

Diagnostic Accuracy Study

Assessment of Prevalence of Cervical Facet Joint Pain with Diagnostic Cervical Medial Branch Blocks: Analysis Based on Chronic Pain Model

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Background: Research into cervical spinal pain syndromes has indicated that the cervical facet joints can be a potent source of neck pain, headache, and referred pain into the upper extremities. There have been multiple diagnostic accuracy studies, most commonly utilizing diagnostic facet joint nerve blocks and an acute pain model, as Bogduk has proposed. Subsequently, Manchikanti has focused on the importance of the chronic pain model and longer lasting relief with diagnostic blocks.

Objective: To assess diagnostic accuracy of cervical facet joint nerve blocks with controlled comparative local anesthetic blocks, with updated assessment of prevalence, false-positive rate, and a description of philosophical paradigm shift from acute to chronic pain model, with concordant pain relief.

Study Design: This diagnostic accuracy study was performed with retrospective assessment of data to assess prevalence and false-positive rates.

Setting: The study was performed in a non-university-based, multidisciplinary, interventional pain management, private practice in the United States.

Methods: Cervical medial branch blocks were performed utilizing lidocaine 1% followed by bupivacaine 0.25% when appropriate response was obtained in an operating room under fluoroscopic guidance with 0.5 mL of lidocaine or bupivacaine from C3-C6 medial branches (levels blocked on joints involved). If a patient failed to respond to lidocaine with appropriate $\geq 80\%$ pain relief, that patient was considered as negative for facet joint pain. If the response was positive with lidocaine block, a bupivacaine block was performed.

Results: The chronic cervical facet joint pain was diagnosed with cervical facet joint nerve blocks at a prevalence of 49.3% (95% CI, 43.6%, 55.0%) and with a false-positive rate of 25.6% (95% CI, 19.5%, 32.8%). This study also showed a single block prevalence rate of 66.3% (95% CI, 71.7%, 60.9%). Assessment of the duration of relief with each block showed greater than 80% for 6 days with lidocaine block and total relief of $\geq 50\%$ of 31 days. In contrast, with bupivacaine, average duration of pain relief of $\geq 80\%$ was 12 days with a total relief of $\geq 50\%$ lasting for 55 days.

Conclusion: Based on this investigation, utilizing a chronic pain model, there was significant difference in the relief patterns. This assessment showed prevalence and false-positive rates of 49.3% and 25.6% in chronic pain. Duration of relief $\geq 80\%$ pain relief was 6 days with lidocaine and 12 days with bupivacaine, with total relief of $\geq 50\%$ of 31 days with 55 days respectively.

Key words: Chronic spinal pain, cervical facet or zygapophysial joint pain, facet joint nerve blocks, medial branch blocks, controlled comparative local anesthetic blocks, diagnostic accuracy, prevalence, false-positive rate

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Bogduk and Marsland have previously described facet joints as a source of idiopathic neck pain (1). Since then, multiple diagnostic accuracy studies, systematic reviews, and guidelines have showed that the diagnosis may not ideally be made with physical examination, pain diagrams, pain complaints, and other noninvasive modalities (2-7). Diagnosis was most appropriately made with controlled diagnostic blocks (2,8-17). The prevalence studies of cervical medial branches of cervical facet joint pain have shown Level II evidence with moderate strength of recommendation utilizing 9 of the 10 studies with either controlled comparative local anesthetic blocks or placebo controls with concordant pain relief with a criterion standard of above 80% (2). The prevalence and false-positive rates ranged from 29% to 60% and 27% to 63%, with high variability (2,8-17). However, multiple discussions continue in reference to the diagnosis of facet joint pain, specifically with medial branch blocks with discussions and, at times, arguments (2,5-7,18-20). Further issues related to the volume of local anesthetic, application of a single block response for diagnostic purposes, controlled comparative local anesthetic blocks of placebo control blocks, the type and concentration of local anesthetic, sedation, and, finally, the criterion standard relief variable from 80% to 100% (2,5-7,18-25). The majority of the studies in the cervical spine were carried out with 80% or 100% relief, except for one study (16). Further, multiple therapeutic approaches with medial branch blocks and radiofrequency neurotomy have been shown to be effective in managing cervical facet joint pain (2,26-32).

