Systematic Review

An Update of Evaluation of Therapeutic Thoracic Facet Joint Interventions

Kavita N. Manchikanti, MD, Sairam Atluri, MD, Vijay Singh, MD, Stephanie Geffert, MLIS, Nalini Sehgal, MD, and Frank J.E. Falco, MD

Background: Chronic mid back and upper back pain caused by thoracic facet joints has been reported in 34% to 48% of patients based on responses to controlled diagnostic blocks. Systematic reviews have established moderate evidence for controlled comparative local anesthetic blocks of thoracic facet joints in the diagnosis of mid back and upper back pain, moderate evidence for therapeutic thoracic medial branch blocks, and limited evidence for radiofrequency neurotomy of thoracic medial branches.


Objective: To determine the clinical utility of therapeutic thoracic facet joint interventions in the therapeutic management of chronic upper back and mid back pain.

Methods: The available literature for the utility of facet joint interventions in the therapeutic management of thoracic facet joint pain was reviewed. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria as utilized for interventional techniques for randomized trials and the criteria developed by the Newcastle-Ottawa Scale criteria for observational studies.

The level of evidence was classified as good, fair, and limited (or poor) based on the quality of evidence developed by the U.S. Preventive Services Task Force (USPSTF).

Data sources included relevant literature identified through searches of PubMed and EMBASE from 1966 to March 2012, and manual searches of the bibliographies of known primary and review articles.

Outcome Measures: The primary outcome measure was pain relief (short-term relief = up to 6 months and long-term > 6 months). Secondary outcome measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake.

Results: For this systematic review, 13 studies were identified. Of these, 7 studies were excluded, and a total of 4 studies (after removal of duplicate publication) met inclusion criteria for methodological quality assessment with one randomized trial and 3 non-randomized studies.

The evidence is fair for therapeutic thoracic facet joint nerve blocks, limited for thoracic radiofrequency neurotomy, and not available for thoracic intraarticular injections.

Limitations: The limitation of this systematic review includes a paucity of literature. The only positive studies were of medial branch blocks performed by the same group of authors.

Conclusion: The evidence for therapeutic facet joint interventions is fair for medial branch blocks, whereas it is not available for intraarticular injections, and limited for radiofrequency neurotomy due to lack of literature.

Key words: Chronic thoracic pain, mid back or upper back pain, thoracic facet or zygapophysial joint pain, facet joint nerve blocks, medial branch blocks, therapeutic thoracic medial branch blocks, thoracic radiofrequency neurotomy, thoracic intraarticular facet joint injections.
While the lifetime prevalence of spinal pain has been reported as occurring in 54% to 80% of the general population, patients suffering from chronic upper or mid back pain secondary to thoracic disorders is relatively small, specifically in interventional pain management settings, where it ranges from a low of 3% to a high of 22% (1-13). Multiple authors have estimated thoracic pain to be less prevalent than low back or neck pain. In fact, Leboeuf-Yde et al (1) reported that low back pain in the past year was most frequent in 43% of patients, followed by neck pain in 32%, and mid back pain in 13%. Regardless of the area of the complaint; however, care seeking and reduced physical activities are common with thoracic pain, greatly affecting quality of life. The prevalence of mid back and upper back pain secondary to involvement of the facet joints has been reported in controlled studies in as many as 34% to 48% of patients (6,14-18). Since conventional clinical and radiologic techniques are unreliable in diagnosing facet or zygapophyseal joint pain (3,16-32), controlled local anesthetic blocks of thoracic facet joints or medial branch blocks are employed to diagnose facet joint pain, and are considered the most reliable means of diagnosis (3,10,16-18,32,33).

Medial branch blocks and radiofrequency neurotomy have been described in managing chronic mid back and upper back pain from thoracic facet joints (10,34-46). However, the evidence has been highly variable.

Previous systematic reviews have provided moderate evidence for therapeutic thoracic medial branch blocks (16-18), whereas evidence for radiofrequency neurotomy of thoracic facet joint nerves was indeterminate (16-18). Consequently, this systematic review has been undertaken in order to update and determine the effectiveness of thoracic facet joint interventions in the management of chronic mid back and upper back pain (16).

1.0 Methods

The methodology utilized in this systematic review followed the review process derived from evidence-based systematic reviews and meta-analysis of randomized trials and observational studies (3,47-56), Cochrane guidelines (52,53,57), Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct of randomized trials (58-61), Standards for Reporting Observational Studies (STROBE) (62), Chou and Huffman's guidelines (63,64), and quality of reporting of analysis (49).

