Randomized Trial

Comparative Effectiveness of a One-Year Follow-Up of Thoracic Medial Branch Blocks in Management of Chronic Thoracic Pain: A Randomized, Double-Blind Active Controlled Trial

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Background: Thoracic facet joints have been implicated as the source of chronic pain in the mid back or upper back in 34% to 42% of patients when the modified criteria of the International Association for the Study of Pain (IASP) is utilized. Various therapeutic techniques utilized in managing chronic thoracic pain of facet joint origin include intraarticular injections, medial branch blocks, and radiofrequency neurotomy of thoracic medial branch nerves.

Study Design: A randomized, double-blind, active controlled trial.

Setting: A private practice, interventional pain management setting, and a specialty referral center setting in the United States.

Objective: To determine the clinical effectiveness of therapeutic local anesthetic medial branch blocks with or without steroid in managing chronic function-limiting mid back or upper back pain of facet joint origin.

Methods: The study was performed in an interventional pain management private practice, a tertiary referral center, in the United States. A total of 100 participants were included, with 50 participants in each of the local anesthetic and steroid groups. All of the participants met the diagnostic criteria of thoracic facet joint pain by means of comparative, controlled diagnostic blocks and the inclusion criteria. Group I participants received thoracic medial branch blocks with bupivacaine, whereas Group II participants received thoracic medial branch blocks with bupivacaine and non-particulate betamethasone.

Outcomes Assessment: Outcomes measures included numeric rating scores (NRS), Oswestry Disability Index (ODI), opioid intake, and return to work status at baseline, 3 months, 6 months, and 12 months. Significant pain relief was defined as ≥ 50% pain relief and/or a positive change in ODI scores.

Results: In Group I and Group II 90% of participants showed significant pain relief and functional improvement at 12 months.

The majority of the participants experienced significant pain relief of 47.2 ± 10.1 weeks in Group I and 46.3 ± 8.4 weeks in Group II, requiring approximately 3.5 treatments per year with an average relief of 15.8 ± 10.5 in Group I and 13.6 ± 3.6 weeks in Group II per episode of treatment.

Limitations: Study limitations include the lack of a placebo group.

Conclusions: Therapeutic thoracic medial branch blocks, with or without steroid, may provide a management option for chronic function-limiting mid back or upper back pain of facet joint origin.

Clinical Trial: NCT00355706

Key words: Chronic spinal pain, thoracic pain, thoracic facet or zygapophysial joint pain, facet joint nerve or medial branch blocks, comparative controlled local anesthetic blocks, therapeutic thoracic medial branch blocks.

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Despite the relatively low proportion of mid back and upper back pain secondary to thoracic disorders, thoracic pain in interventional pain management settings ranges from 3% to 22% compared to the lifetime prevalence of spinal pain of 54% to 80% (1-3). The prevalence of thoracic pain has been estimated as 15% of the general population in contrast to 56% reporting low back pain and 44% reporting neck pain (1,4). Even though involvement of thoracic facet joints as a cause of chronic mid back and upper back pain was described in 1987 (5), thoracic facet joint pain patterns were not described until 1994 (6) and 1997 (7).

In accordance with the modified criteria of the International Association for the Study of Pain (IASP) (8), utilizing 80% pain relief as the criterion standard and the ability to perform multiple prior painful movements with controlled, comparative, local anesthetic blocks, prevalence has been established as 34% to 42% (9-16), with an apparent false-positive rate ranging from 42% to 55% with a single block in a heterogenous population.

Atluri et al (12), evaluating the diagnostic value and therapeutic role of facet joint interventions, determined significant value for diagnostic medial branch blocks and established moderate evidence. However, for therapeutic interventions they were able to establish moderate evidence only for medial branch blocks, with no evidence for intraarticular injections or radiofrequency neurotomy.

Significant debate surrounds the appropriate management of thoracic facet joint pain for diagnostic as well as therapeutic interventions. Further, similar debate surrounds diagnostic and therapeutic medial branch blocks for lumbar and cervical facet joint diagnosis and therapy (15-32).

