

Systematic Reviews

A Systematic Evaluation of the Therapeutic Effectiveness of Sacroiliac Joint Interventions

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Background: The contribution of the sacroiliac joint to low back and lower extremity pain has been a subject of debate with extensive research. It is generally accepted that approximately 10% to 25% of patients with persistent low back pain may have pain arising from the sacroiliac joints. In spite of this, there are currently no definite conservative, interventional, or surgical management options for managing sacroiliac joint pain. In addition, there continue to be significant variations in the application of various techniques as well as a paucity of literature.

Study Design: A systematic review of therapeutic sacroiliac joint interventions.

Objective: To evaluate the accuracy of therapeutic sacroiliac joint interventions.

Methods: The available literature on therapeutic sacroiliac joint interventions in managing chronic low back and lower extremity pain was reviewed. The quality assessment and clinical relevance criteria utilized were the Cochrane Musculoskeletal Review Group criteria for randomized trials of interventional techniques and the criteria developed by the Newcastle-Ottawa Scale for observational studies.

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

Data sources included relevant literature published from 1966 through December 2011 that was identified through searches of PubMed and EMBASE, 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, 56 studies were considered for inclusion. Of these, 45 studies were excluded and a total of 11 studies met inclusion criteria for methodological quality assessment with 6 randomized trials and 5 non-randomized studies.

The evidence for cooled radiofrequency neurotomy in managing sacroiliac joint pain is fair.

The evidence for effectiveness of intraarticular steroid injections is limited (or poor).

The evidence for periarticular injections of local anesthetic and steroid or botulinum toxin is limited (or poor).

The evidence for effectiveness of conventional radiofrequency neurotomy is limited (or poor).

The evidence for pulsed radiofrequency is limited (or poor).

Limitations: The limitations of this systematic review include a paucity of literature on therapeutic interventions, variations in technique, and variable diagnostic standards for sacroiliac joint pain.

Conclusions: The evidence was fair in favor of cooled radiofrequency neurotomy and limited (or poor) for short-term and long-term relief from intraarticular steroid injections, periarticular injections with steroids or botulin toxin, pulsed radiofrequency, and conventional radiofrequency neurotomy.

Key words: Chronic low back pain, sacroiliac joint pain, sacroiliitis, sacroiliac joint injection, sacroiliac joint dysfunction, thermal radiofrequency, pulsed radiofrequency

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The high prevalence of persistent low back pain, the growing number of diagnostic and therapeutic modalities employed to manage back pain, and its societal and economic impact continue to influence health care policy (1-33). Although low back pain is a common complaint in both primary and tertiary care settings, it is often difficult to reach a definitive diagnosis and provide appropriate treatment (2,32-49). Along with muscles, ligaments and nerve roots, the intervertebral discs, facet joints, and sacroiliac joints have all been established, utilizing controlled diagnostic studies (2,32-42), as potential sources of low back pain. Based on systematic reviews (32,33,38,45) and diagnostic accuracy studies (2,32-36,38,45) the prevalence of sacroiliac joint pain ranges between 10% and 25% with strict selection criteria (33,35,36,50-64). One recent review (33) found only moderate evidence for provocation maneuvers, though these tests are frequently used to select patients for diagnostic injections (50,54,57,59,61-68).

There has been an exponential growth in treatment modalities aimed at managing the pain of sacroiliac joint origin. There are many obstacles that arise when evaluating therapeutic sacroiliac joint modalities, including ambiguity and variability in diagnosis, and the fact that many studies evaluated only patients with inflammatory sacroiliitis, whereas these patients account for only a small percentage of cases, and rarely present in interventional pain management settings. Reviews evaluating therapeutic sacroiliac joint pain modalities have resulted in vastly disparate conclusions, reflective of ongoing debate and controversy in the medical community (2,32,33,43,49,69-73).

The sacroiliac joint is most commonly classified as a true diarthrodial joint with matching articular surfaces separated by a joint space containing synovial fluid enveloped by a fibrous capsule, even though it possesses unique characteristics not typically found in other diarthrodial joints (74-79). The sacroiliac joint is characterized by discontinuity of the posterior capsule with the presence of many ridges and depressions that minimize movement and enhance stability (47). It contains fibrocartilage in addition to hyaline cartilage (80). Whereas anteriorly the sacroiliac joint bears characteristics of a true synovial joint, in the posterior part it is more accurately categorized as a syndesmosis, consisting of a myriad of ligaments and muscles, including the piriformis and gluteus medius and minimus (72). The sacroiliac joint appears to be well-innervated, though studies evaluating the nerve supply have been sparse and have

yielded variable findings. The anterior portion may be innervated by the sacral plexus, whereas the posterior portion may derive innervation from the spinal nerves. Many experts cite the predominant innervation to arise from the L4 to S1 nerve roots, with some contribution from the superior gluteal nerve (81,82). Others contend that the joint is innervated only by the sacral dorsal rami (83,84). Dissections of fetal pelvises suggest that the innervation of the sacroiliac joint originates in the dorsal rami because neural filaments have been noted only in the dorsal mesenchyma (84,85). In rats, it has been observed that the sacroiliac joint is innervated by sensory neurons ipsilateral to the joint from L1 to S1, along with fibers from the L1 and L2 dorsal root ganglia that pass through the paravertebral sympathetic trunk (86). Histological analysis of chronically painful sacroiliac joints has verified the presence of nerve fibers within the joint capsule and adjoining ligaments (84,87,88). These fibers consist of both myelinated and unmyelinated neurons, mechanoreceptors, calcitonin gene-related peptide (CGRP), and substance P immunoreactive fibers (88-92).

Extensive communication exists between the sacroiliac joint and adjacent neural structures (47). Patterns of extra-capsular extravasation from the sacroiliac joint have also been observed on post-arthrography computed tomography (CT) (93). These extravasations include posterior extension into the dorsal sacral foramina, the L5 epidural sheath via the superior recess, and ventral leakage into the lumbosacral plexus, with the potential for creating a clinical picture that is difficult to distinguish from other ailments. Following capsular distension, the leakage of inflammatory mediators from the sacroiliac joint into the nearby neural structures has the potential to cause radicular pain in certain patients (88,93). Several mechanisms of injury may be linked to the development of sacroiliac joint pain including falls, motor vehicle accidents, and stepping into an unexpected hole or depression from a miscalculated height (74,94). In an evaluation of 54 patients with suspected sacroiliac joint pain, Chou et al (95) found that 44% experienced a traumatic incited event, 21% reported a cumulative injury, and 35% had either spontaneous or idiopathic onset of pain. Other causes may include degeneration of the sacroiliac joint following fusion surgery (55,70,96,97), anterior dislocation (98), inflammatory and degenerative etiologies (99), and multiple other causes (42-44,46,52,53,100-102).

Sacroiliac joint pain may be managed with intraarticular injections, extraarticular injections, or neurolysis of the nerve supply. However, 3 previous system-

atic reviews (32,103,104) found the evidence supporting therapeutic sacroiliac joint interventions to be limited. An evaluation of the literature through 2002 revealed that European guidelines for the management of chronic non-specific low back pain (105) also concluded that there was limited evidence supporting sacroiliac joint injections with corticosteroids. In contrast to the above Vanelderren et al (72) in an evidence-based evaluation of sacroiliac joint pain provided evidence that intraarticular sacroiliac joint infiltration with local anesthetic and corticosteroids with highest evidence rating of 1B+ (one RCT or more RCTs with methodologic weakness, demonstrate effectiveness, with the benefits clearly outweighing risks and burdens), cooled radiofrequency treatment of the lateral branches of S1 to S4 as 2B+ (one or more RCTs with methodologic weaknesses, demonstrate effectiveness with the benefits closely balanced with risk and burdens). Even though this manuscript provides an evidence-based recommendation, the assessment of evidence was without methodologic quality assessment and the authors also included the studies of spondyloarthropathy. Spondyloarthropathy is not generally managed in interventional pain management settings and is an issue for rheumatologists. Despite, however, the absence of any clear consensus in favor of sacroiliac joint interventions, their use has continued to grow in recent years resulting in multiple, at times indiscriminate, regulations and denial of access (14,20,22-24,106-108). Recent emerging evidence and improving diagnostic capabilities may change these evidence levels.