1.1 Criteria for Considering Studies for This Review

1.1.1 Types of Studies

- Randomized controlled trials
- Non-randomized observational studies
- Case reports and reviews for adverse effects

1.1.2 Types of Participants

Participants of interest were adults aged at least 18 years with chronic upper and mid back pain of at least 3 months duration. Participants must have failed previous pharmacotherapy, exercise therapy, etc., prior to starting interventional pain management techniques.

1.1.3 Types of Interventions

The interventions were therapeutic thoracic facet joint blocks appropriately performed with proper techniques under fluoroscopic or computed tomography (CT) guidance.

1.1.4 Types of Outcome Measures

- The primary outcome parameter was pain relief.
- The secondary outcome measures were functional improvement; change in psychological status; return to work; reduction or elimination of opioid use, other drugs.
- At least 2 of the review authors independently, in an unblinded standardized manner, assessed the outcomes measures. Any disagreements between reviewers were resolved by a third author and consensus.

1.2 Literature Search

Searches were performed from the following sources without language restrictions:

1. PubMed from 1966
2. EMBASE from 1980
   www.embase.com/
3. Cochrane Library
   www.thecochranelibrary.com/view/0/index.html
   www.guideline.gov
5. Previous systematic reviews and cross references
6. Clinical Trials
   www.clinicaltrials.gov

The search period was from 1966 through March 2012.
1.3 Search Strategy
The search strategy emphasized chronic thoracic pain of facet joint origin with a focus on all types of therapeutic interventions. Search terminology included thoracic facet joint, thoracic facet joint pain, thoracic facet joint intraarticular injections, medial branch blocks, and radiofrequency neurotomy.

At least 2 of the review authors independently, in an unblinded standardized manner, performed each search. Accuracy was confirmed by a statistician. All searches were combined to obtain a unified search strategy. Any disagreements between reviewers were resolved by a third author and consensus.

1.4 Data Collection and Analysis
The review focused on randomized trials, observational studies, and reports of complications. The population of interest was patients suffering from chronic upper and mid back pain for at least 3 months. Only thoracic facet joint interventions were evaluated. All of the studies providing appropriate management, statistical evaluations and with outcome evaluations of one month or longer were reviewed. Reports without appropriate diagnosis, non-systematic reviews, book chapters, and case reports were excluded.

1.4.1 Selection of Studies
♦ In an unblinded standardized manner, 2 review authors screened the abstracts of all identified studies against the inclusion criteria.
♦ All articles with possible relevance were then retrieved in full text for a comprehensive assessment of internal validity, quality, and adherence to inclusion criteria.

1.4.2 Inclusion and Exclusion Criteria
Inclusion criteria were studies which documented the existence of thoracic spinal pain of facet joint origin using controlled diagnostic facet joint injections or medial branches. Three types of facet joint interventions were included in this review: intraarticular facet joint injections, medial branch blocks, and medial branch radiofrequency neurotomy. All studies must provide appropriate management with outcome evaluations of at least 6 months and appropriate statistical analysis.

Reports without appropriate diagnosis and elimination of false-positive responses, abstracts beyond 2 years, non-systematic reviews, book chapters, and case reports were excluded.

1.4.3 Clinical Relevance
The clinical relevance of the included studies were evaluated according to 5 questions recommended by the Cochrane Back Review Group (Table 1) (65). Each question was scored as positive (+) if the clinical relevance item was met, negative (–) if the item was not met, and unclear (?) if data were not available to answer the question.

1.4.4 Methodological Quality or Validity Assessment
The quality of each individual article used in this analysis was assessed by Cochrane review criteria (Table 2) (52) for randomized trials or the Newcastle-Ottawa Scale for observational studies (Tables 3 and 4) (66).

Each study was evaluated by at least 2 authors for stated criteria and any disagreements were discussed with a third reviewer. Authors with a perceived conflict of interest for any manuscript were recused from reviewing the manuscript.

For adverse effects, confounding factors, etc., it was not possible to use quality assessment criteria. Thus, these were considered based on interpretation of the reports published and critical analysis of the literature.

<table>
<thead>
<tr>
<th>Table 1. Clinical relevance questions.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>A) Are the patients described in detail so that one can decide whether they are comparable to those who are treated practice?</td>
</tr>
<tr>
<td>B) Are the interventions and treatment settings described in sufficient detail to apply its use in clinical practice?</td>
</tr>
<tr>
<td>C) Were clinically relevant outcomes measured and reported?</td>
</tr>
<tr>
<td>D) Is the size of the effect clinically meaningful?</td>
</tr>
<tr>
<td>E) Do the likely treatment benefits outweigh the potential harms?</td>
</tr>
</tbody>
</table>