Confusion surrounding facet joint interventions is based on lack of understanding of placebo control and the criterion standard (24,25,27). However, the criterion standard is not only limited to biopsy, but also long-term follow-up criteria (33,34). Studies in the lumbar spine have shown the value of controlled comparative local anesthetic blocks with 80% concordant pain relief with long-term follow-up of 2 years (35-38). Further, the influence of multiple confounding factors has also been evaluated without influence on the diagnostic value of cervical and facet joint nerve blocks (39-46). Despite the ongoing debate it appears that diagnostic facet joint nerve blocks are the accurate method of diagnosis at the present time.

Similar to the diagnostic aspects, significant debate surrounds the appropriate management of facet joint pain (22,23,37,38,47-52). The systematic review by Atluri et al (12) showed a lack of evidence for therapeutic thoracic intraarticular facet joint injections and radiofrequency neurotomy, whereas they showed moderate evidence for thoracic medial branch blocks, which has also been reported in other studies (16,17). Previously, Manchikanti et al (49) published preliminary results of a randomized, double-blind trial showing positive results in 79% of the participants receiving local anesthetic blocks with or without steroids. The results of this trial were superior to an observational report (50).

This report consists of the one-year results of a continuation of the preliminary report (49) using a randomized, double-blind controlled trial in participants with a confirmed diagnosis of thoracic facet joint pain by means of comparative, controlled, local anesthetic blocks based on modified IASP criteria with 80% pain relief and the ability to perform previously painful movements (8,12,15,16).

Methods

This evaluation was conducted in the United States on participants suffering with chronic, function-limiting, thoracic facet joint pain. The study site is an interventional pain management practice, a specialty referral center, in a private practice setting. The study was designed to meet clinical protocol criteria and Consolidated Standards of Reporting Trials (CONSORT) guidelines (53-55).

The study protocol was approved by the Institutional Review Board of the Ambulatory Surgery Center. The study was registered on the U.S. Clinical Trial Registry with an assigned number of NCT00355706.

Participants

All the participants were recruited at an interventional pain management practice from consecutive new patients presenting with thoracic pain without suspected disc herniation, radiculitis, thoracic fracture, stenosis, or intercostal neuritis. Eligible patients with a confirmed diagnosis of thoracic facet joint pain by controlled comparative local anesthetic blocks were assigned to one of 2 groups with Group I constituting a nonsteroid group, and Group II encompassing a steroid group. Group I participants received medial branch blocks with injections of bupivacaine 0.25%, whereas Group II participants received medial branch blocks with a mixture of bupivacaine and non-par-

ticulate betamethasone. Non-particulate betamethasone (0.15 mg) was added to each mL of bupivacaine solution.

Inclusion and Exclusion Criteria

Only patients with non-specific mid back or upper back pain were included. Patients suspected of disc related pain with radicular symptoms were excluded based on radiologic testing and symptomatology involving radicular or chest wall pain. Only patients who had failed conservative management, including physical therapy, chiropractic manipulation, exercises, drug therapy, and bedrest were included.

Inclusion criteria were a diagnosis of thoracic facet joint pain by means of controlled comparative local anesthetic blocks; patients who were over 18 years of age; patients with a history of chronic function-limiting thoracic pain of at least 6 months duration; and patients who were competent to understand the study protocol and provide voluntary, written informed consent and participate in the outcome measurements.

Exclusion criteria were a lack of positive response to controlled comparative local anesthetic blocks, uncontrollable or heavy opioid use (morphine equivalence of 300 mg or more), uncontrolled psychiatric disorders, uncontrolled medical illness either acute or chronic, any condition that could interfere with the interpretation of the outcome assessments such as positioning women who were pregnant or lactating, and patients with a history or potential for adverse reaction(s) to local anesthetic or steroid.

Interventions

Diagnostic Facet Joint Nerve Blocks

The diagnosis of facet joint pain was made by controlled comparative local anesthetic blocks in all patients, in accordance with modified IASP criteria (8-10). All thoracic facet joints were evaluated with controlled comparative facet joint nerve blocks with a diagnostic process starting with diagnostic facet joint nerve blocks using 0.5 mL of 1% preservative-free lidocaine, followed by 0.5 mL of 0.25% preservative-free bupivacaine on a separate occasion, usually 3–4 weeks after the first injection, if positive with lidocaine. Target joints were identified by the pain pattern, local or paramedian tenderness over the area of the facet joints, and reproduction of the pain with deep pressure. A positive response was considered when a patient reported at least an 80% reduction of pain assessed by a numeric rating scale (NRS) and the ability to perform previously painful movements with continued relief of at least 80%. In addition, a positive response was only considered if the pain relief lasted at least 2 hours following the lidocaine injection and lasted at least 3 hours or greater than the duration of relief with lidocaine when bupivacaine was used; all other responses were considered as negative.

