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Systematic Review

Systematic Review of the Diagnostic Accuracy and Therapeutic Effectiveness of Sacroiliac Joint Interventions

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Background: The sacroiliac joint is well known as a cause of low back and lower extremity pain. Prevalence estimates are 10% to 25% in patients with persistent axial low back pain without disc herniation, discogenic pain, or radiculitis based on multiple diagnostic studies and systematic reviews. However, at present there are no definitive management options for treating sacroiliac joint pain.

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

Study Design: A systematic review of the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions.

Methods: The available literature on diagnostic and therapeutic sacroiliac joint interventions was reviewed. The quality assessment criteria utilized were the Quality Appraisal of Reliability Studies (QAREL) checklist for diagnostic accuracy studies, Cochrane review criteria to assess sources of risk of bias, and Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB) criteria for randomized therapeutic trials and Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR) for observational therapeutic assessments.

The level of evidence was based on a best evidence synthesis with modified grading of qualitative evidence from Level I to Level V.

Data sources included relevant literature published from 1966 through March 2015 that were identified through searches of PubMed and EMBASE, manual searches of the bibliographies of known primary and review articles, and all other sources.

Outcome Measures: For the diagnostic accuracy assessment, and for the therapeutic modalities, the primary outcome measure of pain relief and improvement in functional status were utilized.

Results: A total of 11 diagnostic accuracy studies and 14 therapeutic studies were included. The evidence for diagnostic accuracy is Level II for dual diagnostic blocks with at least 70% pain relief as the criterion standard and Level III evidence for single diagnostic blocks with at least 75% pain relief as the criterion standard.

The evidence for cooled radiofrequency neurotomy in managing sacroiliac joint pain is Level II to III. The evidence for conventional radiofrequency neurotomy, intraarticular steroid injections, and periarticular injections with steroids or botulinum toxin is limited: Level III or IV.

Limitations: The limitations of this systematic review include inconsistencies in diagnostic accuracy studies with a paucity of high quality, replicative, and consistent literature. The limitations for therapeutic interventions include variations in technique, variable diagnostic standards for inclusion criteria, and variable results.

Conclusion: The evidence for the accuracy of diagnostic and therapeutic effectiveness of sacroiliac joint interventions varied from Level II to Level IV.

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

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Chronic low back pain is highly prevalent, pervasive, expensive, and the number one cause of disability (1-3). The impact of disability has been well delineated with 83 million disability adjusted life years (DALY) or loss of well years of life every year due to ill health, disability, or early death, an increase from 58.2 million DALY in 1990 (1-3). The sacroiliac joint is known as a source of low back and lower extremity pain in some patients who present with chronic low back pain. Sacroiliac joint pain is common, with some claiming that it is an under-appreciated cause of chronic low back pain (4-10).

The sacroiliac joint has matched articular surfaces and is surrounded by a fibrous capsule that separates the articular surfaces (4,5). Consequently, the sacroiliac joint has unique characteristics which are typically not seen in other diarthrodial joints (4,5). Due to its heterogeneity and size, sacroiliac joint pain may be caused by multiple etiologies, making a diagnosis not only challenging, but elusive. A systematic review of the prevalence and diagnostic accuracy of sacroiliac joint interventions (7) showed a highly variable prevalence from 10% to 60% based on the setting, even though the majority of analyzed studies suggested a point prevalence of about 25%, with a false-positive rate for uncontrolled blocks of approximately 20%.

The exponential growth of treatment modalities in the management of spinal pain has been attributed to inaccurate diagnoses (4,6-8,11-14). An accurate diagnosis is fundamental to prevent inappropriate treatments, treatment failures, and wasted health care resources. Thus, the reliability of the test employed to make the diagnosis is fundamental to an accurate diagnosis and to improve health care delivery (6-8,12-17) in the modern era of choice between conservative management, interventional techniques, and surgical interventions (6-9,17-25). Consequently, numerous attempts have been made to continue to improve the accuracy of diagnosing sacroiliac joint pain by multiple means, including physical examination, imaging techniques, and controlled local anesthetic blocks (4-8).