### Table 2. Randomized controlled trials quality rating system.

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Description</th>
<th>Yes/No/Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1. Was the method of randomization adequate?</td>
<td>A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a die (for studies with 2 or more groups), drawing of balls of different colors, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelopes, sequentially ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments. Examples of inadequate methods are alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>B</td>
<td>2. Was the treatment allocation concealed?</td>
<td>Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>C</td>
<td>Was knowledge of the allocated interventions adequately prevented during the study?</td>
<td></td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>3. Was the patient blinded to the intervention?</td>
<td>This item should be scored “yes” if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>4. Was the care provider blinded to the intervention?</td>
<td>This item should be scored “yes” if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>5. Was the outcome assessor blinded to the intervention?</td>
<td>Adequacy of blinding should be assessed for the primary outcomes. This item should be scored “yes” if the success of blinding was tested among the outcome assessors and it was successful: – for patient-reported outcomes in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored “yes” – for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination – for outcome criteria that do not suppose a contact with participants (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome – for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item “4” (caregivers) is scored “yes” – for outcome criteria that are assessed from data of the medical forms: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>D</td>
<td>Were incomplete outcome data adequately addressed?</td>
<td>The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a “yes” is scored. (N.B. these percentages are arbitrary, not supported by literature).</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>6. Was the drop-out rate described and acceptable?</td>
<td></td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>7. Were all randomized participants analyzed in the group to which they were allocated?</td>
<td>All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td>E</td>
<td>8. Are reports of the study free of suggestion of selective outcome reporting?</td>
<td>In order to receive a “yes,” the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>Other sources of potential bias:</td>
<td></td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>9. Were the groups similar at baseline regarding the most important prognostic indicators?</td>
<td>In order to receive a “yes,” groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>10. Were co-interventions avoided or similar?</td>
<td>This item should be scored “yes” if there were no co-interventions or they were similar between the index and control groups.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>11. Was the compliance acceptable in all groups?</td>
<td>The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore, it is necessary to assess how many sessions each patient attended. For single-session interventions (e.g., surgery), this item is irrelevant.</td>
<td>Yes/No/Unsure</td>
</tr>
<tr>
<td></td>
<td>12. Was the timing of the outcome assessment similar in all groups?</td>
<td>Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.</td>
<td>Yes/No/Unsure</td>
</tr>
</tbody>
</table>

Only the randomized trials meeting the inclusion criteria with at least 6 of 12 criteria were utilized for analysis. However, studies scoring lower were described and provided with an opinion and critical analysis. Observational studies had to meet a minimum of 50% of the utilized criteria for cohort and case-control studies. Studies scoring less were also described and provided with an opinion and a critical analysis.
Table 4. *Newcastle-Ottawa quality assessment scale for cohort studies.*

<table>
<thead>
<tr>
<th>Selection</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Representativeness of the exposed cohort</td>
<td></td>
</tr>
<tr>
<td>a) truly representative of the average ________________ (describe) in the community *</td>
<td></td>
</tr>
<tr>
<td>b) somewhat representative of the average ______________ in the community *</td>
<td></td>
</tr>
<tr>
<td>c) selected group of users, e.g. nurses, volunteers</td>
<td></td>
</tr>
<tr>
<td>d) no description of the derivation of the cohort</td>
<td></td>
</tr>
<tr>
<td>2) Selection of the non exposed cohort</td>
<td></td>
</tr>
<tr>
<td>a) drawn from the same community as the exposed cohort *</td>
<td></td>
</tr>
<tr>
<td>b) drawn from a different source</td>
<td></td>
</tr>
<tr>
<td>c) no description of the derivation of the non exposed cohort</td>
<td></td>
</tr>
<tr>
<td>3) Ascertainment of exposure</td>
<td></td>
</tr>
<tr>
<td>a) secure record (e.g. surgical records) *</td>
<td></td>
</tr>
<tr>
<td>b) structured interview *</td>
<td></td>
</tr>
<tr>
<td>c) written self report</td>
<td></td>
</tr>
<tr>
<td>d) no description</td>
<td></td>
</tr>
<tr>
<td>4) Demonstration that outcome of interest was not present at start of study</td>
<td></td>
</tr>
<tr>
<td>a) yes *</td>
<td></td>
</tr>
<tr>
<td>b) no</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comparability</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Comparability of cohorts on the basis of the design or analysis</td>
<td></td>
</tr>
<tr>
<td>a) study controls for _____________ (select the most important factor) *</td>
<td></td>
</tr>
<tr>
<td>b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Assessment of outcome</td>
<td></td>
</tr>
<tr>
<td>a) independent blind assessment *</td>
<td></td>
</tr>
<tr>
<td>b) record linkage *</td>
<td></td>
</tr>
<tr>
<td>c) self report</td>
<td></td>
</tr>
<tr>
<td>d) no description</td>
<td></td>
</tr>
<tr>
<td>2) Was follow-up long enough for outcomes to occur</td>
<td></td>
</tr>
<tr>
<td>a) yes (select an adequate follow-up period for outcome of interest) *</td>
<td></td>
</tr>
<tr>
<td>b) no</td>
<td></td>
</tr>
<tr>
<td>3) Adequacy of follow-up of cohorts</td>
<td></td>
</tr>
<tr>
<td>a) complete follow-up - all subjects accounted for *</td>
<td></td>
</tr>
<tr>
<td>b) subjects lost to follow-up unlikely to introduce bias - small number lost - &gt; ____ % (select an adequate %) follow-up, or description provided of those lost) *</td>
<td></td>
</tr>
<tr>
<td>c) follow-up rate &lt; ____ % (select an adequate %) and no description of those lost</td>
<td></td>
</tr>
<tr>
<td>d) no statement</td>
<td></td>
</tr>
</tbody>
</table>