The facet joint nerve blocks were performed on the ipsilateral side in patients with unilateral pain, and bilateral facet joint nerve blocks were performed if patients had only axial pain or bilateral pain. Each nerve was injected with 0.5 of the local anesthetic and the blocks were performed on a minimum of 2 nerves to block a single joint and 3 nerves on 2 consecutive joints.

Therapeutic Facet Joint Nerve Blocks

Therapeutic facet joint nerve blocks were performed at the same levels as the diagnostic facet joint nerve blocks which led to the inclusion into the study utilizing solutions as assigned into Group I or Group II with or without steroids. All therapeutic facet joint nerve blocks were performed in a sterile setting in the operating room under fluoroscopy with a 22-gauge, 2" spinal needle with injection of a 0.5 to 1 mL mixture.

Co-interventions

New or specific co-interventions such as physical therapy, occupational therapy, or bracing were not offered during this treatment. However, the same co-interventions as scheduled including physical therapy and exercise program along with opioid and non-opioid analgesics, and adjuvant analgesics were continued in all participants as necessary.

Additional Interventions

Participants were followed at 3-month intervals unless otherwise indicated. Thoracic medial branch blocks were repeated based only on improvement in physical and functional status following prior intervention, with deterioration of pain level to below 50%.

Objective

The objective of this randomized, double-blind, active controlled trial was to determine the clinical outcomes of therapeutic thoracic medial branch blocks with local anesthetic with or without steroids in managing chronic thoracic pain of facet joint origin.

Outcomes

Outcomes measured included NRS, Oswestry Disability Index (ODI), work status, and opioid intake in terms of morphine equivalents, assessed at baseline, 3, 6, and 12 months post-treatment.

Significant improvement was defined as at least 50% pain relief and/or improvement in ODI. NRS represented "0" with no pain and "10" with worst pain imaginable. The NRS has been frequently utilized for pain measurements and its value and validity have been reported (54-56). The ODI has been shown to be valid and reliable in patients with mechanical low back pain measured on a scale of 0 to 50 with "0" being no disability and "50" being the worst disability (54,55,57-61). Further, reported thresholds for the minimum clinically important difference for the ODI ranged from a 2% to 40% change, even though recent literature demands higher improvements for outcome measurements (54,55,57-63).

Opioid intake was evaluated based on the dosage frequency and schedule of the drug, with conversion to morphine equivalents (64).

Participants unemployed or employed on a part-time basis with limited or no employment due to pain were classified as employable. Participants who chose not to work, were retired, or were homemakers (not working, but not due to pain) were not considered in the employment pool.

Sample Size

For this evaluation, a sample size of 50 patients for each group was chosen. The sample size was much smaller in previous studies of cervical (65) and lumbar (66) medial branch neurotomies, which included less than 20 participants in each group. The literature evaluating the quality of individual studies has shown a sample size of 50 patients in the smallest group as acceptable (67).

Randomization/Sequence Generation

A total of 100 participants were randomized with 50 participants into each group. Computer generated random allocations sequence concealment was utilized.

Allocation Concealment

Participants were randomized and the drugs were prepared appropriately by the operating room nurse assisting with the procedure. All mixtures consisted of clear solutions of bupivacaine or bupivacaine and non-particulate betamethasone.

Implementation

After the participants met the inclusion criteria, one of the 3 nurses assigned as coordinators of the study enrolled and assigned them to their respective groups. All the participants meeting inclusion criteria were invited to enroll in the study.

Blinding

The random allocation was not revealed to personnel in the recovery room or to the physician performing the procedure. Study participants were mixed with other patients with no specific indication that they were participating in the study.

Participants were unblinded if they requested to be unblinded or after completing 24 months of the study. Participants were provided with an opportunity to discontinue or withdraw from the study for lack of pain relief or for any other reason. All the participants with loss of follow-up or premature unblinding were considered to be withdrawn.