Since there is no universally accepted "gold standard" for diagnosing low back pain from different pathologies not amenable to diagnosis by imaging and clinical examination (4-8,25-42), the recommended reference standards typically involve anesthetic or provocative injections. Controlled local anesthetic blocks have been promoted as the best available tool to identify not only painful intervertebral discs and facets, but also painful sacroiliac joint(s) as the source of low back pain, despite numerous arguments against the diagnostic accuracy of controlled local anesthetic blocks (4-8,25-44). Further, controlled blocks are invasive, expensive, and often difficult to interpret, and so for everyday clinical use might not be appropriate as a first-line diagnostic tool. A systematic review conducted by Hancock et al (32) assessed the tests used to determine whether back pain is caused by a disc, sacroiliac joint, or facet joint. They suggested that a combination of sacroiliac joint pain provocative maneuvers and pain below L5 is useful for determining that the sacroiliac joint is the principal source of symptoms in patients. Similarly, a systematic review conducted by Szadek et al (38) found that the thigh thrust, compression test, and 3 or more positive stressing tests have enough discriminative power that they can be used for diagnosing sacroiliac joint pain. However, Song et al (40), in a systematic review assessing scintigraphy, concluded that it is of limited value at best in establishing sacroiliitis in patients and only in patients with ankylosing spondylitis. Laslett's (33) evidence-based review reported that when 3 or more positive provocation sacroiliac joint tests are present, and there is no "centralization," there is a 77% chance for sacroiliac joint pain and 89% in pregnant women. However, Rubinstein and van Tulder (29), with multiple Cochrane review publications, in a best-evidence review of diagnostic procedures for neck and low back pain, reported that there is moderate evidence for the validity and accuracy of diagnostic injections. Despite their conclusion that there is moderate evidence for the validity and accuracy of sacroiliac joint injections, Chou and Huffman (45), and the Centre for Reviews

and Dissemination (CRD) of the University of York from the National Institute for Health Research (NIHR) have provided contradictory opinions reporting lack of evidence (46-51).

Previous systematic reviews found the evidence supporting therapeutic sacroiliac joint interventions to be limited, except for emerging evidence for cooled radiofrequency neurotomy (8). Spiker et al (23) compared surgical versus injection treatment for injection-confirmed sacroiliac joint pain by identifying 7 surgical articles and 5 injection treatment studies that met their inclusion criteria. The results showed that regardless of the type of treatment, most studies reported over 40% improvement in pain and 20% improvement in function with the majority of complications coming from surgical studies. They commented that surgical fusion and therapeutic injections can likely provide pain relief, improve quality of life, and improve work status. They also concluded that the comparative effectiveness of these interventions cannot be evaluated with the current literature.

Recently, the North American Spine Society (NASS) (11) and the International Society for the Advancement of Spine Surgery (ISASS) (12) provided 2 identical position statements, defining appropriate coverage policies for sacroiliac joint fusion. Based on these recommendations, a patient must meet 5 or 7 rigorous criteria (11,12). The criteria include failed conservative management, nonradiating unilateral pain, localized tenderness, a positive response to 3 provocative tests, an absence of generalized pain behavior, diagnostic imaging studies to rule out other causes, and at least 75% or 80% reduction of pain with controlled diagnostic blocks. The issue relates to the meeting of all of the criteria, although it is highly unlikely for any patient to meet all criteria. Consequently, these documents essentially provide non-coverage policies rather than coverage policies.

Despite the multitude of issues as shown above, sacroiliac joint injections have increased 311% per 100,000 Medicare population from 2000 to 2013 (18,19,21). In addition to sacroiliac joint interventions provided by pain physicians, numerous other modalities including conservative management with drug therapy, physical therapy, and surgical interventions, have resulted in escalating costs which have been considered as uncontrollable (2,20-25,48).

The purpose of this systematic review is to assess the diagnostic accuracy and the therapeutic effectiveness of sacroiliac joint interventions.

1.0 Methods

This systematic review, including diagnostic accuracy studies and therapeutic effectiveness studies, utilized the review process derived from evidence-based systematic reviews and meta-analysis of randomized trials, observational studies, and diagnostic accuracy studies (6,13-17,52-56).

1.1 Criteria for Considering Studies for This Review

1.1.1 Types of Studies

1. Diagnostic accuracy studies
2. Randomized controlled trials (RCTs) and observational studies of therapeutic sacroiliac joint interventions

1.1.2 Types of Participants

Only patients suffering with chronic low back pain of at least 3 months which was suspected to be secondary to sacroiliitis were included.

Patients with acute trauma, fractures, malignancies, and inflammatory diseases were excluded.

1.1.3 Types of Interventions

This systematic review included all sacroiliac joint interventions, both diagnostic and therapeutic, appropriately performed under fluoroscopic or computed tomography (CT) guidance.

1.1.4 Types of Outcome Measures

For diagnostic accuracy studies, the primary outcome parameter was the ability to perform previously painful movements with significant pain relief predetermined to be 50% or greater.

For therapeutic trials and studies, the primary outcome parameter was pain relief, whereas secondary outcome measures included functional status improvement.

1.2 Literature Search

The literature search was performed utilizing all of the available diagnostic accuracy studies and therapeutic intervention studies in all languages from all countries. All of the available trials in all languages from all countries providing appropriate management with outcome evaluations were considered for inclusion. Searches were performed from the following sources without language restrictions:

1. PubMed from 1966

www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
2. Cochrane Library
www.thecochranelibrary.com/view/0/index.html
3. U.S. National Guideline Clearinghouse (NGC)
www.guideline.gov/
4. Previous systematic reviews and cross references
5. Clinical Trials
clinicaltrials.gov/
6. All other sources including non-indexed journals and abstracts

The search period was from 1966 through March 2015.

