

Original Contribution

Accuracy of Diagnostic Lumbar Facet Joint Nerve Blocks: A 2-Year Follow-Up of 152 Patients Diagnosed with Controlled Diagnostic Blocks

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Background: Lumbar facet joint pain is diagnosed by controlled diagnostic blocks. The accuracy of controlled diagnostic blocks has been illustrated in multiple studies and systematic reviews. Controlled diagnostic studies have shown an overall prevalence of lumbar facet joint pain in 31% of the patients with chronic low back pain without disc displacement or radiculitis, with an overall false-positive rate of 30% using a single diagnostic block.

Study Design: An observational report of outcomes assessment.

Setting: An interventional pain management practice setting in the United States.

Objective: To determine the accuracy of controlled diagnostic blocks in managing lumbar facet joint pain at the end of 2 years.

Methods: This study included 152 patients diagnosed with lumbar facet joint pain using controlled diagnostic blocks. The inclusion criteria was based on a positive response to diagnostic controlled comparative local anesthetic lumbar facet joint blocks. The treatment included therapeutic lumbar facet joint nerve blocks.

Outcome Measures: The sustained diagnosis of lumbar facet joint pain at the end of one year and 2 years based on pain relief and functional status improvement.

Results: At the end of one year 93% of the patients and at the end of 2 years 89.5% of the patients were considered to have lumbar facet joint pain.

Limitations: The study is limited by its observational nature and the 2-year follow-up.

Conclusion: Controlled diagnostic lumbar facet joint nerve blocks are valid utilizing the criteria of 80% pain relief and the ability to perform previously painful movements, with sustained diagnosis of lumbar facet joint pain in at least 89.5% of the patients at the end of a 2-year follow-up period.

Key words: Chronic low back pain, lumbar facet or zygapophysial joint pain, facet joint nerve or medial branch blocks, controlled local anesthetic blocks, construct validity, diagnostic studies, diagnostic accuracy

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The initial diagnosis of low back pain poses numerous challenges due to the clinician's inability to diagnose accurately. The primary function for evaluation, after ruling out non-spinal or serious spinal pathology and nerve root pain, is

to identify the cause of spinal pain that is without nerve root pain. Often, this type of pain has been classified as "non-specific" pain, which creates a dilemma in that modern technology, including magnetic resonance imaging (MRI), computed

tomographic scanning (CT), neurophysiologic testing, and comprehensive physical examination with psychological evaluation, can identify the cause of low back pain in only 15% of patients in the absence of disc herniation and neurological deficit (1-22). van Tulder et al (21), in a systematic review of the most commonly used examination procedures by clinicians in patients with low back pain, found the procedure to be conflicting with low reliability. In another study by Hancock et al (22), in evaluating the accuracy of various tests utilizing and diagnosing pain originating from disc, facet joint, and sacroiliac joint, showed that the tests of the facet joint as the source of pain have limited or no diagnostic validity. Rubinstein and van Tulder (17) commented that it was quite remarkable that many named orthopedic tests of the neck and low back often illustrated in orthopedic textbooks had very little evidence to support their diagnostic accuracy, and therefore, their use in clinical practice. In a systematic review, Vroomen et al (19) showed that the straight leg raise (SLR) test was the only sign that was consistently sensitive for sciatica due to disc herniation with a pooled sensitivity of 0.85 (95% CI, 0.38% – 0.98%), but with low specificity of 0.52 (95% CI, 0.25% – 0.76%). Further, diagnostic accuracy of other neurological signs, including paresis, sensory loss, and reflex loss was unclear. Other reviews (20) also showed the limited value of SLR due to low specificity. Multiple imaging studies have been shown to lack accuracy and reliability in the absence of disc herniation, and radiculopathy in the diagnosis of chronic low back pain (1,21,23,24). Further, the physical examination serves primarily to confirm suspicions raised during the history.