All the participants will be unblinded at 24 months.

Statistical Methods

Chi-squared statistic, Fisher's exact test, paired t-test, and one-way analysis of variance were used to analyze the data.

Chi-squared statistic was used to test the differences in proportions. Fisher's exact test was used wherever the expected value was less than 5. A paired t-test was used to compare the pre- and post-treatment results of average pain scores and the ODI measurements at baseline versus 3, 6, and 12 months. The t-test was performed for comparison of mean scores between groups. One-way analysis of variance was used for comparison of means among groups.

Intent-to-Treat-Analysis

An intent-to-treat-analysis was utilized on all participants utilizing the last follow-up data. Initial data were utilized for the participants who dropped out of the study without further follow-up after first treatment. Sensitivity analysis was performed utilizing best case, worst case, average value, and last follow-up scores scenarios.

Results

Participant Flow

Figure 1 illustrates the participant flow.

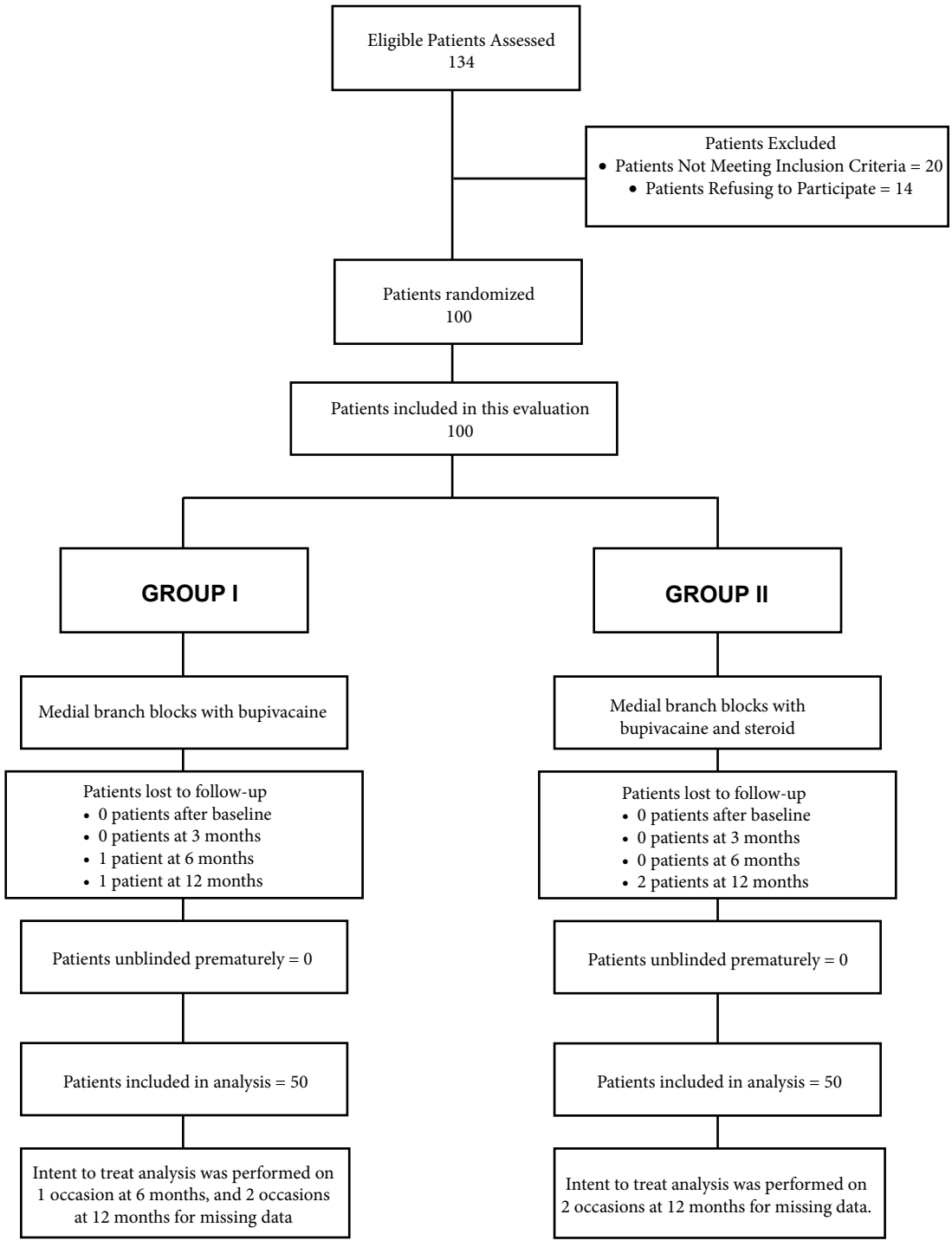

Fig. 1. *Schematic presentation of participant flow at one-year follow-up.*

Recruitment

The recruitment period started in 2003 and lasted through August 2009.

Baseline Data

Demographic characteristics are illustrated in Table 1.

The number of joints was as follows: 2 joints were involved in 22% of the participants, 3 joints were involved in 31% of the participants and 4 joints were involved in 47% of the participants. Bilateral involvement was seen in 67% of the participants.

Analysis of Data

Numbers Analyzed