1.3 Search Strategy and Terminology

Diagnostic accuracy studies and all types of therapeutic interventions were the focus of this systematic review. Excluded from the search were blindly performed interventions or those that used other identification modalities. Those studies that had appropriate outcome evaluations with proper statistical evaluations were reviewed. Reports without an appropriate diagnosis, nonsystematic reviews, book chapters, and case reports were excluded.

Search criteria were as follows:

(((sacrococcygeal[Title/Abstract]) OR sacroiliac[Title/Abstract])) AND ((((chronic low back pain) OR chronic back pain) OR sacroiliac joint pain) OR sacroiliac joint arthritis)

1.4 Data Collection and Analysis

For prevalence and accuracy, all studies of sacroiliac joint blocks utilizing diagnostic blocks with appropriate descriptions were included.

For therapeutic assessment, this review focused on randomized and observational studies. 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 that provided appropriate management and reported outcome evaluations of 3 months or longer with statistical evaluations were reviewed.

1.4.1 Inclusion and Exclusion Criteria

Only studies utilizing controlled diagnostic blocks with appropriate assessment and statistical evaluation were utilized. Further, studies scoring at least 4 on a scale of 12 with assessment utilizing QAREL were utilized for diagnostic accuracy analysis.

Randomized trials with at least 3 months of follow-up and with appropriate sample size determination were included. For nonrandomized studies, only studies that included at least 25 patients in each group or 50 patients in noncomparative studies were included.

1.4.2 Data Extraction and Management

Two review authors independently, in an unblinded standardized manner, developed search criteria, searched for relevant literature, selected the manuscripts, and 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.

Methodological quality assessment was performed by multiple review authors with groups of 2 authors reviewing 4 to 6 manuscripts. The assessment was carried out independently in an unblinded standardized manner to assess the methodological quality and internal validity of all the studies considered for inclusion. The methodological quality assessment was performed in a manner to avoid any discrepancies which were evaluated by a third reviewer and settled by consensus. Continued issues were also discussed with the entire group and resolved.

If a conflict of interest arose with one of the reviewed studies, that author or authors were recused from that particular study's methodological quality assessment.

1.4.3 Methodological Quality or Validity Assessment

For diagnostic accuracy studies, the quality of each individual article used in this assessment was based on the Quality Appraisal of Reliability Studies (QAREL) checklist (Table 1) (16,17). This checklist has been validated and utilized in multiple systematic reviews (6,7). The studies selected for the final sample were assessed with a 12-item checklist (16). This checklist was developed in accordance to the Standards for Reporting Studies of Diagnostic Accuracy (STARD) (13) and the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) (14,15) appraisal tools. Instead of a numeric quality score for each item, they were evaluated individually and given a grade of "yes," "no," "unclear," or "not applicable." A total score was then computed.

The quality of each individual article used in this analysis was assessed by Cochrane review criteria (Table 2) (53) and Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB) for randomized trials (Table 3) (54). For

Table 1. *Quality Appraisal of Diagnostic Reliability (QAREL) checklist.*

Item	Yes	No	Unclear	N/A
1. Was the test evaluated in a spectrum of subjects representative of patients who would normally receive the test in clinical practice?				
2. Was the test performed by examiners representative of those who would normally perform the test in practice?				
3. Were raters blinded to the reference standard for the target disorder being evaluated?				
4. Were raters blinded to the findings of other raters during the study?				
5. Were raters blinded to their own prior outcomes of the test under evaluation?				
6. Were raters blinded to clinical information that may have influenced the test outcome?				
7. Were raters blinded to additional cues, not intended to form part of the diagnostic test procedure?				
8. Was the order in which raters examined subjects varied?				
9. Were appropriate statistical measures of agreement used?				
10. Was the application and interpretation of the test appropriate?				
11. Was the time interval between measurements suitable in relation to the stability of the variable being measured?				
12. If there were dropouts from the study, was this less than 20% of the sample.				
TOTAL				

Source: Lucas NP, Macaskill P, Irwing L, Bogduk N. The development of a quality appraisal tool for studies of diagnostic reliability (QAREL). *J Clin Epidemiol* 2010; 63:854-861 (16).

Table 2. *Sources of risk of bias and Cochrane Review 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?		

Table 2. *Sources of risk of bias and Cochrane Review rating system.*

	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
	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

Source: 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 (48).