In contrast to the mixed picture provided by history, physical examination, imaging, and nerve conduction studies in non-radicular or discogenic pain, controlled diagnostic blocks have been shown to determine the cause of pain in as many as 85% of the patients in contrast to 15% of the patients with other available techniques (25-27). However, multiple issues of diagnostic accuracy of interventional techniques have been described (17,22,28-42).

Conventional clinical features are unreliable in diagnosing lumbar zygapophysial or facet joint pain (1-11,20-30,33-35). Hancock et al (22) found that none of the tests for facet joint pain were found to be informative. Consequently, controlled local anesthetic blocks of the facet joint or its nerve supply are routinely employed to diagnose facet joint pain. The rationale for these blocks

is that anesthetic blockade of a painful joint will abolish pain arising from that joint for the duration of the anesthetic effect, while anesthetic blockade of a non-painful joint will not alter the pain report. The probability that the blocked joint is the actual source of pain is increased if repeating the block with an anesthetic agent that has a different duration of action reproduces the analgesic response (43). To ensure accuracy and validity, these blocks must be controlled and verified for delivery of local anesthetic agent and placebo response. Rubinstein and van Tulder (17) provided a best evidence review of diagnostic procedures for neck and low back pain and concluded that there is strong evidence for the diagnostic accuracy of facet joint blocks in evaluating spinal pain. Further, 4 systematic reviews have concluded the evidence for diagnostic accuracy of lumbar facet joint nerve blocks is Level I or II-1, or strong (30,33-35).

The validity of lumbar facet joint nerve blocks as a gold standard in the diagnosis of lumbar facet joint pain continues to be questioned. Various reference standards applied in surgical situations, such as biopsy, surgery, or autopsy, are difficult to apply in diagnosing chronic low back pain of facet joint origin and the pain relief following the diagnostic block. Even relief of pain provocation following the diagnostic block is looked at with skepticism. Thus, the long-term or dedicated clinical follow-up of the subjects appears to be the only solution (44). In addition, most pain provocative or relieving tests used to diagnose painful conditions of the spine are more closely related to the physical examination than to a laboratory test. Manchikanti et al (45) evaluated the validity of diagnostic lumbar facet joint blocks in 44 patients followed at the end of 2 years. After the diagnosis was made with controlled comparative local anesthetic blocks, this study showed that 85% of the patients available for follow-up withstood the diagnosis of facet joint pain at the end of 2 years. Further, appropriately applied therapeutic modalities have shown to result in amelioration of facet joint pain (2,30,46-53). The recent systematic review by Datta et al (30) illustrated the evidence for therapeutic lumbar facet joint interventions as Level II-1 or II-2 for lumbar facet joint nerve blocks and Level II-2 or II-3 evidence for radiofrequency neurotomy.

Even then, diagnostic lumbar facet joint nerve blocks continue to be under attack. This evaluation was undertaken to establish the accuracy of lumbar facet joint nerve blocks in diagnosing lumbar facet joint pain utilizing a dedicated, long-term follow-up of 2 years in 152 patients.

METHODS

Participants

This observational study was undertaken by evaluating patients diagnosed with lumbar facet joint pain from January 2004 to June 2007. The patients with suspected lumbar facet joint pain received controlled comparative local anesthetic blocks and if they tested positive, they were followed with therapeutic facet joint interventions, either medial branch blocks or radiofrequency neurotomy.

Setting

An interventional pain management setting in a non-university private practice setting in the United States. The procedures were performed in an interventional pain management ambulatory surgery center. The practice provides comprehensive, interventional pain management services.

Inclusion Criteria

The chart review was performed by 3 investigators who were not involved in performing the procedures. Inclusion criteria and methodology have been described elsewhere in detail (54,55).