The approach to the identification of causes of painful facet joints with diagnostic medial branch blocks was pioneered by Bogduk (5,6,8,9,11-13,18-20) as the senior author. Research was also conducted by Manchikanti as the senior author in the United States (15-17,28,32). Bogduk (33) postulated the structural basis of back pain, with the same principles applied in the cervical spine, with a nerve supply being capable of causing pain similar to that seen in clinic, ideally demonstrated in normal volunteers. It should also be susceptible to disease or injuries that are known to be painful, and the structure should have been shown to be a source of pain in patients, using diagnostic techniques of known reliability and validity. Further, accuracy of the intervention may not be proven in cases with facet joint pain as a biopsy, surgery, or an autopsy may not be performed. Consequently, the long-term or dedicated clinical follow-up of patients diagnosed with cervical facet joint pain with

appropriate treatment modalities appears to be the only solution (34). Bogduk, as the senior author, has painstakingly proven that controlled diagnostic blocks provided concordant pain relief based on the duration of local anesthetic action, which has not been determined in chronic pain patients, and there is a potential for high variability on interpretation of individual providers. In fact, Bogduk hypothesized that the relief is the same whether it is in acute pain or chronic pain, even though they did not separately assess them (5,18,19). Further, Bogduk also has described that some have temporary, but inordinately prolonged response to local anesthetics (2,8,12,18). They essentially described that any response longer than the duration of expected local anesthetic as a discordant response was judged as a false-positive. However, later on, they described that discordant or prolonged responses were valid, and for practical purposes, but also stated that as prevalence decreases in the case of the lumbar spine, discordant responses become increasingly less valid because the diagnostic confidence they provide becomes substantially less than that of concordant responses (35). However, this theory does not apply in the cervical spine since the prevalence is higher in the majority of the studies.

In contrast, Manchikanti, as lead author (16), published the first study of the cervical spine in the United States in 2002, after a series of manuscripts published on lumbar spine (15,17,36-41). It was the first study in the United States other than Bogduk's group in a heterogeneous population utilizing 75% pain relief as the criterion standard and estimated the prevalence as 60% (95% CI, 50%, 70%) with a false-positive rate of 40% (95% CI of 34%, 46%). Later studies by Manchikanti's group (15,17) also showed a lower prevalence of 39% and 45% false-positive rate (15). In another study of 255 patients, with 80% or more as the criterion standard, showed 55% rate of prevalence and 63% false-positive rate (16). Overall, the rate showed by Bogduk's group (8,9,11,13) ranged from 54% to 60% prevalence with a false-positive rate of 27%. The studies performed by Speldewinde (10) and Persson et al (14), outside of Bogduk's group or Manchikanti et al, showed lower prevalence, with Speldewinde (10) showing 36%, whereas Persson et al (14) showed 29%. However, in contrast to lumbar spine, neither Manchikanti et al or others have calculated the total relief. All other authors utilized an acute pain model with criterion standard of duration of relief of less than 8 hours with lidocaine and less than 24 hours with bupivacaine. However, as in the lumbar spine, Manchikanti et al observed a significantly longer

duration of relief in the cervical spine also. In a recent manuscript, Manchikanti et al (41) described prevalence, quality, and duration of relief using a chronic pain model.

The present investigation, therefore, was undertaken to update the prevalence and false-positive rates of cervical facet medial branch nerve blocks in the diagnosis of cervical facet joint pain with a criterion standard of 80% pain relief and with a paradigm shift from acute to chronic pain model.

METHODS

Western Institutional Review Board granted and exemption for this retrospective study (WIRB Work Order #1-1294799-1). The methodology and guidance delineated by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (42) and the Standards for Reporting of Diagnostic Accuracy Studies (STARD 2015) (which is an updated list of essential items for reporting diagnostic accuracy studies) were followed (34).

STUDY DESIGN

In order to assess the duration of relief, prevalence, and false-positive rates, this retrospective analysis of chronic neck pain, diagnosed by medial branch blocks, was undertaken.