Table 3. *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

		Scoring
I.	**TRIAL DESIGN AND GUIDANCE REPORTING**	
1.	**CONSORT or SPIRIT**	
	Trial designed and reported without any guidance	0
	Trial designed and reported utilizing minimum criteria other than CONSORT or SPIRIT criteria or trial was conducted prior to 2005	1
	Trial implies it was based on CONSORT or SPIRIT without clear description with moderately significant criteria for randomized trials or the trial was conducted before 2005	2
	Explicit use of CONSORT or SPIRIT with identification of criteria or trial conducted with high level reporting and criteria or conducted before 2005	3
II.	**DESIGN FACTORS**	
2.	**Type and Design of Trial**	
	Poorly designed control group (quasi selection, convenient sampling)	0
	Proper active-control or sham procedure with injection of active agent	2
	Proper placebo control (no active solutions into active structures)	3
3.	**Setting/Physician**	
	General setting with no specialty affiliation and general physician	0
	Specialty of anesthesia/PMR/neurology/radiology/ortho, etc.	1
	Interventional pain management with interventional pain management physician	2
4.	**Imaging**	
	Blind procedures	0
	Ultrasound	1
	CT	2
	Fluoro	3

Table 3 (cont.). *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

		Scoring
5.	**Sample Size**	
	Less than 50 participants in the study without appropriate sample size determination	0
	Sample size calculation with less than 25 patients in each group	1
	Appropriate sample size calculation with at least 25 patients in each group	2
	Appropriate sample size calculation with 50 patients in each group	3
6.	**Statistical Methodology**	
	None or inappropriate	0
	Appropriate	1
III.	**PATIENT FACTORS**	
7.	**Inclusiveness of Population**	
7a.	For epidural procedures:	
	Poorly identified mixed population	0
	Clearly identified mixed population	1
	Disorders specific trials (i.e. well defined spinal stenosis and disc herniation, disorder specific, disc herniation or spinal stenosis or post surgery syndrome)	2
7b.	For facet or sacroiliac joint interventions:	
	No diagnostic blocks	0
	Selection with single diagnostic blocks	1
	Selection with placebo or dual diagnostic blocks	2
8.	**Duration of Pain**	
	Less than 3 months	0
	3 to 6 months	1
	> 6 months	2
9.	**Previous Treatments**	
	Conservative management including drug therapy, exercise therapy, physical therapy, etc.	
	Were not utilized	0
	Were utilized sporadically in some patients	1
	Were utilized in all patients	2
10.	**Duration of Follow-up with Appropriate Interventions**	
	Less than 3 months or 12 weeks for epidural or facet joint procedures, etc. and 6 months for intradiscal procedures and implantables	0
	3 to 6 months for epidural or facet joint procedures, etc., or 1 year for intradiscal procedures or implantables	1
	6 months to 17 months for epidurals or facet joint procedures, etc., and 2 years or longer for discal procedures and implantables	2
	18 months or longer for epidurals and facet joint procedures, etc., or 5 years or longer for discal procedures and implantables	3
IV.	**OUTCOMES**	
11.	**Outcomes Assessment Criteria for Significant Improvement**	
12.	**Analysis of all Randomized Participants in the Groups**	
	Not performed	0
	Performed without intent-to-treat analysis without inclusion of all randomized participants	1
	All participants included with or without intent-to-treat analysis	2
13.	**Description of Drop Out Rate**	
	No description of dropouts, despite reporting of incomplete data or ≥ 20% withdrawal	0
	Less than 20% withdrawal in one year in any group	1
	Less than 30% withdrawal at 2 years in any group	2
14.	**Similarity of Groups at Baseline for Important Prognostic Indicators**	

Table 3 (cont). *Item checklist for assessment of RCTs of IPM techniques utilizing IPM – QRB.*

	Groups dissimilar with significant influence on outcomes with or without appropriate randomization and allocation	0
	Groups dissimilar without influence on outcomes despite appropriate randomization and allocation	1
	Groups similar with appropriate randomization and allocation	2
15.	**Role of Co-Interventions**	
	Co-interventions were provided but were not similar in the majority of participants	0
	No co-interventions or similar co-interventions were provided in the majority of the participants	1
V.	**RANDOMIZATION**	
16.	**Method of Randomization**	
	Quasi randomized or poorly randomized or not described	0
	Adequate randomization (coin toss, drawing of balls of different colors, drawing of ballots)	1
	High quality randomization (Computer generated random sequence, pre-ordered sealed envelopes, sequentially ordered vials, telephone call, pre-ordered list of treatment assignments, etc.)	2
VI.	**ALLOCATION CONCEALMENT**	
17.	Concealed Treatment Allocation	
	Poor concealment of allocation (open enrollment) or inadequate description of concealment	0
	Concealment of allocation with borderline or good description of the process with probability of failure of concealment	1
	High quality concealment with strict controls (independent assignment without influence on the assignment sequence)	2
VII.	**BLINDING**	
18.	**Patient Blinding**	
	Patients not blinded	0
	Patients blinded adequately	1
19.	**Care Provider Blinding**	
	Care provider not blinded	0
	Care provider blinded adequately	1
20.	**Outcome Assessor Blinding**	
	Outcome assessor not blinded or was able to identify the groups	0
	Performed by a blinded independent assessor with inability to identify the assignment-based provider intervention (i.e., subcutaneous injection, intramuscular distant injection, difference in preparation or equipment use, numbness and weakness, etc.)	1
VIII.	**CONFLICTS OF INTEREST**	
21.	**Funding and Sponsorship**	
	Trial included industry employees	-3
	Industry employees involved; high levels of funding with remunerations by industry or an organization funded with conflicts	-3
	Industry or organizational funding with reimbursement of expenses with some involvement	0
	Industry or organization funding of expenses without involvement	1
	Funding by internal resources only with supporting entity unrelated to industry	2
	Governmental funding without conflict such as NIH, NHS, AHRQ	3
22.	**Conflicts of Interest**	
	None disclosed with potential implied conflict	0
	Marginally disclosed with potential conflict	1
	Well disclosed with minor conflicts	2
	Well disclosed with no conflicts	3
	Hidden conflicts with poor disclosure	–1
	Misleading disclosure with conflicts	–2
	Major impact related to conflicts	–3
	TOTAL	48