Diagnostic Facet Joint Nerve Blocks

Lumbar facet joint pain was investigated in all patients starting with diagnostic blocks using 1% lidocaine. Patients with lidocaine-positive results were further studied using 0.25% bupivacaine on a separate occasion, usually 3 to 4 weeks after the first injection. Following each block, the patient was examined and asked to perform previously painful movements. A positive response was defined as at least an 80% reduction of pain and the ability to perform previously painful movements, as assessed using a verbal numeric pain rating scale. To be considered positive, pain relief from a block had to last at least 2 hours when lidocaine was used and at least 3 hours or longer than the duration of relief with lidocaine, when bupivacaine was used. All patients judged to have a positive response with lidocaine blocks underwent subsequent bupivacaine blocks.

Therapeutic Facet Joint Nerve Blocks

In the therapeutic phase, all facet joint nerve blocks were performed under fluoroscopy in an ambulatory surgery center with a 22-gauge, 2-inch spinal needle with injection of 0.5 to 1 mL mixture of bupivacaine with or without Sarapin and DepoMedrol.

Facet joint nerve blocks were repeated based on the response to prior interventions with improvement in physical and functional status and only when increased levels of pain were reported and it was greater than 50% level or relief had deteriorated to below 50%.

Co-Interventions

No specific co-interventions such as physical therapy, occupational therapy, or bracing were provided. However, the same co-interventions as needed with opioid and non-opioid analgesics, adjuvant analgesics, and previously directed exercise programs before enrollment were continued in all patients. Medical therapy was also adjusted based on response and physical and functional needs.

Outcomes

Patients were evaluated with multiple outcome measures including numeric rating scale (NRS), Oswestry Disability Index (ODI), work status, and opioid intake. At least 50% pain relief with at least 40% improvement in ODI was considered as significant improvement.

Sample Size

A sample size of 150 patients was chosen. The estimated sample size was based on previous studies of lumbar and cervical facet joint interventions which included less than 20 patients in each group (56,57), and other literature of interventional techniques identifying 50 patients as acceptable in randomized trials (58), and randomized evaluations of medial branch blocks (49,59) and epidural injections (60-63) with inclusion of 60 patients in each group.

Statistical Methods

Data was recorded on a database using Microsoft Access by a person not participating in the study. The SPSS version 9.0 statistical package was used to generate the frequency tables. Student's t-test was used to test mean significant differences between groups. Categorical data were compared using a chi-squared test. Fisher's exact test was used wherever the expected value was less than 5. Results were considered statistically significant if the *P*-value was less than 0.05.

Intent-to-Treat Analysis

An intent-to-treat analysis was performed. Either the last follow-up data or initial data were utilized in the patients who dropped out of the study and no other data were available.

RESULTS

Participant Flow

Figure 1 illustrates the flow of participants receiving interventional therapy, participants undergoing lumbar diagnostic facet joint nerve blocks, followed by those receiving therapeutic interventions. Of the 152 patients positive for facet joint pain, all of them were treated with therapeutic facet joint interventions. At the end of one year follow-up, 132 patients underwent facet joint blocks and were available for follow-up. However, 8 patients were lost to follow-up and one patient died due to unrelated causes. Thus, intention-to-treat analysis was utilized by the addition of 9 patients to 132 patients. At 2-year follow-up, intention-to-treat analysis was utilized in 24 patients with a total of 5 deaths and 19 patients lost to follow-up.

Diagnosis of Lumbar Facet Joint Pain

Table 1 illustrates the results of lumbar facet joint nerve blocks with a prevalence of 31% (95% CI, 26%–35%) and a false-positive rate of 42% (95% CI, 35%–50%).

Evaluation of Demographic Variables

Table 2 illustrates the demographic characteristics of patients with a continued diagnosis of facet joint pain and others without facet joint pain at the end of 2 years identified as either as positive or false-positive. There were no significant differences noted in any of the baseline demographic characteristics.

Duration of Pain Relief with Diagnostic Blocks as a Variable

Table 3 illustrates the difference between the duration of pain relief in weeks in both groups using screening diagnostic blocks with lidocaine and confirmatory diagnostic blocks with bupivacaine. A positive response was considered to be pain relief of at least 80%. There were no significant differences noted with mean pain relief of 3.6 to 3.8 weeks with the first screening diagnostic block using local anesthetic and of 5.9 to 6.9 weeks with a confirmatory bupivacaine block.