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

If the literature search provided at least 5 randomized trials meeting the inclusion criteria and if they were homogenous for each modality (intraarticular injections, medial branch blocks, and radiofrequency neurotomy) evaluated, a meta-analysis was performed.

**1.4.5 Data Extraction and Management**

Two review authors independently, in an unblinded standardized manner, extracted the data from the included studies. Disagreements were resolved by discussion between the 2 reviewers; if no consensus could be reached, a third author was called in to break the impasse.

**1.4.6 Assessment of Heterogeneity**

Whenever meta-analyses were conducted, the I-squared ($I^2$) statistic was used to identify heterogeneity (67). Combined results with $I^2 > 50\%$ were considered substantially heterogenous.

Analysis of the evidence was based on the modality of treatment provided (i.e., intraarticular injections, medial branch blocks, and radiofrequency neurotomy).

**1.4.7 Measurement of Treatment Effect in Data Synthesis (Meta-Analysis)**

Data was summarized using meta-analysis when at least 5 studies per type of treatment were available that met the inclusion criteria.

**1.5 Analysis of Evidence**

An analysis of the evidence was performed based on USPSTF criteria as illustrated in Table 5, criteria which has been utilized by multiple authors (68).

The analysis was conducted using 3 levels of evidence: good, fair, and limited (or poor).

At least 2 of the review authors independently, in an unblinded standardized manner, analyzed the evidence. Any disagreements between reviewers were resolved by a third author and consensus. If there were any conflicts of interest (e.g., authorship), those reviewers were recused from assessment and analysis.

**1.6 Outcome of the Studies**

In the randomized trials, a study was judged to be positive if the therapeutic thoracic facet joint intervention was clinically relevant and effective, either with a placebo control or active control. This indicates that the difference in effect for primary outcome measure is statistically significant at the conventional 5% level. In a negative study, no difference between the study treatments or no improvement from baseline is identified. Furthermore, the outcomes were judged at the reference point with positive or negative results reported at one month, 3 months, 6 months, and one year.

For observational studies, a study was judged to be positive if the intervention was effective, with outcomes reported at the reference point with positive or negative results at one month, 3 months, 6 months, and one year.

The minimum amount of change in a pain score in order to be clinically meaningful has been described as a 2-point change on a scale of 0 to 10 (or 20 percentage points), based on findings in commonly utilized trials studying general chronic pain (69), chronic musculoskeletal pain (70), and chronic low back pain (47,49,51,52,71,72). However, later descriptions of clinically meaningful improvement showed either pain relief or functional status as 50% (73-86). Consequently, for this analysis, we consider clinically meaningful pain relief of at least a 3-point change on an 11-point scale of 0 to 10, or 50% pain relief from the baseline, or a functional status improvement of 40% as being clinically significant.

**Table 5. Method for grading the overall strength of the evidence for an intervention.**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes (at least 2 consistent, higher-quality RCTs or studies of diagnostic test accuracy).</td>
</tr>
<tr>
<td>Fair</td>
<td>Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies; generalizability to routine practice; or indirect nature of the evidence on health outcomes (at least one higher-quality trial or study of diagnostic test accuracy of sufficient sample size; 2 or more higher-quality trials or studies of diagnostic test accuracy with some inconsistency; at least 2 consistent, lower-quality trials or studies of diagnostic test accuracy, or multiple consistent observational studies with no significant methodological flaws).</td>
</tr>
<tr>
<td>Limited or poor</td>
<td>Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality trials, important flaws in trial design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.</td>
</tr>
</tbody>
</table>

Adapted and modified from methods developed by U.S. Preventive Services Task Force (63,64,68).
2.0 Results

Figure 1 shows a flow diagram of study selection as recommended by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (50). There were 13 studies considered for inclusion (10,35-43,45,46,87).