Source: 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 (53).

observational studies – the Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR) (55) was utilized as shown in Table 4.

Utilizing Cochrane review criteria, studies meeting the inclusion criteria with at least 8 of 12 criteria were considered high quality and 4 to 7 were considered moderate quality. Those meeting criteria of less than 4 were considered as low quality and were excluded.

Based on IPM - QRB criteria for randomized trials, manuscripts meeting the inclusion criteria scoring less than 16 were considered as low quality and were excluded, manuscripts with scores of 16 to 31 were considered as moderate quality, and manuscripts with scores of 32 to 48 were considered as high quality trials.

Based on IPM - QRBNR criteria for observational studies, manuscripts meeting the inclusion criteria scoring less than 16 were considered as low quality and were excluded, manuscripts with scores of 16 to 31 were considered as moderate quality, and manuscripts with scores of 32 to 48 were considered as high quality studies.

Table 4. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.*

I.	**STUDY DESIGN AND GUIDANCE REPORTING**	**Scoring**
1.	**STROBE or TREND Guidance**	
	Case Report/Case Series	0
	Study designed without any guidance	1
	Study designed with minimal criteria and reporting with or without guidance	2
	Study designed with moderately significant criteria or implies it was based on STROBE or TREND without clear description or the study was conducted before 2011 or similar criteria utilized with study conducted before 2011	3
	Designed with high level criteria or explicitly uses STROBE or TREND with identification of criteria or conducted prior to 2011	4
II.	**DESIGN FACTORS**	
2.	Study Design and Type	
	Case report or series (uncontrolled – longitudinal)	0
	Retrospective cohort or cross-sectional study	1
	Prospective cohort case-control study	2
	Prospective case control study	3
	Prospective, controlled, nonrandomized	4
3.	Setting/Physician	
	General setting with no specialty affiliation and general physician	0
	Specialty of anesthesia/PMR/neurology, etc.	1
	Interventional pain management with interventional pain management physician	2
4.	Imaging	
	Blind procedures	0
	Ultrasound	1
	CT	2
	Fluoro	3
5.	Sample Size	
	Less than 100 participants without appropriate sample size determination	0
	At least 100 participants in the study without appropriate sample size determination	1
	Sample size calculation with less than 50 patients in each group	2
	Appropriate sample size calculation with at least 50 patients in each group	3
	Appropriate sample size calculation with 100 patients in each group	4
6.	Statistical Methodology	
	None	0
	Some statistics	1

Table 4 (cont.). *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.*

	Appropriate	2
III.	**PATIENT FACTORS**	
7.	Inclusiveness of Population	
7a.	For epidural procedures:	
	Poorly identified mixed population	1
	Poorly identified mixed population with large sample (≥ 200)	2
	Clearly identified mixed population	3
	Disorders specific trials (i.e. well defined spinal stenosis and disc herniation, disorder specific, disc herniation or spinal stenosis or post surgery syndrome)	4
7b.	For facet or sacroiliac joint interventions:	
	No specific selection criteria	1
	No diagnostic blocks based on clinical symptomatology	2
	Selection with single diagnostic blocks	3
	Selection with placebo or dual diagnostic blocks	4
8.	Duration of Pain	
	Less than 3 months	0
	3 to 6 months	1
	> 6 months	2
9.	Previous Treatments	
	Conservative management including drug therapy, exercise therapy, physical therapy, etc.	
	Were not utilized	0
	Were utilized sporadically in some patients	1
	Were utilized in all patients	2
10.	Duration of Follow-up with Appropriate Interventions	
	Less than 3 months or less for epidural or facet joint procedures, etc., and 6 months for intradiscal procedures and implantables	1
	3-6 months for epidural or facet joint procedures, etc., or one year for intradiscal procedures or implantables	2
	6-12 months for epidurals or facet joint procedures, etc., and 2 years or longer for discal procedures and implantables	3
	18 months or longer for epidurals and facet joint procedures, etc., or 5 years or longer for discal procedures and implantables	4
IV.	**OUTCOMES**	
11.	Outcomes Assessment Criteria for Significant Improvement	
	No descriptions of outcomes OR < 20% change in pain rating or functional status	0
	Pain rating with a decrease of 2 or more points or more than 20% reduction OR functional status improvement of more than 20%	1
	Pain rating with decrease of ≥ 2 points AND ≥ 20% change or functional status improvement of ≥ 20%	2
	Pain rating with a decrease of 3 or more points or more than 50% reduction OR functional status improvement with a 50% or 40% reduction in disability score	2
	Significant improvement with pain and function ≥ 50% or 3 points and 40% reduction in disability scores	4
12.	Description of Drop Out Rate	
	No description despite reporting of incomplete data or more than 30% withdrawal	0
	Less than 30% withdrawal in one year in any group	1
	Less than 40% withdrawal at 2 years in any group	2