SETTING

The setting for this study was a non-university-based, multidisciplinary, interventional pain management, private practice located in the United States.

Participants

The participants were 299 consecutive patients undergoing cervical facet joint nerve blocks, administered by one physician for chronic neck pain.

Figure 1 shows the patient flow schema.

Inclusion Criteria

To be included, patients had to be at least 18 years of age and above. Also, they must have had axial pain with or without somatic radiation, but without a radicular pain pattern for at least 6 months, and have not satisfactorily responded to conservative management, which included physician-ordered physical therapy, drug therapy, chiropractic manipulation, structured exercise program, bedrest, etc. Pain over the facet joints, relief with rest, lack of disc herniation, and intersegmental mobility were also included in the clinical findings (2-4).

Exclusion Criteria

A patient who had a disc protrusion or bulging with a radicular pain pattern and a positive neurological examination with reflex suppression or neurological deficit were excluded. Also, patients with disc herniation were excluded. Disc bulging or protrusion without radicular pain were not a contraindication if they met all the criteria.

Assessment

All examinations and evaluations of patients were performed by one physician (LM). The examination included a comprehensive history, physical examination, and evaluation of the results of prior procedures and investigations. Initially, when the charts were reviewed 309 patients were identified. But, 15 patients who had been scheduled for the procedure and diagnostic facet joint nerve blocks did not receive them. As a result, the sample was 294 patients who underwent at least one diagnostic facet joint nerve block.

Informed Consent

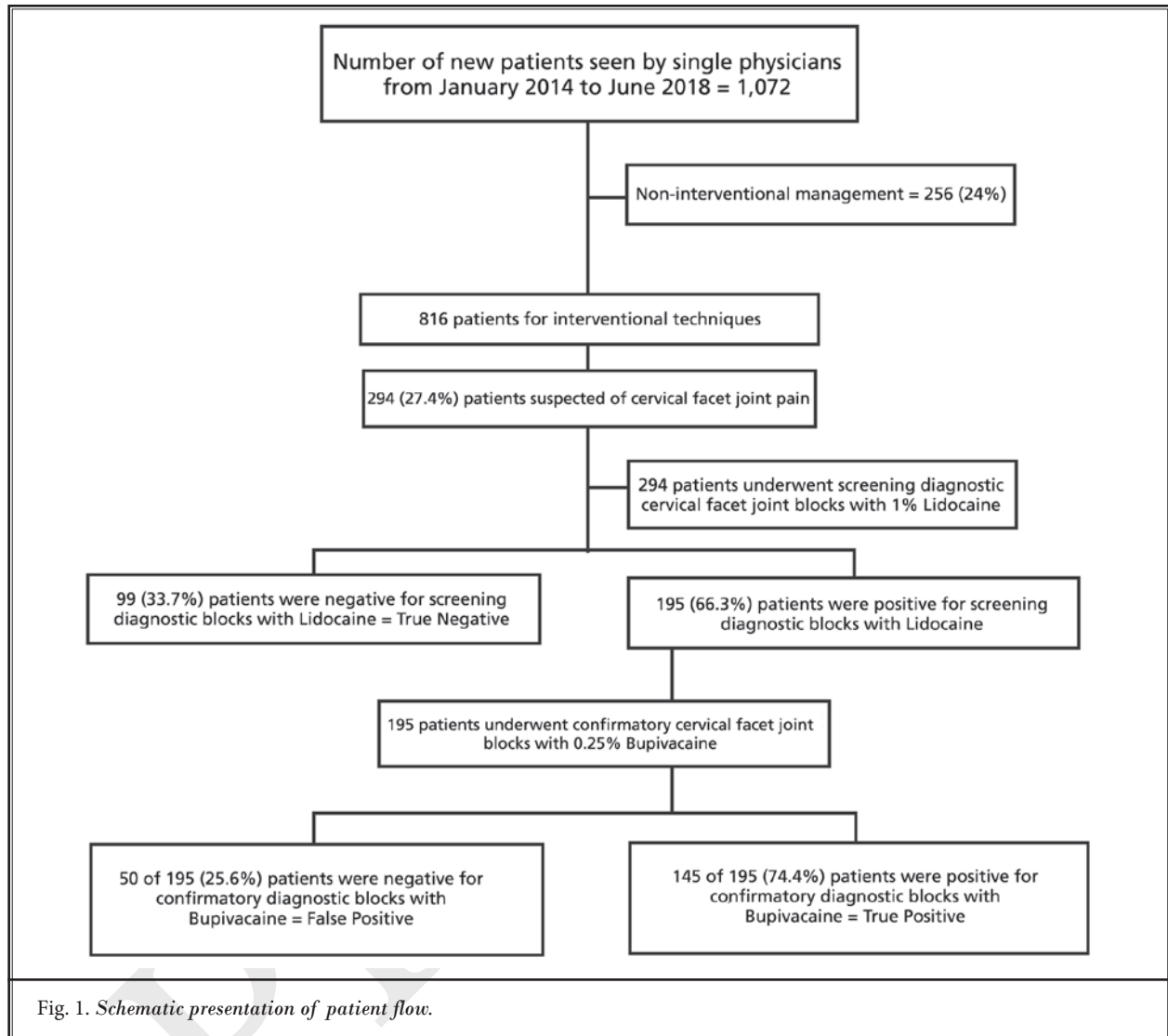
As required, patients received appropriate explanation regarding diagnostic facet joint nerve blocks, along with associated complications, and informed consent was obtained.