Of the 13 studies (10,35-43,45,46,87) identified, 7 were excluded (35,40,41,43,45,46,87). Table 6 shows the reasons for exclusion. Among the included studies, there were 3 publications of one randomized trial (36,38,39), and 3 non-randomized studies (10,37,42).

Table 7 illustrates characteristics of studies considered for inclusion. There was one randomized trial evaluating long-term follow-up (39) with 2 duplicate publications (36,38), one non-randomized study for long-term follow-up (37) of therapeutic medial branch blocks, and 2 studies of thoracic radiofrequency neurotomy (10,42).
Table 6. List of excluded studies.

<table>
<thead>
<tr>
<th>Manuscript Author(s)</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tzaan &amp; Tasker (35)</td>
<td>This study showed results of percutaneous radiofrequency, facet rhizotomy, an experience with 118 procedures; however, the study included only 90 patients for cervical, lumbar, and thoracic regions. Thus, the number of patients treated in the thoracic region was only 17.</td>
</tr>
<tr>
<td>Stolker et al (40)</td>
<td>This was an anatomical study to verify if needle placement for thoracic percutaneous facet denervation, based on bony landmarks, and under fluoroscopic guidance would lead to constant anatomical positioning and adequate placement at the assumed target. The procedures were carried out in 2 cadavers at all 12 levels.</td>
</tr>
<tr>
<td>Stolker et al (41)</td>
<td>This study was undertaken to clarify if needle positioning in percutaneous partial rhizotomy in the thoracic area based on bony landmarks and guided by fluoroscopic control led to adequate placement in or at the target area of dorsal root ganglion in cadavers.</td>
</tr>
<tr>
<td>Chua et al (43)</td>
<td>This manuscript described mechanisms and potential indications of pulsed radiofrequency.</td>
</tr>
<tr>
<td>Golovac (45)</td>
<td>Review of radiofrequency neurolysis.</td>
</tr>
<tr>
<td>Haufe &amp; Mork (87)</td>
<td>Authors described endoscopic facet debridement of facet arthritic pain.</td>
</tr>
</tbody>
</table>

2.1 Clinical Relevance

Four studies were assessed for clinical relevance (Table 8). All studies met criteria with a score of 5 (10,37,39,42).

2.2 Methodological Quality Assessment

A methodological quality assessment of the randomized controlled trials meeting inclusion criteria was carried out utilizing Cochrane review criteria as shown in Table 9. Studies achieving Cochrane scores of 9 or higher were considered as high quality; scores of 6 to 8 were considered as moderate quality, and studies scoring less than 6 were excluded.

There was only one randomized trial (after combining duplicates) evaluating a long-term response of 6 months or longer (36,38,39) that was considered high quality.

A methodological quality assessment of observational studies meeting inclusion criteria was carried out utilizing Newcastle-Ottawa Scales as illustrated in Table 10. For cohort studies, studies achieving scores of 75% or higher were considered high quality; scores of 50% were considered as moderate quality; and studies scoring less than 50% were considered as low quality and were excluded.

There was only one non-randomized or observational study evaluating the long-term effectiveness of thoracic facet joint medial branch blocks with follow-up of 6 months or longer (37). This study was considered as being of moderate quality. There were 2 observational studies evaluating thoracic radiofrequency (10,42).

2.3 Meta-Analysis

There was only one trial for medial branch blocks, with none for intraarticular injections or radiofrequency neurotomy. Consequently, no meta-analysis was feasible.

2.4 Analysis of Evidence

The evidence was synthesized based on the specific condition for which the thoracic facet joint interventions were provided. Table 11 illustrates the results of thoracic facet joint interventions.

2.5 Summary of Evidence

In summary, the evidence is fair for medial branch blocks, whereas it is not available for intraarticular injections, and limited for radiofrequency neurotomy.

3.0 Discussion

This systematic review evaluating the effectiveness of therapeutic facet joint interventions with the inclusion of one double-blind randomized trial (36,38,39), 2 duplicate publications (36,38), and one observational report (37) of medial branch blocks provides fair evidence for medial branch blocks in managing chronic mid back or upper back pain. Two observational studies of radiofrequency neurotomy (10,42) provide limited evidence for radiofrequency neurotomy. There was no evidence to be reviewed for intraarticular injections. In addition, due to a paucity of evidence, non-randomized studies were also included with only 25 patients and without comparative groups. Even then, we were un-
Table 7. Study characteristics of published reports of therapeutic thoracic medial branch blocks and radiofrequency neurotomy.