Table 4 (cont.). *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.*

13.	Similarity of Groups at Baseline for Important Prognostic Indicators	
	No groups or groups dissimilar with significant influence on outcomes	0
	Groups dissimilar without significant influence on outcomes	1
	Groups similar	2
14.	Role of Co-Interventions	
	Dissimilar co-interventions or similar co-interventions in some of the participants	1
	No co-interventions or similar co-interventions in majority of the participants	2
V.	**ASSIGNMENT**	
15.	Method of Assignment of Participants	
	Case report/case series or selective assignment based on outcomes or retrospective evaluation based on clinical criteria	1
	Prospective study with inclusion without specific criteria	2
	Retrospective method with inclusion of all participants or random selection of retrospective data	3
	Prospective, well-defined assignment of methodology and inclusion criteria (quasi randomization, matching, stratification, etc.)	4
VI.	CONFLICTS OF INTEREST	
16.	Funding and Sponsorship	
	Trial included industry employees with or without proper disclosure	-3
	Industry employees involved; high levels of funding with remunerations by industry or an organization funded with conflicts	-3
	Industry or organizational funding with reimbursement of expenses with some involvement or no information available	0
	Industry or organization funding of expenses without involvement	1
	Funding by internal resources only	2
	Governmental funding without conflict such as NIH, NHS, AHRQ	3
TOTAL MAXIMUM		48

Source: Manchikanti L, et al. Development of an interventional pain management specific instrument for methodologic quality assessment of non-randomized studies of interventional techniques. Pain Physician 2014; 17:E291-E317 (55).

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

If the literature search provided more than 2 diagnostic accuracy studies or randomized trials meeting the inclusion criteria and they were clinically homogenous for each modality, a meta-analysis was performed.

Qualitative (the direction of a treatment effect) and quantitative (the magnitude of a treatment effect) conclusions were evaluated. A random-effects meta-analysis to pool data was also used. For placebo-controlled trials, the net effect between 2 treatments was utilized. However, for active-controlled trials, the differences between baseline and at the follow-up period were utilized.

1.4.5 Outcome of the Studies

For diagnostic purposes, the outcome was based on pre-determined relief criteria and concordant response with short-acting and long-acting local anesthetic, or placebo for controlled diagnostic blocks (6-8,25-28,35,41).

In assessing therapeutic interventions, often a 2-point change in pain ratings on a scale of 0 to 10, or 20% improvement, has been commonly utilized in trials assessing general chronic pain, chronic musculoskeletal pain and chronic low back pain (54,55). However, this minimalist approach has been questioned and multiple descriptions of clinically meaningful improvement have been advocated. The differences have been described utilizing item response theory models (57) and health-related quality-of-life outcomes (58). Further, multiple approaches for estimating minimally clinically important differences have been described (59). Thus, it is advantageous to base outcomes on patient perspective (60,61) and clinically meaningful measures. Consequently, it also becomes evident that there are various differences between placebo control trials and active control trials in which outcomes are measured between groups for placebo control trials, whereas, these are measured between initial baseline

parameters compared to after treatment parameters. In interventional pain management, multiple trials have been published adapting rather clinically relevant outcome measures often much more robust than the previously recommended 10% or 20% improvement in assessing placebo control as well as active control trials (62-73).

Observational studies were determined to be positive if the intervention was effective; outcomes were reported at baseline and at 3, 6, and 12 months. If fewer than 5 randomized trials met the inclusion criteria for evidence synthesis for each region and assessed modality, then observational studies were included.

1.4.6 Summary Measures

For diagnostic accuracy studies, summary measures included ≥ 50% or ≥ 80% pain relief with the ability to perform previously painful movements concordant with the duration of local anesthetic.