The purpose of this review is to systematically assess and update the literature of therapeutic sacroiliac joint interventions.

1.0 METHODS

The methodology utilized in this systematic review followed the review process derived from evidence-based systematic reviews and meta-analyses of randomized trials and observational studies (2,18,109-117), Consolidated Standards of Reporting Trials (CONSORT) guidelines for the conduct of randomized trials (118-121), Standards for Reporting Observational Studies (STROBE) (122-124), Cochrane guidelines (18,113,114), and Chou and Huffman's guidelines (20).

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 low back and/or lower extremity 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 sacroiliac joint injections appropriately performed with proper technique under fluoroscopic or 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, or other interventions; and complications.
- 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
www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. EMBASE from 1980
www.embase.com/
3. Cochrane Library
www.thecochranelibrary.com/view/0/index.html
4. U.S. National Guideline Clearinghouse (NGC)
www.guideline.gov/
5. Previous systematic reviews and cross references
6. Clinical Trials
clinicaltrials.gov/

The search period was from 1966 through December 2011.

1.3 Search Strategy

The search strategy emphasized chronic low back pain, sacroiliac joint pain/arthritis, and therapeutic sacroiliac joint interventions and techniques.

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 with chronic low back and/or lower extremity pain for at least 3 months. All types of sacroiliac joint interventions were evaluated. All of the studies providing appropriate management and reporting outcome evaluations of one month or longer with statistical evaluations were reviewed. Reports without appropriate diagnosis, non-systematic reviews, book chapters, and case reports were excluded. The studies of spondyloarthropathy and any studies performed without imaging or imaging other than fluoroscopy, CT, or magnetic resonance imaging (MRI) (i.e. ultrasound) were not assessed.

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 comprehensive assessment of internal validity, quality, and adherence to inclusion criteria.

1.4.2 Inclusion and Exclusion Criteria

The following are the inclusion and exclusion criteria utilized:

1. Are the patients described in sufficient detail to allow one to decide whether they are comparable to those that are seen in interventional pain management clinical practices?

- A. Setting – office, hospital, outpatient, inpatient
 - B. Physician – interventional pain physician, general physician, anesthesiologist, physiatrist, neurologist, rheumatologist, orthopedic surgeon, neurosurgeon, etc.
 - C. Patient characteristics - duration of pain
 - D. Non-interventional techniques or surgical intervention in the past
2. Is the intervention described in sufficient detail to enable one to apply its use to patients in interventional pain management settings?
 - A. Nature of intervention
 - B. Frequency of intervention
 - C. Duration of intervention
 3. Were clinically relevant outcomes measured?
 - A. Proportion of pain relief
 - B. Disorder/specific disability
 - C. Functional improvement
 - D. Allocation of eligible and non-eligible patients to return to work
 - E. Ability to work

1.4.3 Clinical Relevance

The clinical relevance of the included studies was evaluated according to 5 questions recommended by the Cochrane Back Review Group (Table 1) (112,125). 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

Even though none of these instruments or criteria have been systematically validated, the advantages and disadvantages of each system were debated.

The methodological quality assessment was performed by 2 review authors who independently assessed, in an unblinded, standardized manner, the in-

Table 1. *Clinical relevance questions.*

	P (+)	N (-)	U (unclear)
A) Are the patients described in detail so that one can decide whether they are comparable to those who are treated practice?			
B) Are the interventions and treatment settings described in sufficient detail to apply its use in clinical practice?			
C) Were clinically relevant outcomes measured and reported?			
D) Is the size of the effect clinically meaningful?			
E) Do the likely treatment benefits outweigh the potential harms?			

Scoring adapted and modified from Staal JB, et al. Injection therapy for subacute and chronic low-back pain. *Cochrane Database Syst Rev* 2008; 3:CD001824 (125).

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ternal validity of all the studies. Any discrepancies were evaluated by a third reviewer and settled by consensus.

The quality of each individual article used in this analysis was assessed by Cochrane review criteria (Table 2) (113) for randomized trials, and Newcastle-Ottawa

Scale for observational studies (Tables 3 and 4) (126). For nonrandomized observational studies, the patient population should have had at least 50 total or at least 25 in each group if they were comparison groups.

Authors with a perceived conflict of interest for

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

A	1. Was the method of randomization adequate?	A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with 2 groups), rolling a dice (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.	Yes/No/Unsure
B	2. Was the treatment allocation concealed?	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.	Yes/No/Unsure
C	Was knowledge of the allocated interventions adequately prevented during the study?		
	3. Was the patient blinded to the intervention?	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.	Yes/No/Unsure
	4. Was the care provider blinded to the intervention?	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.	Yes/No/Unsure
	5. Was the outcome assessor blinded to the intervention?	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 or: –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.	Yes/No/Unsure
D	Were incomplete outcome data adequately addressed?		
	6. Was the drop-out rate described and acceptable?	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.	Yes/No/Unsure
	7. Were all randomized participants analyzed in the group to which they were allocated?	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.	Yes/No/Unsure
E	8. Are reports of the study free of suggestion of selective outcome reporting?	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.	Yes/No/Unsure
F	Other sources of potential bias:		
	9. Were the groups similar at baseline regarding the most important prognostic indicators?	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).	Yes/No/Unsure

Table 2 (cont.). *Randomized controlled trials quality rating system.*

10. Were co-interventions avoided or similar?	This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.	Yes/No/Unsure
11. Was the compliance acceptable in all groups?	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.	Yes/No/Unsure
12. Was the timing of the outcome assessment similar in all groups?	Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.	Yes/No/Unsure

Adapted and Modified: Furlan AD, Pennick V, Bombardier C, van Tulder M; Editorial Board, Cochrane Back Review Group. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. *Spine (Phila Pa 1976)* 2009; 34:1929-1941 (113)

Table 3. *Newcastle-Ottawa quality assessment scale: Case control studies.*

Selection
1) Is the case definition adequate? a) yes, with independent validation* b) yes, e.g. record linkage or based on self reports c) no description
2) Representativeness of the cases a) consecutive or obviously representative series of cases * b) potential for selection biases or not stated
3) Selection of Controls a) community controls * b) hospital controls c) no description
4) Definition of Controls a) no history of disease (endpoint) * b) no description of source
Comparability
1) Comparability of cases and controls 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.)
Exposure
1) Ascertainment of exposure a) secure record (e.g. surgical records) * b) structured interview where blind to case/control status * c) interview not blinded to case/control status d) written self report or medical record only e) no description
2) Same method of ascertainment for cases and controls a) yes * b) no
3) Non-Response rate a) same rate for both groups * b) non respondents described c) rate different and no designation

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

Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (126).

Table 4. *Newcastle-Ottawa quality assessment scale for cohort studies.*

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

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.

Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of non-randomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (126).

any manuscript were recused from reviewing the manuscript.

It was not possible to use quality assessment criteria for adverse effects, confounding factors, etc. These deviations were considered based on the interpretation of published reports, and a critical analysis of the literature.

Randomized trials meeting at least 6 of 12 inclusion criteria were utilized for analysis. A description of the study, an opinion and a critical analysis were provided for studies scoring lower.

Observational studies had to meet a minimum of 50% of the utilized criteria for cohort studies and case-control studies. Studies scoring less were also described, with an opinion and a critical analysis.

If the literature search provided at least 5 randomized trials meeting the inclusion criteria and they were homogenous for each modality evaluated (intraarticular injections, extraarticular injections, lateral branch nerve blocks, conventional radiofrequency neurotomy, cooled radiofrequency neurotomy, and pulsed radiofrequency), 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 (I²) statistic was used to identify heterogeneity (127). Combined results with I² > 50% were considered substantially heterogenous.