As illustrated in Fig. 1, all 100 participants were utilized in the analysis.

Outcomes

Pain Relief

Numeric pain scale scores are illustrated in Table 2 and Fig. 2. The percentage of participants with significant pain relief was 90% at one-year follow-up in both groups.

Table 3 illustrates therapeutic procedural characteristics with average pain relief over a period of one-year. Average relief per procedure was 15.8 ± 10.5 and 13.6 ± 3.6 weeks per procedure, whereas it was 47.2 ± 10.1 and 46.3 ± 8.4 weeks over a period of one-year respectively for total pain relief.

Functional Assessment

Table 4 illustrates functional assessment characteristics evaluated by ODI. At least 50% improvement was seen in 80% and 84%, at one-year in Groups I and II respectively.

Table 1. *Demographic characteristics*.

		Group I (N=50)	Group II (N=50)	*P* value
Gender	Male	38% (19)	36% (18)	0.836
	Female	62% (31)	64% (32)	
Age	Mean ± SD	44.7 ± 11.7	42.8 ± 12.3	0.431
Height (inches)	Mean ± SD	67.5 ± 3.9	65.9 ± 3.9	0.042
Weight (lbs.)	Mean ± SD	197.6 ± 53.2	172.3 ± 37.1	0.007
BMI		30.2 ± 6.6	28.0 ± 3.3	0.079
Duration of pain (months)	Mean ± SD	78.0 ± 68.8	77.0 ± 73.6	0.994
Mode of onset of Pain	Non-Traumatic	68% (34)	72% (36)	0.663
	Traumatic	32% (16)	28% (14)	
History of previous thoracic surgery		2% (1)	6% (3)	0.617

Group I = bupivacaine only
Group II = bupivacaine and steroid

Table 2. *Pain relief characteristics*

		Group I (N=50)	Group II (N=50)	*P* value
Average Pain Scores (Mean ± SD)	Baseline	7.9 ± 0.93	7.8 ± 1.0	0.840
	3 months	3.1* ± 0.9	3.1* ± 0.7	1.000
	6 months	3.0* ± 0.9	3.2* ± 0.8	0.481
	12 months	3.2* ± 0.9	3.1* ± 1.0	0.833

* indicates significant difference with baseline values ($P < 0/05$)