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

1.4.7 Analysis of Evidence

The analysis of the evidence was performed based on modified grading of qualitative evidence developed with modification of multiple available criteria including those of the United States Preventive Task Force (USPSTF) criteria as illustrated in Table 5 (56).

The analysis was conducted using 5 levels of evidence ranging from Level I to Level V.

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.

2.0 Results

Figure 1 shows the flow diagram of study selection.

2.1 Diagnosis of Sacroiliac Joint Pain

There were multiple studies of diagnostic sacroiliac joint injections reporting accuracy and outcomes (25-27,34,35,37,39,41,41,74-110). Of these, 11 studies (25-28,34,35,41,42,89,93,101) assessed prevalence, 8 studies evaluated pain referral patterns (39,94-99), and 7 studies (37,81-84,87,88) looked at factors influencing the diagnosis. Table 6 shows the reasons for excluding select studies. Additional information was requested from the authors of multiple manuscripts (25,28,37), but none responded.

2.1.1 Methodological Quality Assessment

A methodological quality assessment of prevalence or diagnostic accuracy studies meeting inclusion criteria was carried out utilizing QAREL criteria as shown in Table 7. Studies achieving 4 of 12 or higher scores were included. Scores of 8 to 12 were considered to be high

Table 5. *Modified grading of qualitative evidence.*

Level I	Evidence obtained from multiple relevant high quality randomized controlled trials or Evidence obtained from multiple high quality diagnostic accuracy studies
Level II	Evidence obtained from at least one relevant high quality randomized controlled trial or multiple relevant moderate or low quality randomized controlled trials or Evidence obtained from at least one high quality diagnostic accuracy study or multiple moderate or low quality diagnostic accuracy studies
Level III	Evidence obtained from at least one relevant moderate or low quality randomized controlled trial study or Evidence obtained from at least one relevant high quality non-randomized trial or observational study with multiple moderate or low quality observational studies or Evidence obtained from at least one moderate quality diagnostic accuracy study in addition to low quality studies
Level IV	Evidence obtained from multiple moderate or low quality relevant observational studies or Evidence obtained from multiple relevant low quality diagnostic accuracy studies
Level V	Opinion or consensus of large group of clinicians and/or scientists.

Source: Manchikanti L, Falco FJE, Benyamin RM, Kaye AD, Boswell MV, Hirsch JA. A modified approach to grading of evidence. Pain Physician 2014; 17:E319-E325 (56).