Analysis of the evidence was based on the modality (i.e., intraarticular injections, extraarticular injections, lateral branch nerve blocks, conventional radiofrequency neurotomy, or pulsed radiofrequency) to reduce any clinical heterogeneity.

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

Data were summarized using meta-analysis when at least 5 studies per type of modality were available that met the inclusion criteria, such as for intraarticular injections, extraarticular injections, lateral branch nerve blocks, conventional radiofrequency neurotomy, and pulsed radiofrequency.

Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. Random-effects meta-analysis to pool data was also used (128).

The minimum amount of change in pain score 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 trials studying general chronic pain

(129), chronic musculoskeletal pain (130), and chronic low back pain (110-112,115,131,132). However, recent studies evaluating interventional techniques have used $\geq 50\%$ pain relief as the cutoff threshold for clinically meaningful improvement in pain relief or functional status (133-146). For this analysis, we defined clinically meaningful pain relief as at least a 3-point change on an 11-point scale of 0 to 10, and clinically significant functional improvement as $\geq 40\%$ using a validated instrument.

1.4.8 Integration of Heterogeneity

The evidence was assessed separately by administration of each modality. A meta-analysis was performed only if there were at least 5 studies meeting inclusion criteria for each variable.

1.5 Summary Measures

Summary measures included 50% or more reduction of pain in at least 40% of the patients, or at least a 3-point decrease in pain scores, and a relative risk of adverse events including side effects.

1.6 Analysis of Evidence

The analysis of the evidence was performed based on United States Preventive Services Task Force (USPSTF) criteria as illustrated in Table 5. These criteria have been utilized by multiple authors (146).

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

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

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

Grade	Definition
Good	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).
Fair	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).
Limited or Poor	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.

Adapted and modified from methods developed by US Preventive Services Task Force (20,146).

1.7 Outcome of the Studies

In the randomized trials, a study was judged to be positive if the sacroiliac joint intervention was clinically relevant and effective, either against a placebo or an active control. This indicates that the difference in effect for a primary outcome measure is statistically significant on the conventional 5% level. In a negative study, no significant difference between the treatment groups or no improvement from baseline could be identified. Outcomes were judged at distinct reference points 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 sacroiliac joint intervention was effective, with outcomes reported at one month, 3 months, 6 months, and one year. Observational studies were only included in the evidence synthesis if there were less than 5 randomized trials per modality meeting inclusion criteria.

2.0 RESULTS

Figure 1 shows a flow diagram of the study selection of therapeutic intervention trials and studies. There were 56 studies ultimately considered for inclu-

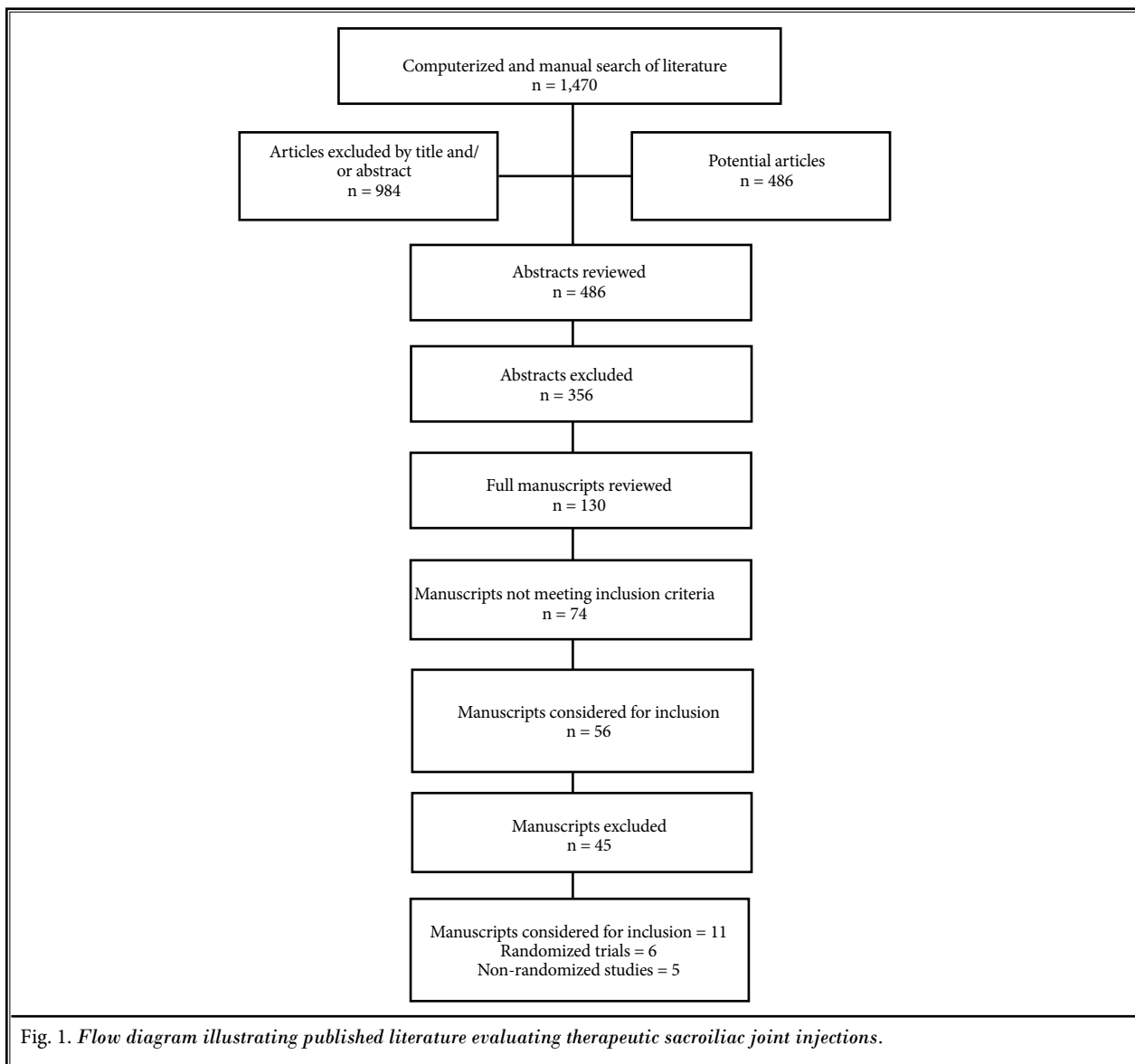


Fig. 1. Flow diagram illustrating published literature evaluating therapeutic sacroiliac joint injections.

sion (63,97,99,147-199). Seven studies were excluded based on the use of ultrasound (182,186-191). As illustrated in Table 6, 38 other reports were excluded for a variety of reasons.

Table 6. Description of studies excluded from methodological quality assessment.