Group I = bupivacaine only
Group II = bupivacaine and steroid

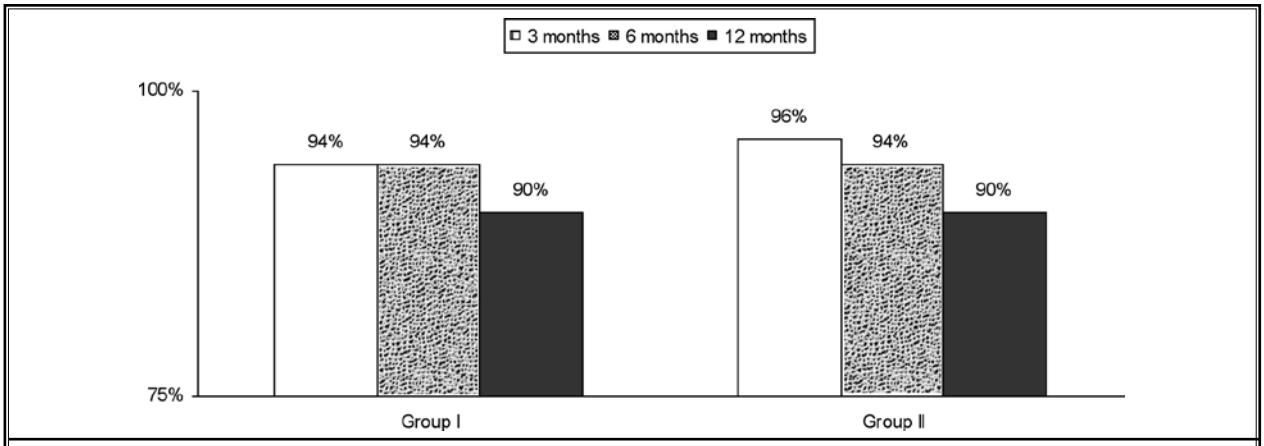

Fig. 2. *Illustration of significant pain relief (≥ 50%).*

Table 3. *Therapeutic procedural characteristics with procedural frequency, average relief per procedure, and average total relief in weeks over a period of 1-year.*

	Group I (N=50)		**Group II (N=50)**	
Number of Procedures	Average relief **Per procedure**	Average **Total relief**	Average relief **Per procedure**	Average **Total relief**
One	52 (3)	52 (3)	22.7 ± 5.8 (3)	22.7 ± 5.8 (3)
Range	52	52	16 - 26	16 -26
Two	19.3 ± 11.4 (7)	38.6 ± 22.9 (7)	19.5 ± 6.5 (3)	39.0 ± 13.0 (3)
Range	4 - 52	2 - 52	13 - 52	26 - 52
Three	14.8 ± 2.4 (8)	44.4 ± 7.1 (8)	14.9 ± 2.2 (9)	44.7 ± 6.8 (9)
Range	3 - 52	36 - 52	13 - 52	35 - 52
Four	12.3 ± 1.2 (32)	49.1 ± 4.8 (32)	12.4 ± 1.0 (35)	49.4 ± 3.9 (35)
Range	0 - 20	37 - 52	0 - 30	38 - 52
Five			-	
Range	9 - 14	47 - 52		
Average/Total Per 1 year	15.8 ± 10.5 (50)	47.2 ± 10.1 (50)	13.6 ± 3.6 (50)	46.3 ± 8.4 (50)
Range	2 - 52	4 - 52	10 - 26	16 - 52

Table 4. *Functional assessment evaluated by Oswestry Disability Index.*

		Group I (N=50)	**Group II (N=50)**	***P* value**
Disability Scores (Mean ± SD)	Baseline	27.1 ± 6.6	27.5 ± 5.8	0.708
	3 months	13.0* ± 4.9	11.6* ± 3.7	0.122
	6 months	13.0* ± 4.2	11.9* ± 3.8	0.636
	12 months	12.0* ± 4.0	11.8* ± 3.9	0.780

* indicates significant difference with baseline
Group I = bupivacaine only
Group II = bupivacaine and steroid