Table 1. Results of lumbar facet joint nerve blocks (single block with lidocaine and double block with lidocaine and bupivacaine).

Blocks	Results	
Single Block	Positive	Negative
Positive	152	109
Negative		230
Double total	152	339
Prevalence	31% (95% CI, 26%, 35%)	
False-positive rate	42% (95% CI, 35%, 50%)	

Table 2. Baseline demographic characteristics.

		Positive	False positive	P value
Number		136	16	
Gender	Male	46% (62)	38% (6)	0.366
	Female	54% (74)	62% (10)	
Age	Main ± SD	47 ± 15.0	50 ± 15.0	0.428
Height (inches)	Main ± SD	67 ± 3.9	67 ± 3.8	0.470
Weight (pounds)	Main ± SD	184 ± 49.1	190 ± 34.7	0.648
Duration of Pain (months)	Main ± SD	114 ± 115.7	123 ± 130.0	0.789
Mode of Onset of Pain	Non-traumatic	63% (86)	81% (13)	0.122
	Traumatic	37% (50)	19% (3)	
Previous Surgery		14% (19)	6% (1)	0.696
Pain Distribution	Unilateral	21% (29)	12% (2)	0.527
	Bilateral	79% (107)	88% (14)	
Employment Status	Working	20% (27)	38% (6)	0.168
	Unemployed	12% (16)	0%	
	Housewife	10% (13)	6% (1)	
	Disabled	46% (63)	31% (5)	
	Over 65	12% (17)	25% (4)	