Procedures

All cervical facet joint nerve blocks were performed in a sterile operating room under appropriate monitoring with mild sedation with midazolam alone, or when appropriate, without sedation. Fentanyl was not administered. For the first block procedures were performed using 1% lidocaine with 0.5 mL at each level from C3 through C6, either unilaterally or bilaterally. Those patients with lidocaine positive results (\geq 80% reduction of pain and with the ability to perform previously painful movements) further received 0.25% bupivacaine on a separate occasion, on average 4 to 6 weeks after the first injection.

All blocks were performed on the ipsilateral side in patients with unilateral pain or bilaterally in patients with bilateral or axial pain, and were performed at a minimum of 2 levels, blocking 2 joints or 3 nerves; however, additional joints were blocked as necessary. Using a 22-gauge, 2.5 inch spinal needle at each of the indicated medial branch levels, the blocks were performed with intermittent fluoroscopic visualization.

All diagnostic blocks were performed as described by Manchikanti et al (7).



Assessment of the Response

The Numeric Rating Scale (NRS) was used for response assessment and was administered by someone other than the physician who performed the block. To be considered positive, the response had to be $\geq 80\%$ reduction of pain and with the ability to perform previously painful movements and thus after each block, that is how the patient was assessed. In order to be considered positive, pain relief from a block had to have a duration of a minimum of 24 hours with $\geq 80\%$ relief, plus an overall relief of one week following lidocaine and greater than the duration of relief with bupivacaine than lidocaine.

Discharge and Postoperative Assessment

After completion of the diagnostic block, all patients were discharged within 30 to 45 minutes, and were contacted within 24 hours by a registered nurse and responses were recorded. Follow-up visits were scheduled for all patients in 2 to 4 weeks with assessment of pain relief and functional status improvement, the duration of 80% relief, and total duration of $\geq 50\%$ relief.

Criterion Standard

Any patient who had less than the proposed response was considered as not to have facet joint pain

following the first block. Patients who had appropriate relief following the first block with lidocaine also received a second block with bupivacaine and responses were assessed after 6 to 8 weeks. If they obtained a concordant response, they were considered positive and further treatment with therapeutic facet joint nerve blocks or radiofrequency neurotomy was considered. Failure to show concordant relief, i.e., longer than lidocaine with bupivacaine, they were considered false-positives and no further facet joint therapy was performed.

Variables and Measures

For this study, analysis was carried out for the prevalence of cervical facet joint pain, false-positive rates with a single block, and duration of relief with each block.

Bias

Because this was a retrospective evaluation utilizing all consecutive patients, and the data was collected by a physician and clinical coordinator not involved in the provision or assessment of the patients during the period of treatment, and because it was based on a reasonably large sample size, with no external funding, there is no investigator bias in this study.