Manuscript Author(s)	Reason for Exclusion
Standford & Burnham (63)	This study evaluated whether it was useful to repeat sacroiliac joint provocative tests post-block in 34 patients.
Amoretti et al (97)	This manuscript described computed axial tomography-guided fixation of sacroiliac joint disruption.
O'Shea et al (99)	No therapeutic techniques were applied.
Maugars et al(147)	The study evaluated effectiveness of corticosteroid injections of the sacroiliac joint in patients with zero negative spondyloarthropathy.
Maugars et al(148)	The study assessed the efficacy of sacroiliac joint corticosteroid injections in spondyloarthropathies in a randomized, double-blind design.
Muhlner (149)	This is a review article describing radiofrequency neurotomy for the treatment of sacroiliac joint syndrome.
Speldewinde (150)	This manuscript evaluated sacroiliac joint neurotomy. They evaluated 4 total cohorts with a total of 40 patients and there were only 20 patients in the 2 cohorts. When they combined both of the cohorts there were only 10 patients in the 2 cohorts, even though they have reported success rate in 80% of the population.
Kennedy et al (152)	This was a review article evaluating sacroiliac and lumbar zygapophyseal joint corticosteroid injections without original data.
Ferrante et al (153)	Authors studied 33 patients who underwent 50 intraarticular sacroiliac joint radiofrequency denervation procedures.
Dussault et al (154)	This was a retrospective study evaluating fluoroscopically guided sacroiliac joint injections.
Buijs et al (155)	Authors evaluated 43 patients in an observational study comparing radiofrequency at the first 3 sacral dorsal rami, described as a minimal approach, to L4-S3 radiofrequency denervation.
Buchowski et al (156)	Authors evaluated functional and radiographic outcomes of sacroiliac arthrodesis in 20 patients. Diagnoses were made using intraarticular sacroiliac joint injections under fluoroscopic guidance.
Burnham & Yasui (158)	Authors evaluated an alternate method of radiofrequency neurotomy (bipolar lateral branch denervation) of the sacroiliac joint in a pilot study of 9 subjects.
Al Khayer et al (161)	Authors described percutaneous sacroiliac joint arthrodesis in 9 patients after diagnosing them with sacroiliac joint blocks.
Chakraverty & Dias (164)	This was a retrospective audit evaluating multiple interventions for facet and sacroiliac joint pain, including 33 patients who underwent intraarticular sacroiliac joint injections and 19 patients who underwent sacroiliac ligament prolotherapy.
Sadreddini et al (165)	This study evaluated non-image-guided sacroiliac joint injections.
Stone & Bartynski (166)	Review article describing the treatment of facet and sacroiliac joint arthropathy with steroid injections and radiofrequency ablation.
Fritz et al (167)	This study evaluated MRI-guided steroid injections of the sacroiliac joints in children with refractory enthesitis-related arthritis.
Gupta (168)	Described an alternative method using a double needle technique for performing difficult sacroiliac joint injections.
Aydin et al (169)	Authors performed a meta-analysis of the role of radiofrequency ablation for sacroiliac joint pain.
Dreyfuss et al (171)	Evaluated the ability of single site, single depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex.
Dreyfuss et al (172)	Evaluated the ability of multi-site, multi-depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex.
Kapural et al (173)	This study evaluated the records of 27 patients with sacroiliac joint pain who underwent cooled radiofrequency denervation of L5-S3.
Buijs et al (174)	Small case series describing 3 cases of sacroiliac joint pain misdiagnosed as sciatica.
Cohen & Abdi (175)	The study evaluated lateral branch radiofrequency denervation as a treatment for sacroiliac joint pain in 18 patients.
Tullberg et al (176)	This study described the role of manipulation for sacroiliac joint dysfunction.
Hart et al (180)	Described short-term follow-up of sacroiliac joint steroid injections after spinal fusion.

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Table 6 (cont). *Description of studies excluded from methodological quality assessment.*

Manuscript Author(s)	Reason for Exclusion
Günaydin et al (183)	Small observational study evaluating MRI-guided sacroiliac joint injections for spondyloarthropathy.
Rosenberg et al (184)	Double-blind study evaluating the accuracy of non-image guided sacroiliac joint injections.
Hansen (185)	Authors describe the importance of fluoroscopy in performing sacroiliac joint injections.
Wong et al (192)	Report of an outbreak of infection after interventional pain management procedures in New York City.
Datta et al (193)	Letter to the editor in reference to sacroiliac joint injections.
Slipman et al (194)	Retrospective evaluation of therapeutic sacroiliac joint injections in 31 patients.
Yin et al (195)	Retrospective evaluation of sensory stimulation-guided sacroiliac joint radiofrequency neurotomy.
Karaman et al (196)	The study evaluated the effectiveness of cooled radiofrequency in a total of 15 patients in a non-randomized observational study.
Murakami et al (197)	Authors in this novel study evaluated the role of periarticular and intraarticular lidocaine injections for sacroiliac joint pain in a prospective comparative study with 25 patients in each group; however, the follow-up was only 5 minutes. There was no follow-up data beyond 5 minutes available.
Braun et al (198)	This was an evaluation of 30 patients with ankylosing spondylitis or undifferentiated spondyloarthropathy with sacroiliitis.
Bollow et al(199)	The authors in this report studied CT-guided intraarticular corticosteroid injections into the sacroiliac joints in patients with spondyloarthropathy and described indication and follow-up with contrast enhanced MRI.

Table 7. *Clinical relevance of included studies.*

Manuscript Author(s)	A) Patient description	B) Description of interventions and treatment settings	C) Clinically relevant outcomes	D) Clinical importance	E) Benefits versus potential harms	Total Criteria Met
Hawkins & Schofferman (151)	+	+	+	+	+	5/5
Vallejo et al (157)	+	+	+	+	+	5/5
Cohen et al (159)	+	+	+	+	+	5/5
Patel et al (160)	+	+	+	+	+	5/5
Liliang et al (162)	+	+	+	+	+	5/5
Luukkainen et al (163)	+	+	+	+	+	5/5
Cohen et al (170)	+	+	+	+	+	5/5
Kim et al (177)	+	+	+	+	+	5/5
Lee et al (178)	+	+	+	+	+	5/5
Borowsky & Fagen (179)	+	+	+	+	+	5/5
Luukkainen et al (181)	+	+	+	+	+	5/5

+ = positive; - = negative

Scoring adapted and modified from Staal JB, et al. Nelemans P. Injection therapy for subacute and chronic low-back pain. *Cochrane Database Syst Rev* 2008; 3:CD001824 (125).

2.1 Clinical Relevance

Of the 11 studies assessed for clinical relevance, all of them met criteria with scores of 5 out of 5 (151,157,159,160,162,163,170,177-179,181). Table 7 illustrates the assessment of clinical relevance.

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 8. All 6 trials (159,160,163,177,178,181) were

Table 8. Methodological quality assessment of randomized trials.

	Cohen et al (159)	Patel et al (160)	Luukkainen et al (163)	Kim et al (177)	Lee et al (178)	Luukkainen et al (181)
Randomization adequate	Y	Y	Y	Y	Y	Y
Concealed treatment allocation	Y	Y	Y	Y	Y	Y
Patient blinded	Y	Y	Y	Y	Y	Y
Care provider blinded	N	N	N	N	Y	N
Outcome assessor blinded	Y	Y	Y	Y	Y	Y
Drop-out rate described	Y	Y	Y	Y	Y	Y
All randomized participants analyzed in the group	Y	Y	Y	Y	Y	Y
Reports of the study free of suggestion of selective outcome reporting	Y	Y	Y	Y	Y	Y
Groups similar at baseline regarding most important prognostic indicators	Y	Y	Y	Y	Y	Y
Co-interventions avoided or similar	Y	Y	Y	Y	Y	Y
Compliance acceptable in all groups	Y	Y	Y	Y	Y	Y
Time of outcome assessment in all groups similar	Y	Y	Y	Y	Y	Y
SCORE	11/12	11/12	11/12	11/12	12/12	11/12

Y=yes; N=no; U=undecided

considered high quality based on Cochrane scores of 9 or higher.

A methodological quality assessment of the observational studies meeting inclusion criteria was carried out utilizing Newcastle-Ottawa Scales as illustrated in Tables 9 and 10. For cohort studies, studies achieving scores of 10 or higher were considered high quality; 7 to 9 were considered moderate quality; studies scoring less than 7 were considered low quality and were excluded.

For case-control studies, 8 or higher was considered as high quality, 5 to 7 was considered as moderate quality, and less than 5 was considered low quality and excluded.

There were 5 non-randomized or observational studies evaluating effectiveness of sacroiliac joint interventions (151,157,162,170,179). Of these, one was considered high quality (157), 4 were considered moderate quality (151,162,170,179).