Accuracy of Diagnostic Lumbar Facet Joint Nerve Blocks

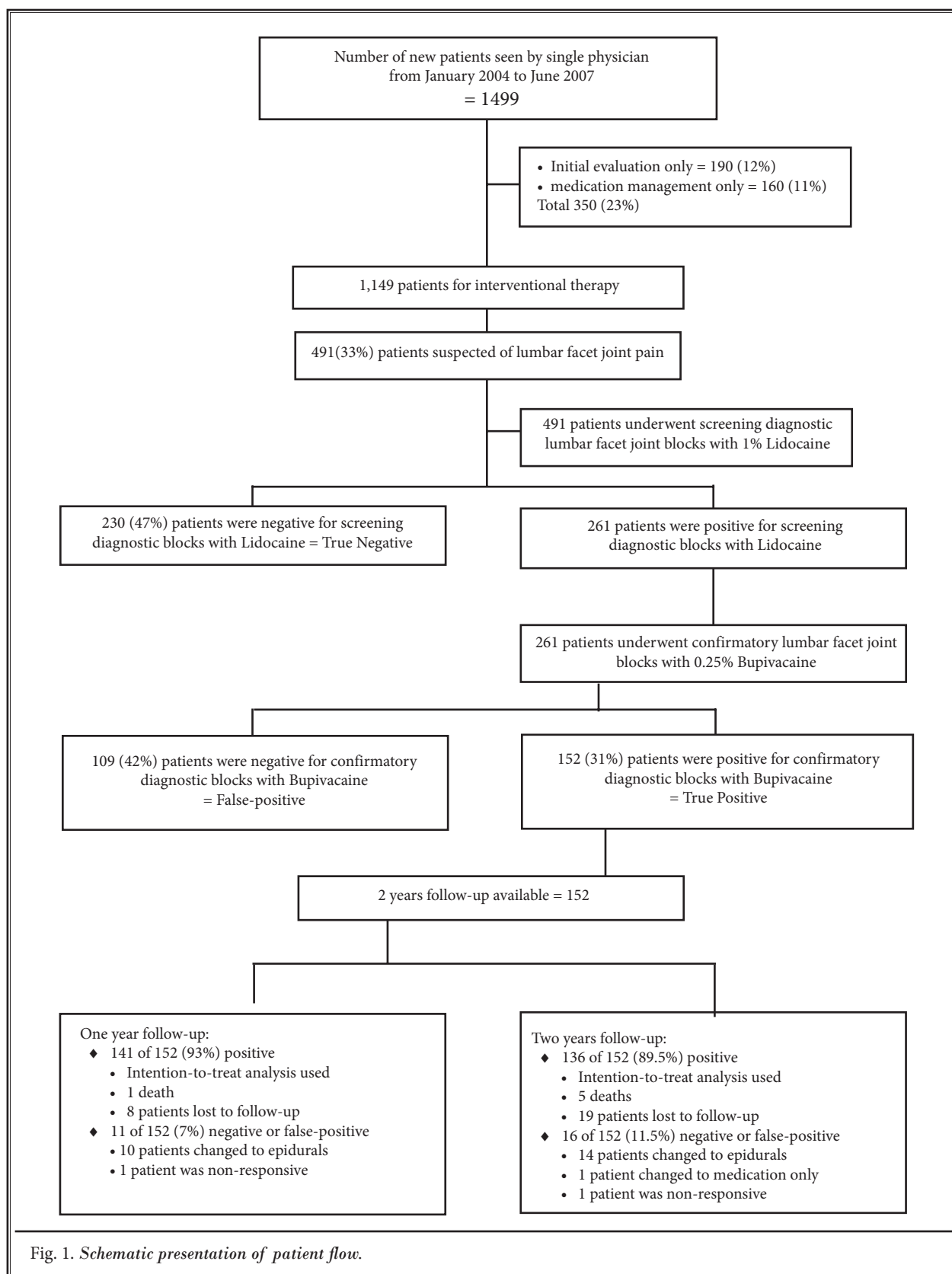


Fig. 1. Schematic presentation of patient flow.

DISCUSSION

This observational report of 152 patients evaluating the validity of controlled facet joint nerve blocks in the diagnosis of lumbar facet joint pain presents an accuracy of diagnosis in 93% of the patients at one-year follow-up and 89.5% of the patients at 2-year follow-up. Thus, only 9 of 152 patients at one-year follow-up and 16 of 152 patients at 2-year follow-up either changed to a different diagnosis or failed to respond to therapeutic facet joint interventions. Further, of the patients judged to be falsely diagnosed for facet joint pain or false-positives, 6 of them received only one therapeutic injection and 4 received 2 therapeutic injections. The remaining 4 patients received 4 therapeutic injections and ceased to respond. Of these, one patient suffered interval trauma and only 3 failed to respond to the facet joint interventions. Two patients stopped receiving treatment: one failed to respond and no other treatments were provided prior to one-year and the second patient responded well for over 12 months and ceased response. Thus, if one additional diagnostic block is utilized the accuracy would increase to 142 of 152 patients with an accuracy of 93% and; if 2 diagnostic injections are added to 4 patients the accuracy will increase to 96%. This study indicates that approximately 10% of patients demonstrated a false-positive diagnosis of facet joint pain. However, accuracy may be increased to 96% with further evaluation with less than 7% of the patients (10 of 152). Even then, as many as 4% to 10% of the patients may not be accurately diagnosed providing false-positive results. The study also illustrated no correlation between pain relief with diagnostic blocks and demographic characteristics in judging if the diagnostic facet joint blocks are accurate.