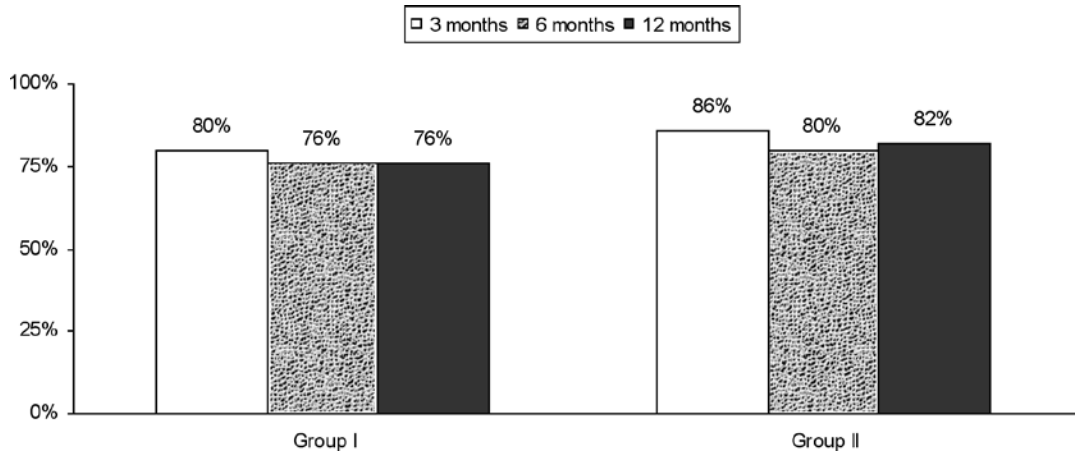

Fig. 3. *Illustration of significant pain relief (≥ 50%) and reduction (at least 50%) in Oswestry Disability Index from baseline.*

Table 5. *Opioid intake (morphine equivalence mg).*

Narcotic intake (Morphine Equivalence mg)	Group I (60)	Group II (60)	*P* value
	Mean ± SD	Mean ± SD	
Baseline	48.0 ± 53.75	47.9 ± 48.6	0.992
3 months	38.0 ± 44.2	40.3 ± 33.9	0.769
6 months	38.2 ± 46.1	39.3 ± 34.8	0.889
12 months	37.6 ± 38.4	37.8 ± 33.2	0.976

Pain and Functional Status Improvement

Figure 3 illustrates the proportion of patients with significant pain relief (>50%) in combination with reduction of at least 50% in the disability scores from baseline, which was seen in 76% of the patients in Group I and 82% in Group II at 12 months.

Opioid Intake

Table 5 illustrates opioid intake with no significant change in intake of opioids.

Employment Characteristics

Table 6 illustrates the summary of employment characteristics in both groups.

Adverse Events

No major adverse events were reported during this study including infection, pneumothorax, nerve root trauma, or spinal cord trauma.

Discussion

This randomized, double-blind trial, of 100 patients undergoing therapeutic thoracic medial branch nerve blocks who had chronic, function-limiting mid back or upper back pain secondary to thoracic facet joint involvement showed significant improvement with decreased pain and improved functional status. Significant pain relief of 50% or greater of varying duration was seen in 90% of participants in both groups. Functional assessment measured by ODI also showed significant improvement with at least a 50% reduction of disability scores in 80% of participants in Group I and 84% of participants in Group II over a period of one-year. Combined ≥ 50% pain relief and ≥ 50% improvement in ODI scores was seen in 76% and 82% of participants in Group I and II respectively at 12 months. The average pain relief per procedure ranged from 14 to 16 weeks and participants experienced 46 to 47 weeks of significant pain relief during one-year.

Table 6. *Employment characteristics*.

Employment status	Group I		Group II	
	Baseline	12 months	Baseline	12 months
Employed part-time	5	5	1	3
Employed full-time	10	14	14	16
Unemployed	3	1	3	1
Unemployed - Student	1	0	0	0
Total Employed	15	19	15	19
Eligible for employment	19	19	18	18
Housewife	2	1	3	2
Disabled	23	23	27	25
Over 65 years of age	6	6	2	3
Total number of participants	50	50	50	50

However, there were no differences in opioid use or employment.

This randomized trial was designed to reflect everyday clinical practice as others have also done (38,53). The results showed that the combination of steroid with local anesthetic failed to provide additional improvement. There were no significant differences of any clinical importance in any of the parameters. This is one of the largest studies with the longest follow-up of an interventional technique, specifically in managing thoracic facet joint pain. This study, similar to other studies, evidently resolves the issue of adding steroids to local anesthetic in therapeutic medial branch blocks. The evidence shows that there is no significant role for steroids in thoracic medial branch blocks.

The basis for intraarticular injections has been that if there is inflammation, steroids are used to treat the inflammation. Further, the literature is replete with descriptions of epidural corticosteroids providing a certain level of efficacy by their anti-inflammatory, immuno-suppressive, anti-edema effects, and inhibition of neurotransmission within the C-fibers (68-71). At the same time, local anesthetics also have been described to provide long-term symptomatic relief, even though the mechanism of this relief continues to be an enigma and widely debated (37,38,52,53,72-82). However, multiple postulations have lead to the impressions that local anesthetics provide relief by suppression of nociceptive discharge (72), the blockade of the axonal transport (83,84), the blockade of sympathic reflex arc, the blockade of sensitization (85,86), and by exerting anti-inflammatory effects (87).