2.3 Meta-Analysis

There were a total of 6 randomized trials (159,160,163,177,178,181) meeting the inclusion criteria with 2 trials evaluating cooled radiofrequency (159,160) and 4 trials evaluating intraarticular injections (151,162,177,179). Thus, no meta-analysis could be performed.

2.4 Study Characteristics

Table 11 illustrates the study characteristics of the included studies for both randomized trials (159,160,163,177,178,181) and non-randomized studies (151,157,162,170,179).

2.5 Analysis of Evidence

The evidence was synthesized based on the modality of treatment. Tables 12-14 illustrate the results of therapeutic studies. Analyses were conducted for intraarticular injections, periarticular injections, conventional radiofrequency neurotomy, cooled radiofrequency neurotomy, and pulsed radiofrequency.

2.5.1 Intraarticular Injections

There were a total of 4 studies (Table 12) performed evaluating intraarticular injections (151,162,177,179). Only one study was randomized using an active-control design (177). This study by Kim et al (177) compared prolotherapy to steroid injections. The authors found no significant differences at 3 months; however, on a long-term basis, prolotherapy was more effective. In a large retrospective study, Hawkins and Schofferman (151) reported positive results with intraarticular injections performed appropriately under fluoroscopy. Liliang et al (162) showed short-term effectiveness for intraarticular steroid injections. Borowsky and Fagen (179) compared

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Table 9. *Methodological quality assessment of case control studies.*

Borowsky & Fagen (179)	
Selection	
1) Is the case definition adequate?	
a) yes, with independent validation *	X
b) yes, e.g. record linkage or based on self reports	
c) no description	
2) Representativeness of the cases	
a) consecutive or obviously representative series of cases *	X
b) potential for selection biases or not stated	
3) Selection of Controls	
a) community controls *	
b) hospital controls	
c) no description	
4) Definition of Controls	
a) no history of disease (endpoint) *	
b) no description of source	
Comparability	
1) Comparability of cases and controls on the basis of the design or analysis	
a) study controls for _____ (Select the most important factor.) *	X
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)	
Exposure	
1) Ascertainment of exposure	
a) secure record (eg surgical records) *	X
b) structured interview where blind to case/control status *	X
c) interview not blinded to case/control status	
d) written self report or medical record only	
e) no description	
2) Same method of ascertainment for cases and controls	
a) yes *	
b) no	
3) Non-Response rate	
a) same rate for both groups *	X
b) non respondents described	
c) rate different and no designation	
SCORE	6/10

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

Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (126).

Table 10. *Methodological quality assessment of cohort studies.*

	Hawkins & Schofferman (151)	Vallejo et al (157)	Liliang et al (162)	Cohen et al (170)
Selection				
1) Representativeness of the exposed cohort				
a) truly representative of the average _____ (describe) in the community *	X	X	X	X
b) somewhat representative of the average pain patients in the community *				
c) selected group of users e.g. nurses, volunteers				
d) no description of the derivation of the cohort				
2) Selection of the non exposed cohort				
a) drawn from the same community as the exposed cohort *		X	X	X
b) drawn from a different source				
c) no description of the derivation of the non exposed cohort				
3) Ascertainment of exposure				
a) secure record (eg surgical records) *	X	X	X	X
b) structured interview *		X		
c) written self report				
d) no description				
4) Demonstration that outcome of interest was not present at start of study				
a) yes *	X	X	X	X
b) no				
Comparability				
1) Comparability of cohorts on the basis of the design or analysis				
a) study controls for _____ (select the most important factor) *	X	X	X	X
b) study controls for any additional factor * (This criteria could be modified to indicate specific control for a second important factor.)		X		
Outcome (Exposure)				
1) Assessment of outcome				
a) independent blind assessment *				
b) record linkage *	X	X	X	X
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) *	X	X	X	X
b) no				
3) Adequacy of follow up of cohorts				
a) complete follow up - all subjects accounted for *	X	X	X	X
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	7/13	10/13	8/13	8/13

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.

Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomized studies in meta-analysis. www.ohri.ca/programs/clinical_epidemiology/oxford.asp (126).

Table 11. Summary characteristics of included studies.

Reference, Year	Type of Study	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses	Methodological Quality Assessment Score
RANDOMIZED									
Cohen et al 2008 (159)	R, DB	28 patients were studied with a positive response for sacroiliac joint pain. 14 patients each were included in the placebo group and cooled RF denervation group.	Placebo groups received local anesthetic injection followed by placebo radiofrequency.	Cooled radiofrequency of L5 primary dorsal rami and S1 to S3 lateral branch radiofrequency denervation using cooling probe technology after a local anesthetic block.	Significant pain relief, NRS pain scores, ODI, and global perceived effect	1, 3, and 6 months after the procedure.	At 1, 3, and 6 months after the procedure, 11 (79%), 9 (64%), and 8 (57%) radiofrequency treated patients experienced pain relief of 50% or greater and significant functional improvement. In contrast, only 2 patients (14%) in the placebo group experienced significant improvement at their one-month follow-up, and none experienced benefit 3 months after the procedure.	Strengths: First placebo-controlled study in evaluating sacroiliac joint pain. Weaknesses: This may be considered as an active control rather than placebo control based on the injection of local anesthetic.	11/12
Patel et al 2012 (160)	R, DB, PC	51 patients randomized on a 2:1 basis to lateral branch neurotomy and sham groups, respectively. Patients were selected after dual blocks, controlled comparative local anesthetic lateral branch blocks.	Placebo groups received local anesthetic injections followed by placebo radiofrequency.	Cooled radiofrequency with ablation of the S1 to S3 lateral branches and L5 dorsal ramus	NRS, ODI, SF-36 BP, QOL	1, 3, 6, and 9 months	Statistically significant changes in pain, physical function, disability, and quality of life were found at 3-month follow-up, with all changes favoring the lateral branch neurotomy group. At 3-month follow-up, 47% of treated patients and 12% of sham subjects achieved treatment success. At 6 and 9 months, 38% and 59% of treated subjects achieved treatment success, respectively.	Strengths: This is the second randomized, double-blind, placebo controlled, cooled radiofrequency trial available in the literature. The study was conducted with appropriate design and sample size determination. Weaknesses: The injection of local anesthetic, may be considered by some as active control trial. All the patients were unblinded at the end of 3 months. It is difficult to explain the proportion of successful patients as 47% at 3 months, 38% at 6 months, and 59% at 9 months.	11/12
Luukkainen et al (163)	R, B, AC	24 patients Methylprednisolone and lidocaine =13 patients Isotonic sodium chloride solution and lidocaine=11 patients	24 consecutive non-spondyloarthritic patients were included with proper selection. There were no diagnostic blocks.	Periarticular infiltration with either methylprednisolone with lidocaine with sodium chloride solution.	VAS, pain index	one month	Patients in the steroid group showed significant improvement in pain scores compared to the sodium chloride group.	Strengths: A randomized, double-blind study Weaknesses: Performed blindly with a periarticular injection. A small number of patients with periarticular injection showing positive results when steroid was injected.	11/12

Table 11 (cont.) Summary characteristics of included studies.