Accuracy of a diagnostic test is based on reliability and validity. The validity of a diagnostic test is typically demonstrated by comparing it to a gold or criterion standard. A criterion standard is a well-accepted and commonly applied method of identifying the disease or clinical entity of interest. Sensitivity of a test is the proportion of people with the disease who will have a

positive result, whereas specificity is the proportion of people without the disease who will have a negative test result (64). Thus, it is interpreted that a valid diagnostic test has the ability to correctly identify people with a condition (positive for the condition or at risk for that condition) or absence of the condition (negative for the condition or not at risk for the condition). Validity incorporates concept validity, content validity, face validity, and construct validity. However, of the 4 components, construct validity is considered the most critical of all subtypes establishing if the test actually achieves what it is supposed to achieve by measuring the extent to which a test correctly distinguishes the presence, but also the absence, of the condition that test is supposed to detect. In essence, the construct validity measures if the test actually works or not, and how well it works (65). The criterion standard may be obtained in many ways, including laboratory tests, imaging tests, function tests, and pathology, but also dedicated clinical follow-up of the participants. If no single reference standard is available, the most likely state of the patients can be derived from careful clinical follow-up (66). Essentially, the criterion or reference standard is a proxy for the target condition and therefore often not perfect, a factor which is not well appreciated (67).

In the practice of interventional pain management 3 types of diagnostic tests are utilized — laboratory tests, imaging tests, and interventional diagnostic tests. The usefulness of diagnostic tests is evaluated by a hierarchy of 6 possible endpoints to determine the utility of a test, thus, the more criteria in the scheme that are fulfilled, the more useful the test. For obvious reasons, tests that fulfill fewer criteria have only limited usefulness (68). These criteria are as follows: 1) technical aspects including reliability, accuracy, and feasibility; 2) diagnostic accuracy with validity; 3) diagnostic thinking — whether the test is going to make a change in the diagnosis or therapy; 4) therapeutic effectiveness with either change in the management as a result of the outcome of test or the diagnostic test may result in initiation or cessation of therapy; 5) the ability to improve patient outcomes or at least provide diagnosis and; 6) societal outcomes which essentially translates and raises the question of whether or not the test is effective for the society as a whole.

The first criteria of a diagnostic test includes the technical aspects such as reliability, accuracy, and feasibility. Technical aspects of lumbar facet joints have been studied extensively providing technical feasibility

Table 3. Duration of pain relief in weeks (Mean \pm SD).

	Positive	False-positive	P value
Number	136	16	
1st diagnostic block	3.6 \pm 3.82	3.8 \pm 1.24	0.377
2nd diagnostic block	6.9 \pm 4.55	5.9 \pm 2.46	0.399

ity, reliability, and accuracy (26,30,33-35,43,54,55,69-74). Potential intravascular injection and false-negative results were shown to be present in approximately 8% of patients (73). Medial branch blocks may be performed safely with minimal risk under fluoroscopic visualization.

The second criteria relates to diagnostic accuracy and validity. Multiple systematic reviews have evaluated diagnostic facet blocks and validity (30,33-35). Datta et al (30) included 7 studies meeting strict criteria to assess the diagnostic accuracy involving 1,320 patients (26,54,55,69-72). They evaluated the prevalence as well as false-positive rates with a single diagnostic block with lidocaine and concluded there was an overall prevalence of 31% (95% CI, 28% – 33%) and a false-positive rate of 30% (95% CI, 27% – 33%). The present study illustrates a prevalence of 31% (95% CI, 26% – 35%) and a false-positive rate of 42% (95% CI, 35% – 50%) with a single block. In a large study (55), it was reported that the prevalence was 27% (95% CI, 22% – 33%) and a false-positive rate was 45% (95% CI, 36% – 53%). In addition, these authors illustrated the importance of controlled diagnostic blocks using a stricter criteria of 80% pain relief and the ability to perform previously painful movements. The influence of multiple confounding factors was also evaluated including sedation (76,77), psychological factors (78,79), age (80), previous surgery (70), occupational injury (81), body mass index (81), and gender or smoking status (81).