Sample Size

For diagnostic accuracy studies, the sample size of this study is considered appropriate and on the larger side based on the previous study (15). With 95% sensitivity and 39% prevalence, a required sample size is 120 and with 80% specificity and 39% prevalence, the required sample size is 400.

Data collection and analysis was collected by RK and KC. Analysis was performed by VP.

Statistical Analysis

Microsoft Access database was used to enter data, while tables were generated using the IBM SPSS® Statistics version 22. Chi square test was used to compare between gender, age, and body mass index (BMI). Prevalence, Sensitivity (true positive rate), specificity (true negative rate), and accuracy were also calculated.

RESULTS

Participants

All the new patients from 2014 to 2018 were assessed. Figure 1 shows schematic presentation of patient flow.

Patient Characteristics

Table 1 shows the demographic features.

Results of Diagnostic Blocks

As shown in Table 2, prevalence of facet joint pain utilizing double-blocks was 49.3% \pm (95% CI, 43.6%, 55.0%). The study also showed a false-positive rate of 25.6% (95% CI, 19.5%, 32.8%), sensitivity of 100% accuracy of 82.9%, and specificity of 66.4% (95% CI, 58.3%, 74.0%).

Lidocaine blocks were performed in 294 patients enrolled. Of these, 99 patients were judged to be negative for facet joint pain with a prevalence rate of cervical facet joint pain of 66.3% (95% CI, 71.7%, 60.9%) with a single block with lidocaine. The remaining 195 patients underwent a second block with bupivacaine. Of these, 145 patients were positive. This provided a prevalence of 49.3% (95% CI, 43.6%, 55.0%), This also provided a false-positive rate of 25.6% (95% CI, 19.5%, 32.8%). Table 2 also shows sensitivity and specificity with both single and dual blocks.

As shown in Table 3, prevalence and false-positive rates by gender, age, and BMI were assessed.

Table 4 shows the duration of relief with each block described in days as an average with the first block with lidocaine in patients with ultimately controlled comparative local anesthetic positive block. 4.15 days \geq 80% relief was reported with a total relief of 23.29 days of \geq 50%. In contrast, with the second block, the \geq

Table 1. *Demographic characteristics.*

Gender	
Male	35% (103)
Female	65% (191)
Age	
Mean \pm SD	49.6 \pm 11.6
< 45 year	36.4% (107)
45-60 Years	47.6% (140)
> 60 Years	16% (47)
Weight	187.8 \pm 51.4
Height	66.3 \pm 3.8
BMI	
Mean \pm SD	30.0 \pm 7.8
< 25	27.9% (82)
25-29.99	29.3% (86)
30-39.99	31.2% (92)
\geq 40	11.6% (34)

Table 2. Results of single and dual controlled comparative local anesthetic cervical facet joint nerve blocks with 1% lidocaine and 0.25% bupivacaine.

1st diagnostic block	2nd Diagnostic Block		Single Total
	Positive	Negative	
Positive	145	50	195
Negative	0	99	99
Double block total	145	149	294
Single block prevalence	66.3% (95% CI, 71.7%, 60.9%)		
Double block prevalence	49.3% (95% CI, 43.6%, 55.0%)		
False positive rate	25.6% (95% CI, 19.5%, 32.8%)		
False negative rate	0% (95% CI, 0%, 0.05%)		
Specificity	66.4% (95% CI, 58.3%, 74.0%)		
Sensitivity	100% (95% CI, 97.49%, 100%)		
Accuracy (true positive + true negative)	82.9%		

Table 3. Prevalence by gender, age and body mass index.

	Prevalence	FPR
Gender		
Male	37.9% (39/103)	36.1% (22/61)
Female	55.5% (106/191)	20.9% (28/134)
P value	0.005	0.033
Age (years)		
< 45	47% (51/107)	26.1% (18/69)
46-60	48.6% (68/140)	28.4% (27/95)
> 60	55.3% (26/47)	16.1% (5/31)
P value	0.662	0.394
BMI		
< 25	51.2% (42/82)	27.6% (16/58)
25-30	51.2% (44/86)	27.9% (17/61)
30-40	44.6% (41/92)	22.0% (12/43)
> 40	52.9% (18/34)	21.7% (5/23)
P value	0.742	0.871

*FPR=false positive rate

Table 4. Duration of relief in days (average).