Reference, Year	Type of Study	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses	Methodological Quality Assessment Score
Luukkainen et al (181)	R, B, AC	20 patients with zero negative spondyloarthropathy and clinical sacroiliitis with lidocaine=10 patients Sodium chloride solution and lidocaine=10 patients	20 consecutive non-spondyloarthritic patients were included. There were no diagnostic blocks.	Periarticular infiltration with either methylprednisolone with lidocaine with sodium chloride solution.	VAS, pain index	2 months	Significant improvement was observed in patients receiving steroids.	Strengths: A randomized, double-blind study Weaknesses: Performed blindly with a periarticular injection. A small number of patients with periarticular injection showing positive results when steroid was injected.	11/12
Kim et al 2010 (177)	R, F, AC	50 patients Prolotherapy group=24 Steroid Group=26 The study included patients with sacroiliac joint pain, confirmed by > 50% relief improvement in response to local anesthetic block, lasting 3 months or longer and who failed medical treatment	None	Prolotherapy group received 2.5 mL of 25% dextrose solution prepared by diluting 50% dextrose water with 0.25% levobupivacaine. The steroid group received 2.5 mL of 0.125% levobupivacaine with 40 mg of triamcinolone. Number of injections = 3	NRS, ODI, significant improvement 50% relief	2 weeks and monthly after completion of treatment for 15 months	The pain and disability scores were significantly improved from baseline in both groups at the 2-week follow-up, with no significant differences between them. The cumulative incidence of greater than 50% pain relief at 15 months was 58.7% in the prolotherapy group and 10.2% in the steroid group.	Strengths: This is a first randomized, double-blind, active control trial comparing intraarticular prolotherapy to steroid injections in sacroiliac joint pain illustrating significantly superior results with prolotherapy. Weaknesses: Small study without appropriate follow-up. At 3 months and at 6 month follow-up 27.2% of patients showed continued improvement. The text states that duration of pain was 2 months, whereas the abstract describes 3 months.	11/12
Lee et al 2010 (178)	R, F, AC	39 patients Botox Group (n=20) Steroid Group (n=19) Positive for sacroiliac joint provocation maneuvers, failure to respond to conservative management, and positive for diagnostic periarticular injections.	A periarticular injection with mixture of steroids and local anesthetics (2 cc of 0.5% lidocaine) served as control.	Periarticular injection of botulinum toxin (1,000 units of Botox Type A). Number of injections= 1	NRS, ODI.	1, 2 and 3 months	Although there were no differences at one month among steroid and Botox groups, at 2 and 3 months, the Botox group had significantly lower scores in NRS and ODI than did the steroid group.	Strengths: This is the first ever randomized trial utilizing periarticular injections with 2 different solutions in an active control design. Weaknesses: Small number of patients with a short-term follow-up of only 3 months. Included some patient with short (< 3 months) duration of pain.	12/12

Table 11 (cont.). Summary characteristics of included studies.

Reference, Year	Type of Study	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses	Methodological Quality Assessment Score
NON-RANDOMIZED									
Hawkins & Schofferman 2009 (151)	NR, F	155 patients were tested and 120 were positive responders for diagnostic blocks.	None	Intraarticular local anesthetic and steroid injection. Number of injections= 1 to 4	Significant pain relief of 50% or more	Follow-up clinic visits. Mean follow-up 44 months (26-101)	Of the 120 patients, 118 were considered as positive responders receiving a mean of 2.7 injections per patient. The mean duration of response for those receiving more than one injection was 9.3 months per injection.	Strengths: A large study of the database mimicking the actual interventional pain management practice with diagnostic interventions. Weaknesses: A retrospective evaluation with a single block.	7/13
Vallejo et al 2006 (157)	NR	Out of the 126 patients with presumptive sacroiliac joint pain, 52 (41.3%) had greater than 75% pain relief with 2 consecutive diagnostic injections with concordant relief.	None	Patients were treated with pulsed radiofrequency of the medial branch of L4, posterior rami of L5, and lateral branches of S1 and S2.	VAS and quality of life assessment	6 months	16 patients (72.7%) experienced good or excellent pain relief following pulsed radiofrequency. Duration of pain relief range was variable with 6 to 9 weeks in 4 patients, 10 to 16 weeks in 5 patients, and 17 to 32 weeks in 7 patients. 6 patients (26.1%) did not respond to pulsed radiofrequency.	Strengths: The study describes a practice pattern which is common in contemporary interventional pain management settings. Weaknesses: Absence of evidence supporting pulsed radiofrequency for nociceptive pain.	10/13
Liliang et al 2009 (162)	NR, F	Dual sacroiliac joint blocks confirmed sacroiliac joint pain in 39 (26%) of 150 .	None	Sacroiliac joint injections with 1 mL of 0.5% bupivacaine or 2% lidocaine mixed with 40 mg triamcinolone acetamide. Number of injections = 1 to 3	Pain recurrence within 6 weeks after the block was considered treatment failure and no further blocks were performed on these patients. VAS, ODI	Patients were followed after the second block for an average period of 45.4 weeks.	26 patients (66.7%) experienced significant pain reduction for more than 6 weeks: the overall mean duration of pain reduction in these responders was 36.8 9.9 weeks.	Strengths: Well conducted study arriving at the diagnosis with dual blocks with positive results in 66.7% using strict inclusion criteria. Weaknesses: Small prospective observational study. Eliminated patients with < 6 weeks of relief.	8/13
Cohen et al 2009 (170)	NR, F	77 patients with refractory, injection-confirmed sacroiliac joint pain underwent sacroiliac joint denervation.	None	Radiofrequency denervation with lesioning of the L4 and L5 primary dorsal rami and S1 to S3 or 4 lateral branch denervation.	Global perceived effect, ODI, medication reduction, and retention on active duty for soldiers.	6 months	Of 40 patients, 52% obtained a positive outcome	Strengths: A prospective evaluation with a fairly large proportion of patients with stringent outcome measures. Patient selection based on diagnostic blocks. Weaknesses: Nonrandomized, observational study	8/13

Table 11 (cont.). Summary characteristics of included studies.

Reference, Year	Type of Study	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses	Methodological Quality Assessment Score
Borowsky & Fagen (179)	NR, F	The medical records of 120 patients sequentially enrolled from practice billing records were reviewed. Inclusion criteria included pain in the low back below L4 in the buttock, thigh, groin, or lower extremity	Intraarticular injection alone	Intraarticular injection along with periarticular injection Number of injections= 1	Percent change in VAS pain scores Patient self-reported activities of daily living	3 weeks and 3 months	For intraarticular injection alone, the rate of positive response at 3 months was 12.5% versus 31.25% for the combined injection.	Strengths: Authors present evidence supporting the existence of extraarticular sources for sacroiliac region pain suggesting that intraarticular anesthetic blockade alone may underestimate the true prevalence of sacroiliac joint region pain. Weaknesses: A retrospective evaluation with all its inherent flaws.	6/10

R = Randomized
 DB = Double-blind
 PC = Placebo control
 B = Blind
 F = Fluoroscopy
 AC = Active-control
 NR = Non-randomized
 NRS = Numeric Rating Scale
 ODI = Oswestry Disability Index
 VAS = Visual Analog Scale
 SF-36 BP=Short-form 36 bodily pain
 QOL = Quality of life

intraarticular injections with a combination of intra- and periarticular injections. The results were suboptimal with both techniques, but were somewhat better in the combined injection group. Among the excluded studies, there were positive results illustrated by Maugars et al (148) in patients with spondyloarthropathy. In addition, Murakami et al (197) in a short-term follow-up showed the superiority of periarticular injections over intraarticular injections.

2.5.1.1 Effectiveness

There is limited (or poor) evidence for the effectiveness of intraarticular steroid injections.

2.5.2 Periarticular Injection

As shown in Table 13, periarticular injections were evaluated in 3 observational studies (163,178,181). The study by Lee et al (178) was a randomized trial, whereas Borowsky and Fagen (179) retrospectively compared intraarticular to a combination of intraarticular and periarticular injections. In the randomized trial by Lee et al (178) the authors showed that a periarticular injection of botulinum toxin was effective in a significant proportion of patients at 3 month follow-up. Borowsky and Fagen (179) showed that patients receiving intraarticular and periarticular injections fared better than the patients receiving intraarticular injections only; however, only 31.25% of patients who received the combination of injections experienced relief at 3 months. Luukkainen et al evaluated the role of periarticular injections in 2 randomized trials (163,181). Both the studies showed periarticular injection of local anesthetic with steroids to be superior, though only in a short-term follow-up. Murakami et al (197), in a 5 minute follow-up also showed superiority for periarticular injections over intraarticular injections.