The third criteria relates to if the diagnostic test is going to make a change in the diagnosis or therapy. Appropriate diagnosis of lumbar facet joint pain may provide improved choices in therapeutic interventions in managing chronic function-limiting low back pain as illustrated in well conducted randomized trials either with lumbar facet joint nerve blocks or radiofrequency neurotomy (49-51). Datta et al (30) concluded that there was Level II-1 to II-2 for lumbar facet joint nerve blocks and II-2 to II-3 for radiofrequency neurotomy in a systematic review. It is well recognized that precise anatomical diagnosis in low back pain has been described not only as elusive, but frustrating for both physicians and patients. History, physical examination, and imaging provide limited information, providing diagnosis in only approximately 15% of the patients when pain is of other sources than disc herniation or radiculitis. Rubinstein and van Tulder (17) concluded that there was strong evidence for diagnostic lumbar facet joint nerve blocks, and, Datta et al (30) concluded that

the evidence was Level I or II-1. Consequently, precision diagnostic blocks in general, and lumbar facet joint nerve blocks in particular are used to clarify challenges in clinical situations in order to determine the pathophysiology of clinical pain, the site of nociception, and the pathway of afferent neural signs.

The fourth criteria refers to therapeutic effectiveness with either change in the management as a result of the outcome of the test or the diagnostic test may result in initiation or cessation of therapy. As illustrated in the above discussion, therapeutic feasibility and effectiveness has been illustrated in appropriately diagnosed patients. Datta et al (30) showed the evidence for therapeutic lumbar facet joint interventions as Level II-1 or II-2 for lumbar facet joint nerve blocks, and Level II-2 or II-3 evidence for radiofrequency neurotomy.

The fifth criteria relates to the ability of a diagnostic test to improve patient outcomes or at least provide diagnosis. Lumbar facet joint nerve blocks improve outcomes. This has been shown in controlled trials with appropriate outcome assessments. Manchikanti et al (49) illustrated in a randomized controlled trial of pain relief in 82% of patients along with functional status improvement measured by appropriate outcome parameters. Nath et al (51) illustrated in a randomized controlled trial the reduction of VAS scores in the active treatment group of 1.93 units compared to placebo group 0.38 units ($P=0.02$, 004). Dreyfuss et al (53) illustrated that 60% of the patients obtained at least 90% relief of pain at 12 months, and 87% obtained at least 60% relief.

Finally, the sixth item is related to social outcomes which essentially translates and raises the question of whether or not the test is effective for society as a whole in providing pain relief with appropriate outcomes including improvement in functional status, and quality of life, and also increases the work force, thus creating a positive effect socially as well as economically. In fact, lumbar facet joint nerve blocks have been shown to be cost effective compared to various other interventions including surgery (3,50).

Construct validity, which is the crucial and most argued part of the diagnostic evaluation, is avoiding false-positives and proving the accuracy of the test on a long-term basis. The construct validity essentially establishes that the test actually achieves what it is supposed to achieve by measuring the extent to which a test correctly distinguishes the presence, and also the absence, of the condition that the test is supposed to

detect — namely false-positive results. This evaluation confirms that over a long period of time controlled comparative diagnostic lumbar facet joint nerve blocks have been shown to be accurate in at least 90% of the population with a strict criteria of 80% relief and the ability to perform previously painful movements.

Limitations of this study include the lack of placebo controlled diagnostic blocks, and a 2-year follow-up which may be considered by some as short-term, however, 2-year follow-up for injection therapy such as facet joint nerve blocks is appropriate.

Overall, evidence in this report demonstrates that lumbar facet joint pain diagnosed by controlled, comparative local anesthetic blocks with a criteria of 80% pain relief, which is sustained after prior painful movements for the appropriate duration of action of the local anesthetics, and treated appropriately with lumbar facet joint nerve blocks, provides appropriate validity to the diagnosis of facet joint pain by controlled comparative diagnostic blocks at a 2-year follow-up with sustained diagnosis at 2-year follow-up.

CONCLUSION

The results of this observational evaluation of the accuracy of diagnosis of lumbar facet joint pain by controlled comparative diagnostic blocks demonstrates the validity in 90% of the patients at a 2-year follow-up with the confirmation of initial diagnosis.

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