<table>
<thead>
<tr>
<th>Study/Methods</th>
<th>Participants</th>
<th>Intervention(s)</th>
<th>Outcome(s)</th>
<th>Result(s)</th>
<th>Conclusion(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stolker et al, 1993 (10) Prospective outcome study</td>
<td>40 patients with thoracic pain were evaluated</td>
<td>Radiofrequency neurotomy</td>
<td>Pain relief with numeric rating scale</td>
<td>Forty patients underwent 51 percutaneous facet denervation sessions. Nine patients underwent more than one session, 7 patients 2 sessions, and 2 patients 3 sessions. The results per treatment based on a numeric rating scale were 84% of the patients reporting greater than 50% pain reduction, 36 patients were followed on a long-term basis. Of these, 23 patients responded with good or excellent results (64%).</td>
<td>Effectiveness of radiofrequency was demonstrated in this early study with positive short-term and long-term relief.</td>
</tr>
<tr>
<td>Manchikanti, et al, 2008, 2010,2012 (36,38,39) Randomized, double-blind, controlled trial</td>
<td>100 patients were included with 50 patients in each of the local anesthetic and steroid groups</td>
<td>Group I patients received thoracic medial branch blocks with bupivacaine. Group II patients received thoracic medial branch blocks with bupivacaine and non-particulate betamethasone.</td>
<td>Numeric pain scores, Oswestry Disability Index, opioid intake, and return to work status. All outcomes were assessed at baseline, 6 months, 12 months, and 24 mos. Significant pain relief was defined as &gt; 50% relief. Significant functional improvement was &gt; 40% reduction of Oswestry Disability Index.</td>
<td>In Group I, 80% of patients showed significant pain relief and functional improvement at 12 and 24 months. In Group II, 84% of patients showed significant pain relief and functional improvement at 12 months and 24 mos. The majority of patients experienced significant pain relief for 46 to 47 weeks, requiring approximately 3 to 4 treatments with an average relief of 14 to 16 weeks per episode of a treatment.</td>
<td>The majority of patients in both groups experienced significant pain relief and improvement in functional status. 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. Positive short-term and long-term relief.</td>
</tr>
<tr>
<td>Manchikanti et al, 2006 (37) Prospective outcome study</td>
<td>55 consecutive patients, all meeting diagnostic criteria for thoracic facet joint pain</td>
<td>Thoracic facet joint nerve blocks performed using bupivacaine with or without Sarapin and depomethylprednisolone</td>
<td>Measured numeric pain scores, Oswestry Disability Index, employment status, and Pain Patient Profile at 3, 6, 12, 24, and 36 months.</td>
<td>Significant (≥ 50%), was observed in 71% of the patients at 3 months and 6 months, 76% at 12 months, 71% at 24 months, and 69% at 36 months.</td>
<td>Therapeutic thoracic medial branch blocks were an effective modality of treatment in managing chronic thoracic pain secondary to facet joint involvement confirmed by controlled, comparative local anesthetic blocks. Positive short-term and long-term relief.</td>
</tr>
<tr>
<td>Speldewinde, 2011 (42) Prospective outcome evaluation</td>
<td>28 patients with thoracic pain as part of outcomes of percutaneous zygapophysial and sacroiliac joint neurotomy in a community setting with total of 379 patients included</td>
<td>Radiofrequency neurotomy</td>
<td>Numeric rating scale, functional rating index, activities of daily living scale, general health questionnaire, depression and anxiety scale, duration of pain relief.</td>
<td>Successful outcome defined as at least 50% reduction of pain, for at least 2 months, in the region relevant to the joint or joints treated was present in 68% of the patients in the thoracic region with radiofrequency neurotomy.</td>
<td>The results also showed 85% pain relief for 9 months in 18 of 28 patients (64%). Radiofrequency neurotomy of thoracic facet joint nerve may provide positive short-term and long-term relief.</td>
</tr>
</tbody>
</table>
able to assess any evidence for intraarticular injections. However, with medial branch blocks, both the studies (36–39), with 2 duplicate publications (36,38), meeting the inclusion criteria were performed by the same group of authors.

In this evaluation, a total of 4 studies meeting inclusion criteria were included (10,36,37,38,39,42), with 2 duplicate publications (36,38). Only one randomized trial was available which was of high quality (36,38,39), whereas the observational studies included for medial branch nerve blocks (37) and for radiofrequency neurotomy were of moderate quality (10,42). Consequently, the paucity of published reports describing the effectiveness of thoracic facet joint interventions for the treatment of chronic thoracic pain is the obvious shortcoming of this review. Even though thoracic facet joint pain is lower in incidence and prevalence than lumbar and cervical pain, the disability may be similar. The only one randomized trial to date (36,38,39) of medial branch blocks showed effectiveness for patients with chronic pain secondary to thoracic facet joint arthropathy. The results were also supported by an observational study which was published prior to the randomized trial. In reference to radiofrequency neurotomy there were multiple studies. Although, there have not been any randomized trials. Among the observational studies only 2 studies met inclusion criteria.