2.5.2.1 Effectiveness

Based on the limited results, there is limited (or poor) evidence for periarticular injections of local anesthetic and steroid or botulinum toxin.

2.5.3 Conventional Radiofrequency Neurotomy

There was only one study (170) evaluating conventional radiofrequency neurotomy that met the criteria; it was a retrospective evaluation reporting positive results for up to 6 months (Table 14). Cohen et al (170) retrospectively evaluated 77 patients with refractory, injection-confirmed sacroiliac joint pain who underwent sacroiliac joint denervation at 2 academic institutions.

Table 12. Results of randomized and observational studies of effectiveness of intraarticular sacroiliac joint injections.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results						Comment		
					3 mos.	6 mos.	12 mos	Short-term ≤ 6 mos.			Long-Term					
								> 6 mos	1 year							
Hawkins & Schofferman (151)	NR, F	7/13	155	Local anesthetic and steroids Number of injections= 1 to 4	77%	77%	77%	P	NA	NA	P	NA	NA	NA	NA	Positive study
Liliang et al (162)	NR, F	8/13	150	Local anesthetic and steroids Number of injections = 1 to 3	66.7%	NA	NA	P	NA	NA	NA	NA	NA	NA	NA	Positive study
Kim et al (177)	R, AC, F	11/12	50 Prolotherapy group = 24 Steroid group = 26	25% dextrose solution with levobupivacaine or levobupivacaine with triamcinolone. Number of injections = 3	Prolotherapy = 77.6% vs. Steroids = 70.5%	Prolotherapy = 63.6% vs. Steroids = 27.2%	Prolotherapy = 58.7% vs. Steroids = 10.2%	P	P*	NA	N	NA	NA	P*	NA	positive for prolotherapy
Borowsky & Fagen (179)	NR, F	6/10	120	Intraarticular or with extraarticular injection. Number of injections= 1	12.5% vs. 31.25%	NA	NA	N	N	N	N	N	N	N	N	Negative study

*Prolotherapy; R = Randomized; F = Fluoroscopy; AC = Active-control; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable

Table 13. Results of randomized and observational studies of effectiveness of periarthicular sacroiliac joint injections.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function			Results					Comment			
					3 mos.	6 mos.	12 mos	Short-term ≤ 6 mos.								
								Long-Term								
					> 6 mos.					1 year						
Luukkainen et al (163)	R, B, AC	11/12	24	Methylprednisolone with local anesthetic vs. sodium chloride solution Number of injections= 1	Significant improvement in steroid group	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Positive for steroids with local anesthetic
Lee et al (178)	R, AC, F	12/12	39 patients Botox Group (n=20) Steroid Group (n= 19)	Number of injections= 1	Botox = 88.2% vs. Steroid = 26.7%	NA	NA	NA	P**	NA	NA	NA	NA	NA	NA	Positive for Botox
Luukkainen et al (181)	R, B, AC	11/12	20	Methylprednisolone with local anesthetic vs. sodium chloride solution Number of injections= 1	Significant improvement in steroid group	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Positive for steroid
Borowsky and Fagen (179)	NR,F	6/10	120	intraarticular and periarthicular	12.5% vs 31.25%	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	Small study with negative results

** Botulinum Toxin; R = Randomized; B = Blind; F = Fluoroscopy; AC = Active-control; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable

Table 14 Results of randomized and observational studies of effectiveness of radiofrequency lesioningsacroiliac joint.

Study	Study Characteristics	Methodological Quality Scoring	Participants	Interventions	Pain Relief and Function				Results			Comment		
					3 mos.	6 mos.	12 mos	Short-term ≤ 6 mos.	Long-Term					
									> 6 mos	1 year				
CONVENTIONAL RADIOFREQUENCY NEUROTOMY														
Cohen et al (170)	NR, F	8/13	77	Conventional or cooled radiofrequency from L4/5 to S3/4	NA	66.7% improvement	NA	RF	Sham	RF	Sham	RF	Sham	Positive study
								P	NA	P	NA	NA	NA	
COOLED RADIOFREQUENCY NEUROTOMY														
Cohen et al (159)	R, DB, PC	11/12	Total: 28 placebo = 14 radiofrequency = 14	Cooled radiofrequency or Sham	Treatment group: 64% success rate Control Group: 14%	Treatment group: 57% success rate Control Group: 0%	Treatment group: 14% in open-label follow-up	RF	Sham	RF	Sham	RF	Sham	Positive trial
								P	N	P	N	N	NA	
Patel et al (160)	R, DB, PC	11/12	51 (34 treatment, 17 control)	Cooled radiofrequency versus Sham	Treatment group: 47% success rate Control Group: 12%	Treatment group: 38% success rate Control Group: NA	NA	RF	Sham	RF	Sham	RF	Sham	Positive trial
								P	N	P	N	NA	NA	
PULSED RADIOFREQUENCY NEUROTOMY														
Vallejo et al (157)	NR	10/13	126	Pulsed radiofrequency	55%	32% had between 17 and 32 weeks worth of relief	NA	PRF	Sham	PRF	Sham	PRF	Sham	Positive study
								P	N	P	N	P	N	

R = Randomized; DB = Double-blind; PC = Placebo control; F = Fluoroscopy; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable

Forty patients (52%) obtained a positive outcome. In multivariate analysis, preprocedure pain intensity, age older than 65 years, and pain radiating below the knee were significant predictors of failure. A trend was noted whereby patients receiving regular opioid therapy were more likely to experience a negative outcome. The use of cooled radiofrequency, rather than conventional radiofrequency, was also associated with a higher percentage of positive outcomes. The authors concluded that although several factors were found to possibly influence outcomes, no single clinical variable reliably predicted treatment results. The use of more stringent selection criteria was not associated with better outcomes.

2.5.3.1 Effectiveness

Based on one retrospective evaluation (170), the evidence for the effectiveness of conventional radiofrequency neurotomy is limited (or poor).

2.5.4 Cooled Radiofrequency Neurotomy

Two randomized controlled trials (159,160) evaluated the efficacy of cooled radiofrequency neurotomy using a placebo control design (Table 14). Although there were some potential shortcomings with the control group, both studies illustrated the effectiveness of cooled radiofrequency neurotomy.

2.5.4.1 Effectiveness

The evidence for cooled radiofrequency neurotomy in managing sacroiliac joint pain is fair based on 2 randomized, double-blind placebo-controlled trials (159,160).

2.5.5 Pulsed Radiofrequency Neurotomy

There was only one study, by Vallejo et al (157) that evaluated pulsed radiofrequency neurotomy over a period of 6 months, with 72.7% of the patients experiencing positive results.

2.5.5.1 Effectiveness

Based on one non-randomized prospective evaluation (157), the evidence for pulsed radiofrequency is limited (or poor).

2.5.6 Summary of Evidence

The evidence was fair for cooled radiofrequency neurotomy; limited (or poor) for short-term and long-term relief from intraarticular steroid injections; limited (or poor) for periarticular injections with steroids or botulin toxin; and limited (or poor) for both pulsed radiofrequency and conventional radiofrequency neurotomy.

3.0 DISCUSSION

This systematic review of therapeutic sacroiliac joint interventions showed fair evidence for cooled radiofrequency neurotomy based on 2 randomized, placebo-controlled trials (159,160). However, the evidence was either lacking or limited (or poor) for all other interventions including intraarticular injections, periarticular injections, conventional radiofrequency neurotomy, and pulsed radiofrequency. There was some evidence for intraarticular prolotherapy, but this was based on only a single active-controlled trial.