The limitations of this study include a lack of placebo control. As it is not well known to some, placebo control in any neural blockade is an extremely difficult task. In addition, placebo control is complicated with ethical issues and difficulty with recruitment in the United States. Further, multiple investigators performing placebo-controlled studies in interventional pain management have incorporated substantial design flaws (22,23,47,48,54,55 ,88,89). Many researchers ignore the fact that any solution injected into a closed space such as the intraarticular space or epidural space or over a nerve root, whether it is placebo or an active agent, has not been well studied and we are not aware of the effects of placebo solutions. Carette et al (90,91) in widely acclaimed studies, showed that patients responded similarly to an intraarticular injection or epidural injection whether it contained a sodium chloride solution or local anesthetic with steroid, with low response in all the groups. However, the results have been misinterpreted by some. They concluded that since sodium chloride solution injected into an intraarticular space or epidural space has similar results to local anesthetic with steroid, then intraarticular steroids or epidural steroids are not only an effective therapy and that any local anesthetic injection provides only placebo effect. Further, in the recent literature, the issue has been exemplified by Birkenmaier et al (92), who described the utilization of either pericapsular injections or medial branch blocks before performing cryoneurolysis. Not surprisingly, the results were superior in patients who were diagnosed using medial branch blocks rather than pericapsular injections of local anesthetic. This study was the basis for Chou and Huffman (88) to discard the value of diagnostic lumbar facet joint nerve blocks.

In addition, the literature shows differing effects with injections of various solutions such as local anesthetic, normal saline, or dextrose, and also shows differing effects by injection into the disc, facet joint, or multifidus muscle (28-31,93-95). It was also demonstrated that a small volume of local anesthetic or normal saline abolishes muscle twitching caused by a low current (0.5 mA) during electrode location (28,29,93). Further, complicating the understanding of placebo analgesia, there is also direct evidence for spinal cord involvement (94). In addition, it has been reported that epidurally administered sodium chloride solution provides significant improvement in pain and function (29,95). Thus, the evidence here in this manuscript leads to the conclusion that the effect of local anesthetic on thoracic medial branch blocks cannot be attributed to placebo effect, even though some have mistakenly misinterpreted this to be the case for facet joint nerve blocks (25,27,96). Placebo effects are not expected to be seen in a high proportion of patients, nor are they expected to be long-lasting with repeat interventions over a period of 1-2 years. Even then, the limitations of lack of placebo must not be underestimated. If feasible, a placebo-controlled study with appropriate design that includes not injecting the placebo solution over the medial branches, and subsequent results, would be highly valid and provide conclusive knowledge on the issue of placebo-controlled blocks.

The second issue is related to the reliability of the controlled, comparative local anesthetic blocks, which have been criticized and their validity as precision diagnostic techniques has been questioned and debated (8-16,19-22). The issues related to the accuracy of diagnostic facet joint nerve blocks include the reference standard, prior exposure to opioids, sedation, systemic local anesthetic, and non-specific effect resulting in positive results have been essentially resolved (8-16,19-22, 35-38,51,52,97).

The results of this trial illustrate the practice patterns from a real world setting, specifically private practice settings in the United States specializing in the practice of interventional pain management. Consequently, the results may be generalizable to similar settings. In the modern arena of comparative effectiveness research and evidence-based medicine, the practical clinical trials (98) measuring effectiveness are considered more appropriate than explanatory trials measuring efficacy (99). Considering that practical trials are best designed to provide results of the benefit of treatments produced in routine clinical practice and also to address questions about the risks, benefits, and costs of intervention as they occur in routine, clinical practice better than explanatory trials, the design of this study and the results of this study are not only appropriate, but also are applicable. However, the results of this study are not applicable in the general population unless the same methodology is utilized with diagnosis and therapy. Further, the generalizability of the findings of this study may only be feasible with the publication of studies utilizing larger populations in multiple settings.

Conclusions

The evidence in this report demonstrates that thoracic facet joint pain diagnosed by controlled, comparative local anesthetic blocks with criteria of 80% pain relief, which is sustained even during previously painful movements for an appropriate duration of action of the local anesthetic, may be treated with therapeutic thoracic medial branch blocks with or without steroid.

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