Multiple complications are similar to those of the cervical or lumbar region (88-99), these include bleeding, infection, and neural trauma. In the United States, facet joint interventions are one of the most commonly utilized modalities of treatments in managing chronic thoracic pain, similar to neck and low back pain (3,100-108). The facet joint interventions are administered by 3 approaches utilizing either intraarticular injection, medial branch block, or by performing radiofrequency neurotomy. Radiofrequency neurotomy may be performed with conventional heat radiofrequency, pulsed radiofrequency, or cooled radiofrequency.

Atluri et al (16) in a systematic review of the effectiveness of thoracic facet joint interventions discussed the effectiveness as well as complications arising from interventions, along with a paucity of the literature. They concluded that there was fair evidence supporting therapeutic medial branch nerve blocks. However, there was no significant evidence for radiofrequency

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**Table 8. Clinical relevance of included studies.**

<table>
<thead>
<tr>
<th>Manuscript Author(s)</th>
<th>A) Patient description</th>
<th>B) Description of interventions and treatment settings</th>
<th>C) Clinically relevant outcomes</th>
<th>D) Clinical importance</th>
<th>E) Benefits versus potential harms</th>
<th>Total Criteria Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stolker et al (10)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>5/5</td>
</tr>
<tr>
<td>Manchikanti, et al (36,38,39)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>5/5</td>
</tr>
<tr>
<td>Manchikanti, et al (37)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>5/5</td>
</tr>
<tr>
<td>Speldewinde (42)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>5/5</td>
</tr>
</tbody>
</table>

+ = positive; - = negative; U = unclear


**Table 9. Methodological quality assessment of randomized trials.**

<table>
<thead>
<tr>
<th>Manchikanti et al (36,38,39)</th>
<th>Randomization adequate</th>
<th>Concealed treatment allocation</th>
<th>Patient blinded</th>
<th>Care provider blinded</th>
<th>Outcome assessor blinded</th>
<th>Drop-out rate described</th>
<th>All randomized participants analyzed in the group</th>
<th>Reports of the study free of suggestion of selective outcome reporting</th>
<th>Groups similar at baseline regarding most important prognostic indicators</th>
<th>Co-interventions avoided or similar</th>
<th>Compliance acceptable in all groups</th>
<th>Time of outcome assessment in all groups similar</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>10/12</td>
</tr>
</tbody>
</table>

+ = positive; - = negative; U = unclear
Table 10. Methodologic quality assessment of cohort studies utilizing Newcastle-Ottawa quality assessment scale.

<table>
<thead>
<tr>
<th>Selection</th>
<th>Stolker et al (10)</th>
<th>Manchikanti et al (37)</th>
<th>Speldewinde (42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Representativeness of the exposed cohort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) truly representative of the average (describe) in the community *</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>b) somewhat representative of the average pain patients in the community</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) selected group of users (e.g. nurses, volunteers)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) no description of the derivation of the cohort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Selection of the non exposed cohort</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>a) drawn from the same community as the exposed cohort *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) drawn from a different source</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) no description of the derivation of the non exposed cohort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Ascertainment of exposure</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>a) secure record (e.g. surgical records) *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) structured interview *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) written self report</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) no description</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Demonstration that outcome of interest was not present at start of study</td>
<td>+</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) yes *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) no</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comparability

1) Comparability of cohorts on the basis of the design or analysis         
   a) study controls for (select the most important factor) *               
   b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)

Outcome (Exposure)

1) Assessment of outcome                                                   
   a) independent blind assessment *                                        
   b) record linkage *                                                     
   c) self report                                                          
   d) no description                                                       

2)Was follow-up long enough for outcomes to occur                          
   a) yes (select an adequate follow-up period for outcome of interest) *   
   b) no                                                                   

3) Adequacy of follow up of cohorts                                        
   a) complete follow-up - all subjects accounted for *                   
   b) subjects lost to follow-up unlikely to introduce bias - small number lost - > ___% (select an adequate %) follow-up, or description provided of those lost) * 
   c) follow-up rate < ___% (select an adequate %) and no description of those lost 
   d) no statement                                                        

| SCORE | 8/13 | 7/13 | 7/13 |

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

neurotomy, as in past reviews, and there was no literature available for intraarticular injections. In reference to therapeutic medial branch blocks, there was no difference noted between local anesthetic alone compared to local anesthetic with steroids.