In this evaluation, a total of 6 randomized trials and 5 non-randomized studies were included. Only studies meeting at least moderate quality criteria were included in the analysis. Our review yielded superior results to a previous systematic review by Rupert et al (32), as well as guidelines published by the American Pain Society (APS) (26) and the American College of Occupational and Environmental Medicine (ACOEM) (200). In addition to reaching conclusions different from the findings of this review, the negative recommendations of these guidelines also conflict with 2 other reviews evaluating radiofrequency neurotomy for the treatment of sacroiliac joint syndrome. In a meta-analysis assessing the role of radiofrequency ablation for sacroiliac joint pain, Aydin et al (169) concluded that radiofrequency ablation was an effective treatment for sacroiliac joint pain for at least 6 months. This systematic review was more inclusive than ours, and included multiple studies which failed to meet the criteria for this evaluation. Among the multiple studies included in the review by Aydin et al, only 2 studies met our inclusion criteria based on methodological quality assessment (159,170).

In a narrative review by Muhlner(149), the author concluded that there was limited evidence to support radiofrequency neurotomy as a treatment for sacroiliac joint pain. However, since the publication of this manuscript, there have been 2 positive randomized, double-blind controlled trials for cooled radiofrequency neurotomy (159,160), as well as positive studies for other sacroiliac joint interventions.

Vanelderden et al (72) in evidence-based interventional pain medicine according to clinical diagnosis concluded that therapeutic intraarticular sacroiliac joint infiltrations with local anesthetic and corticosteroids held the highest evidence rating with 1B+ followed by 2B+ evidence for cooled radiofrequency treatment, with pulsed radiofrequency procedures with 2C+ evidence. However, the evidence assessment in this evaluation is rather confusing. The evidence for intraarticular injections is based on 2 diagnostic studies (35,201), 2 studies

evaluating spondyloarthropathy (163,181), and finally only one study (179) which evaluated sources of sacroiliac joint region pain with intraarticular injection with a technique combining intra- and periarticular injection. Borowsky & Fagen (179) was the only one non-randomized fluoroscopically directed study included in this systematic review. This was a retrospective evaluation with multiple inherent flaws. The study reaches conclusions after the review of medical records of 120 patients sequentially enrolled from practice billing records. Even though the study met the inclusion criteria with moderate methodologic quality, this is not a randomized trial to yield the evidence as described by Vanelderden (72). In fact, they described lower evidence for cooled radiofrequency. The basis is not explainable, specifically considering the present evidence with one new study which has been described as fair in this evaluation.

Not all guidelines are as negative as those published by the APS and ACOEM. Guidelines from the American Society of Anesthesiologists (ASA) and the American Society of Regional Anesthesia and Pain Medicine (ASRA) assert that there is favorable evidence supporting sacroiliac joint injections (202). Since the negative guidelines by Chou and Huffman and ACOEM were written, multiple positive randomized, controlled studies have been published.

Many studies that failed to meet our strict inclusion criteria demonstrated positive results. Overall, this systematic review provides positive evidence; fair for cooled radiofrequency neurotomy for short- and long-term follow-up, and limited (or poor) for intraarticular steroid injections and prolotherapeutic injections, and periarticular injections, with local anesthetic and steroids or botulinum toxin. For conventional radiofrequency neurotomy and pulsed radiofrequency the evidence is still emerging, which limits the conclusions one can draw. Specifically, the large retrospective evaluation of Hawkins and Schofferman (151) indicates major potential to prove effectiveness in controlled trials.

One of the controversial issues regarding sacroiliac joint interventions is whether intraarticular, periarticular, or combination injections are more useful. Despite the limited evidence in favor of the latter, this systematic review failed to show conclusive evidence demonstrating the superiority of one technique over the other.

A second important issue revolves around the main purpose behind diagnostic sacroiliac joint injections and the ideal number to perform. Diagnostic injections are widely considered the reference standard identifying spinal pain generators. Even though they afford

a pain relief benefit of only 3 to 6 weeks on average with the first and second blocks (203,204), perhaps the most important reason for performing injections is for their prognostic value (i.e., to select patients for radiofrequency denervation or continuing therapeutic injections). Viewed from this perspective, since the lateral branches targeted during radiofrequency denervation more reliably transmit nociceptive information from the periarticular posterior ligaments rather than from the joint capsule itself (172), the use of prognostic periarticular blocks would seem to make more sense than intraarticular injections. Although the question regarding how many, if any, prognostic blocks to perform before proceeding with radiofrequency denervation is an area of intense controversy in the pain medicine community (203-205), there is a strong consensus that the only means to reliably identify a painful sacroiliac joint is via the use of diagnostic blocks (33). Whereas the use of double-blocks can reduce the high false-positive rate associated with uncontrolled sacroiliac joint injections and is associated with a lower prevalence rate than when single blocks are employed, the use of multiple blocks may result in an increase in the false-negative rate.

The limitations of this systematic review include scant literature available for analysis, the flawed methodology in many studies leading to their exclusion, and a myriad of discrepancies in the techniques, outcome measures, and follow-up periods. Although 2 studies evaluating cooled radiofrequency utilized a placebo-controlled design (159,160), one might question whether or not the control group received a "true placebo," since the needles were positioned over the nerves and local anesthetic administered. Thus, these could also be construed as an active comparator. It is not always feasible to perform placebo-controlled studies in an interventional setting, and the absence of these studies has led to some third party payers denying payment for effective therapies. Non-analgesic solutions (e.g., saline) injected into painful structures have been reported to result in significant pain relief not only for spinal pain, but also for other chronic pain conditions as well (206-220). For local anesthetic and corticosteroids, these effects may be enhanced. It is believed that neural blockade can result in the long-term alleviation of pain by interrupting nociceptive input, disrupting the reflex arc of afferent pain fibers, inhibiting ectopic discharges from injured nerves, and possibly reversing central sensitization (1,221). Corticosteroids may also inhibit the synthesis or release of a number of pro-inflammatory mediators, and cause a reversible local an-

esthetic effect (222-226). Local anesthetics can provide short- to long-term symptomatic relief through their mitigating effects on excessive nociceptive processing, reducing the release of neurotransmitters implicated in pain, increasing blood flow to ischemic nerve tissue, and phenotypic changes (225-232). A prolonged effect for local anesthetics has been demonstrated in multiple studies evaluating epidural injections and facet blocks (133,134,137,143,144,233-240). Sato et al (241) evaluated the analgesic effects of repetitive administration of epidural ropivacaine in a rat model of neuropathic pain, and found evidence of plastic changes in the peripheral nervous system. In a preclinical study conducted by Tachihara et al (242) evaluating the effects of local anesthetic, corticosteroid, and combination treatment in an experimental model of lumbar disc herniation, the authors found that nerve root infiltration in all treatment groups prevented mechanical allodynia; however, no additional benefit was observed by the addition of corticosteroid.

The results of this systematic review may be applied in interventional pain management practices (234). For this systematic review, placebo and active control trials were included. Active control or practical clinical trials measure effectiveness, and may better reflect how a treatment will fare in clinical practice than placebo-controlled studies evaluating efficacy, which frequently have poor generalizability (110,115,243-247). The differences between placebo-controlled trials and active controlled trials include the fact that whereas placebo controlled trials measure absolute effect size, active controlled trials compare different therapies (248).

The limitations of this review include the fact that we were only able to find 9 studies that met our inclusion criteria and were clinically relevant; the small sample sizes; and the widespread variations in methodology, selection criteria, outcome measures, and technique. Nevertheless, the results of this systematic review suggest that significant improvements in pain scores and functional status can be obtained with radiofrequency neurotomy and injections in carefully selected patients.

4.0 CONCLUSION

The results of this systematic review evaluating the effects of sacroiliac joint interventions in managing sacroiliac joint pain demonstrate fair evidence for cooled radiofrequency neurotomy, both for short- and long-term relief of chronic pain, and limited (or poor) evidence for intraarticular steroid and prolotherapy in-

jections, periarticular injections of local anesthetic and steroid, or botulinum toxin injections, pulsed radiofrequency, and conventional heat radiofrequency neurotomy. Better randomized studies emphasizing proper selection criteria, larger sample sizes, and relevant long-term outcome measures are needed to determine how best to treat this challenging condition.

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