mitigated by blinding the evaluating physicians. Second, this study was not designed to determine efficacy. Consequently, our use of 3 months as the cutoff for designating a response as positive may have had the unintended effect of including more placebo responders among purported successes in group 0. Yet, partially counteracting this bias might be the strong expectations among group 2 patients who responded to not just one, but two diagnostic MBB. In addition, this threshold was predetermined by both pilot interviews with doctors and patients and by an extensive prestudy chart review (C.S.). Third, the outcomes for group 2, and hence our conclusions, might have been different had we used a "placebo" control instead of the comparative block model to select patients for radiofrequency denervation. However, concerns regarding "ethics," reimbursement, and patient participation precluded the use of this paradigm. Fourth, analyses performed *post hoc* (*i.e.*, breakdown of outcomes by demographic and clinical variables) must be interpreted with caution. In particular, baseline differences in pain scores and functionality may not have been statistically significant despite *P* values less than 0.05 due to the increased chance of finding a statistically significant result with multiple comparisons. Fifth, it is possible that some patients who underwent radiofrequency lesioning might have derived sustained benefit from the local anesthetic and corticosteroid injected preemptively that inflated our results.[47] It should be emphasized that the complications of lumbar facet denervation have been heretofore minor and infrequent.[1,48] In addition, any possible beneficial effect would likely have been distributed proportionately across treatment groups. Finally, the "cost per successful treatment" measure is an artificial construct subject to capricious, administrative reimbursement decisions. For example, if the reimbursement rate for MBB decreased, or that for radiofrequency increased, our cost per effective treatment would change in concordance. Therefore, the conclusions drawn today might differ from those drawn tomorrow, contingent on decisions from third-party payers.

In summary, the results of this study demonstrate that although the double-block paradigm results in the highest success rate for radiofrequency denervation, the overall success rate for subjects treated in this group was the lowest at 1 month and only slightly higher than group 1 at 3 months. In contrast, although the denervation success rate was lowest in the 0-block treatment group, the overall number of successful outcomes was highest at all time points. Presumably, these findings represent both the exclusion of true disease sufferers in group 2 and the inclusion of placebo-responders among successes in group 0. At current reimbursement rates in the United States, these results augur against using double-screening blocks as the criterion standard for selecting radiofrequency candidates. However, this conclu-

sion is not irrevocable, being dependent on flexible and changeable third-party payer decisions.

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