The present systematic review shows that therapeutic medial branch blocks, when appropriately performed, should result in significant improvement with or without steroids. There is also emerging evidence for conventional radiofrequency neurotomy of medial branches. With the majority of interventional techniques, as with thoracic facet joint interventions, a common problem encountered is the lack of studies with placebo control. However, placebo controlled neural blockade is not realistic and has been misinterpreted (109). As a result, many authors have reported that any local anesthetic injection that yields a result similar to that of steroids is considered a placebo, though inappropriately and inaccurately. The experimental and clinical findings from investigations of the electrophysiological effects of 0.9% sodium chloride and dextrose 5% in water solution have illustrated a potential inaccuracy created by 0.9% sodium chloride solution versus 5% dextrose (110,111). In addition to this, the evidence also shows that sodium chloride solution when injected into either the disc, the facet joint, or paraspinal muscles, exerts differing effects with interactions between the porcine lumbar intervertebral disc, zygapophysial joints, and paraspinal muscles (112,113). They also showed that the introduction of lidocaine or physiologic saline into the zygapophysial joint reduces the stimulation pathway from the intervertebral disc or paraspinal muscle activation.
caused by nerve stimulation in the annulus fibrosis of a lumbar intervertebral disc could be altered by saline injections into the zygapophysial joints. In addition, intraarticular facet joint sodium chloride injections along with epidural sodium chloride injections have exerted active and therapeutic effects (114-117). Furthermore, for the placebo effect to be evident, it has to be non-existent with prior treatments and present progressively with repeat treatments. It also has been illustrated that there was no significant difference in therapeutic effect whether or not steroids were utilized (118-120). Finally, the placebo effects, along with various considerations of placebo and nocebo effects, have not been appropriately evaluated in performing interventional techniques (121-128). However, in a manuscript by Ghahreman et al (129), they describe how appropriate results were obtained utilizing a proper placebo-sodium chloride solution by injection into the inactive tissue.

The underlying mechanism of action of steroid and local anesthetic injections is still not well understood. It is believed that the achieved neural blockade alters or interrupts nociceptive input, the reflex mechanism of the afferent fibers, self-sustaining activity of the neurons, and the pattern of central neuronal activities (3,130). Corticosteroids have been shown to reduce inflammation by inhibiting either the synthesis or release of a number of proinflammatory mediators and by causing a reversible local anesthetic effect (130-135). Similarly, local anesthetics also have been described to provide short- to long-term symptomatic relief based on the alteration of various mechanisms including excess nociceptive process, excess release of neurotransmitters, nociceptive sensitization of the nervous system, and phenotype changes (120,130,136-141). The prolonged effect of local anesthetics in facet joint nerve blocks and epidural injections has been demonstrated in multiple studies (3,6,14,15,25,29,31,34,36-39,73,75-86). Sato et al (120) evaluated the prolonged analgesic effect of epidural bupivacaine in a rat model of neuropathic pain with repeated administration, possibly by inducing a plastic change in nociceptive input. Furthermore, Tachihara et al (118) demonstrated that nerve root infiltration in a rat prevented mechanical allodynia, even though no additional benefit from using corticosteroids was observed.

In recent years, multiple manuscripts have been published in reference to evidence, preferences, and recommendations with the intent of finding the right balance in patient care (142-144). The literature has been replete with manuscripts in reference to randomization, evidence-based medicine requiring medicine-based evidence, and the necessity of integrating clinical research with medical practice. These evaluations and the recent flurry of criticism of evidence-based guidelines (145,146) illustrate the difficulties associated with providing practical recommendations based on evidence dependent only on randomized trials. Thus this systematic review incorporates not only the observational studies, but also emerging evidence derived from these observational studies apart from randomized trials. Furthermore, even among the randomized trials only active-control trials have been available due to the extreme difficulty in designing an appropriate randomized trial with proper sample size and utilizing appropriate outcome parameters.

The results of this systematic review may be applied in interventional pain management practices. For this systematic review, only placebo-active control trials and observational studies in practical settings were included. Active-control or practical clinical trials measure effectiveness, and may better reflect how a treatment will fair in clinical practice than placebo-control studies evaluating efficacy, which frequently have poor generalizability (73-86,147-151). The differences between placebo-control trials and active-control trials include the fact that whereas placebo-control trials measure an absolute effect size, active-control trials compare different therapies (152).

Even though the study is limited by the inclusion of only one randomized trial and 3 clinically relevant observational studies meeting inclusion criteria, radiofrequency observational studies add to the small sample sizes with perceived variations in methodology, selection criteria, outcome measures, and technique. Even then, the results of this systematic review suggest that significant improvements in pain scores and functional status can be obtained with medial branch blocks with or without steroids with fair evidence and with the radiofrequency neurotomy illustrating only limited evidence.

### 4.0 Conclusion

Based on the results of this systematic review, there is fair evidence for therapeutic medial branch blocks, with a lack of available evidence for intraarticular injections, and limited evidence for radiofrequency neurotomy.
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