Outcome	n	1st Diagnostic Block			2nd Diagnostic Block		
		50-79%	≥ 80%	Total Relief	50-79%	≥ 80%	Total Relief
False positive	50	24.54	6.64	31.18	26.25	0.18	26.43
Negative	99	8.11	0.04	8.15	0.00	0.00	0.00
Positive	145	24.81	6.10	30.91	43.28	11.86	55.29
Total	294	19.14	4.15	23.29	38.71	8.82	47.64

80% pain relief was noted in 8.82 days with total relief (> 50%) of 47.64 days.

DISCUSSION

In the present investigation, a diagnostic accuracy study has shown a prevalence of facet joint pain with dual diagnostic blocks and using ≥ 80% pain relief as the criterion standard of 49.3% (95% CI, 43.6%, 55.0%) and a false-positive rate of 25.6% (95% CI, 19.5%, 32.8%).

Recently, a diagnostic accuracy study (41) updated the prevalence and false positive rates of facet joint pain in the lumbar region with controlled comparative local anesthetic utilizing the hypothesis of a chronic pain algorithm expecting the duration of relief to be longer than the pharmacological action of each local anesthetic. This study showed similar results as previous studies have in reference to a prevalence of 29%-60% and false-positive rates of 27%-63% with 80% pain

relief as the criterion standard; however, more importantly, the study once again affirmed the longer lasting duration of relief with both lidocaine and bupivacaine utilizing the chronic pain paradigm. The total relief ≥ 50% in the lumbar spine with diagnostic blocks was shown to be of 32 days with lidocaine and 55 days with bupivacaine. Similar to the results found in the lumbar spine, the present assessment also showed significantly longer improvement with ≥ 80% relief of 6 days with lidocaine and almost 13 days with bupivacaine and with a total relief of ≥ 50% for 31 days with lidocaine and 55 days with bupivacaine. The study showed a false-positive rate of 25.6% (95% CI, 19.5%, 32.8%) with a single block prevalence rate of 66.3% (95% CI, 71.7%, 60.9%). Consequently, a single block is not recommended, considering that there is a significant difference (34.4% higher) in the prevalence rate with single blocks compared to dual blocks. Further, instead of considering long-lasting relief as discordant or out

of the normal, we should consider the chronic pain hypothesis and an appropriate time period should elapse with proper assessment before embarking on therapeutic interventions. Assumptions and hypothesis that local anesthetic activity dissipates must be discarded.

The duration of relief was not reported with cervical diagnostic blocks even though they have made such an observation with diagnostic blocks in the past. However, both groups, Bogduk and colleagues (8,9,11-13) and others (10,14), continue to utilize the acute pain model. In contrast, Manchikanti et al utilized a chronic pain model (15-17,36-41). Additionally, Bogduk and colleagues' (8,9,11-13) patients and patients of others (10,14) were recruited from Australia. As described earlier, there is no biopsy surgery or autopsy available in any of the patients. Consequently, comparison and analysis should be based on the philosophy that accuracy of an intervention may be proven with long-term follow-up or a dedicated clinical follow-up of patients undergoing diagnostic facet joint nerve blocks (34). This has been demonstrated in multiple publications and systematic reviews with cervical facet joint nerve blocks (28), with cervical medial branch blocks (17,28,31,32,43), and with radiofrequency neurotomy (26,27,29-31,43).

There persists a significant misunderstanding in reference to the relief provided by local anesthetics and the duration of relief, with the hypothesis that duration is 1 or 2 hours based on the acute pain model. Rather, we have approached this discussion with a change of philosophical approach introducing a paradigm shift from acute pain to chronic pain. We view acute pain as unidimensional with only a nociceptive component. In contrast, chronic pain is a complex biopsychosocial phenomenon, which is multidimensional. As a result, many authors have missed this aspect. Manchikanti et al (2,15-17,36-41,43,44) have described the role of local anesthetics in multiple manuscripts, where it is longer lasting than acute pain and is also similar to using steroids with lidocaine, as well as bupivacaine. Multiple other authors have also echoed this in their publications (43-48). In chronic pain, local anesthetics provide long-term relief based on various principles, in addition to the traditional duration of pharmacological actions. The effectiveness of local anesthetics on the duration of relief in chronic pain is based on antiinflammatory activities (43-45), alteration of multiple pathophysiologic mechanisms, including noxious peripheral stimulation, excess nociception, sensitization of pain pathways and excess release of neurotransmitters, causing complex central responses including hyperalgesia windup, no-

ceptive sensitization, and phenotype changes, all of which are considered as components of neural plasticity (43-45,49-62). There are numerous clinical and experimental studies that have shown extended pain relief utilizing local anesthetic only, while at the same time showing no significant prolongation of the duration of relief by the addition of steroids (28-30,32,43-45,51-70).

Regarding the utilization of interventional techniques in fee-for-service (FFS) Medicare population (71-76) analysis has shown an overall decline in utilization of interventional techniques from 2009 to 2018 of 6.7% with an annual decline of 0.8% per 100,000 FFS Medicare population, despite an increase of 0.7% per year of population growth of 3.2% of those 65 years or older, and a 3% annual increase in Medicare participation from 2009 to 2018. In addition, analysis of utilization patterns of epidural procedures (73,74) showed a decline at a rate of 20.7% per 100,000 Medicare enrollees from 2009 to 2018, with an annual decline of 2.5%. On the other hand, these analyses (72,76) showed that lumbosacral facet joint nerve block sessions decreased at an annual rate of 0.2% from 2009 to 2018 compared with an increase of 15.2% from 2000 to 2009. This is in contrast to lumbosacral facet joint neurolysis sessions, which increased at an annual rate of 7.4% from 2009 to 2018, compared to an annual increase of 23% from 2000 to 2009. In the cervical spine, there are similar, but less dramatic patterns observed. Manchikanti et al (76) also published trends in the expenditures in 2013 and updated it in 2020 to cover from 2009 to 2018. These analyses showed that expenditures increased by 79% from 2009 to 2018 in the form of total cost for facet joint interventions. At the same time, cervical and lumbar facet joint injections increased 35% and 37%, whereas cervical and lumbar radiofrequency neurotomy increased 185% and 169%, totaling an increase of costs of 79% at an annual rate of 6.7%. Additionally, it should be noted that inflation-adjusted expenditures using 2018 US dollars, showed still an overall increase of 53% and an annual increase of 4.9%.

In summary, the major advantages of this investigation is that it used a chronic pain model (rather than an acute model) with a proven diagnostic approach and used controlled comparative local anesthetic blocks with concordant pain relief. Additionally, it was conducted using the guidance and direction based on STROBE and STARD criteria. What this study clearly shows is that relief using this methodology lasts much longer than the hours of duration reported previously by others. It demonstrated that appropriate selection of patients

utilizing the chronic pain model may improve success rate, access to service, and, very importantly, utilization. Patients who do not respond or are negative to facet joint nerve blocks may subsequently undergo epidural injections as has been described for discogenic pain in multiple manuscripts (44,45,47,49,50,77-83).

Limitations of this study are its retrospective nature, patient recall bias, and lack of acceptance of the chronic pain hypothesis by other investigators.

CONCLUSION

The study of prevalence of cervical facet joint pain and false-positive rates with diagnostic facet joint nerve blocks with 80% criterion standard showed 49.3% and 25.6%. Assessment of the duration of relief with each block showed $\geq 80\%$ for 6 days with lidocaine block and total relief of $\geq 50\%$ relief for a total of 31 days. Further, this diagnostic accuracy study also showed that bupivacaine relief of $\geq 50\%$ averaged 12 days with a total relief of $\geq 50\%$ for 55 days. Based on this study, utilizing a

chronic pain model, there was significant difference in the relief patterns. Further, this study clearly eliminates the assumptions and hypothesis that local anesthetic activity dissipates within 24 hours.

Author Contributions

The study was designed by LM, AK, VP and JH. Statistical analysis was performed by VP. All authors contributed to preparation of the manuscript, reviewed, and approved the content of the final version.

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