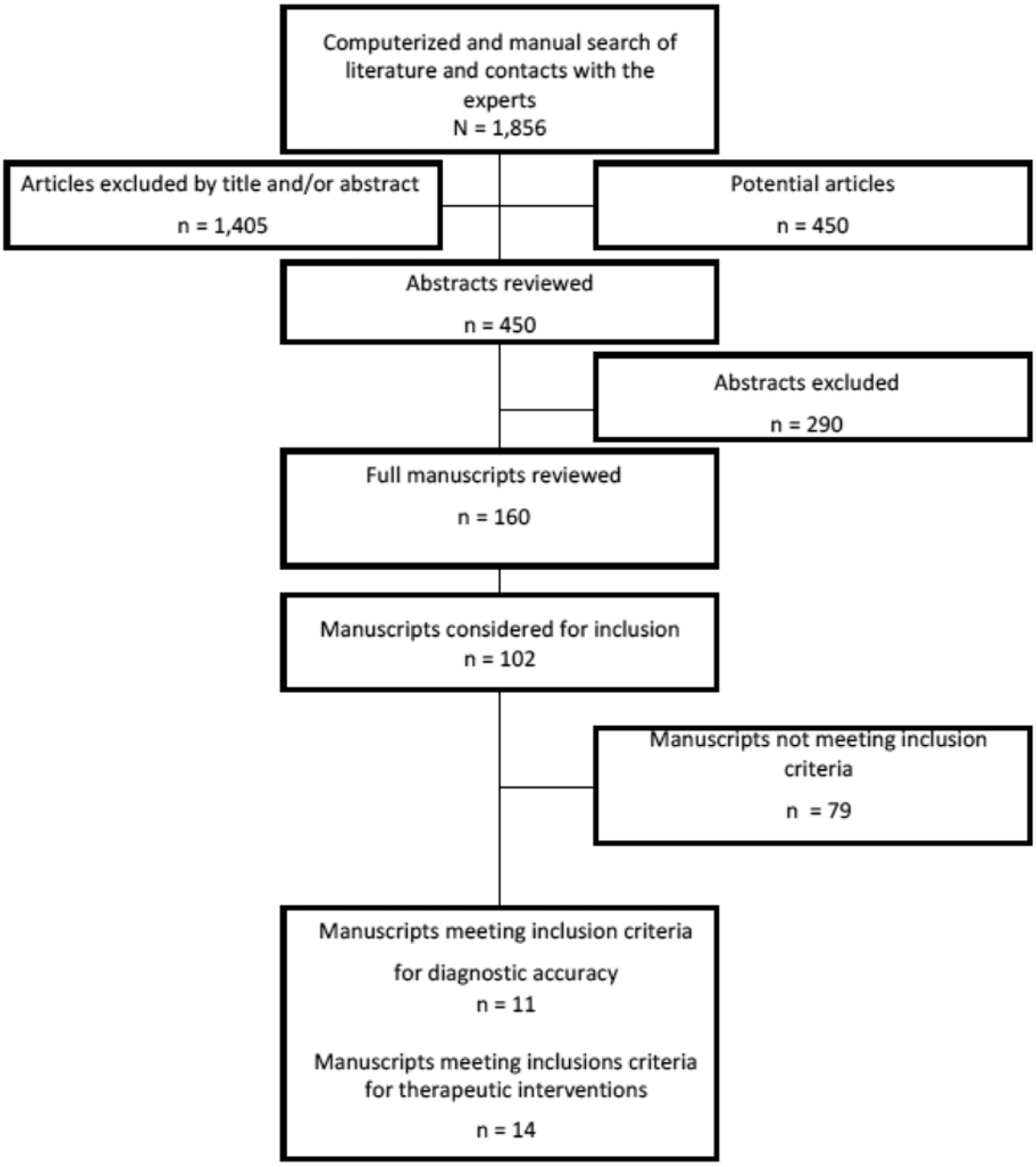

Fig. 1. *Flow diagram illustrating published literature evaluating the diagnosis and therapy of sacroiliac joint pain by sacroiliac joint interventions.*

Table 6. *List of select excluded diagnostic studies and reasons for exclusion.*

Manuscript Author(s)	Reason for Exclusion
DePalma et al (75)	This study was a retrospective evaluation of 28 fusion cases from a larger sample of 156 patients (28) with 12 patients suspected of sacroiliac joint pain. The study sample is extremely small, consequently, it was excluded.
DePalma et al (77)	This was a study of patients with or without surgical discectomy with only 11 patients being included who had surgical discectomy with 0% prevalence of sacroiliac joint pain in patients with surgical discectomy and 18.1% in patients without surgery.
Shemshaki et al (78)	This was a retrospective chart review without appropriate information. The details of the diagnostic blocks were not provided.
Berthelot et al (79)	This was a review article rather than a diagnostic accuracy study.
Klauser et al (80)	This study evaluated the feasibility of ultrasound-guided sacroiliac joint injection with landmarks at 2 different levels.
Maigne et al (85)	Inclusion criteria was of patients suffering with 7 weeks of pain pattern compatible with sacroiliac joint pain – acute pain.
Broadhurst & Bond (86)	In this double-blind trial of 60 patients, the authors sought to determine the sensitivity and specificity of 3 commonly used pain provocation tests for sacroiliac joint dysfunction. This study also injected large volumes of solutions without determination of prevalence.
Dreyfuss et al (90)	An evaluation of the ability of single site, single depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex showed significant anatomic limitations with single site, single depth lateral branch injections rendering them physiologically ineffective on a consistent basis.
Dreyfuss et al (91)	The evaluation of the ability of multi-site, multi-depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex showed that there is physiologic evidence that the intraarticular portion of the sacroiliac joint is innervated from both ventral and dorsal sources.
Harmon & Alexiev (102)	Sonoanatomy and injection technique of iliolumbar ligament were evaluated.
Gupta (103)	An alternative method with a double needle technique for performing difficult sacroiliac joint injections was evaluated.
Hart et al (104)	Intraarticular injections of the sacroiliac joint were evaluated after lumbar stabilization as a therapeutic modality.
Migliore et al (105)	A technical contribution for ultrasound-guided injection of sacroiliac joints was evaluated.
Streitparth et al (106)	Evaluation included image-guided spinal injection procedures in open high field MRI with vertical field orientation studying its feasibility and technical features.
Sadreddini et al (107)	An evaluation of unguided sacroiliac joint injections showing effectiveness.
Borowksy & Fagen (108)	This study evaluated the sources of sacroiliac region pain to gain insight into intraarticular injection compared to a combination of intraarticular and periarticular injection rather than determining prevalence. The prevalence estimates were not available. Only outcomes were available.
Murakami et al (109)	This study was a comparative evaluation of periarticular and intraarticular lidocaine injections for sacroiliac joint pain. Did not assess diagnostic accuracy.

quality, 4 to 7 were considered to be moderate quality, and studies scoring less than 4 were considered to be of poor quality and excluded.

There were 11 studies evaluating diagnostic accuracy which met inclusion criteria (25-28,34,35,41,42,89,93,101). All the studies were assessed by 3 authors. All conflicts were resolved by 3 authors (TTS, LM, JAH). All the studies were considered to be of high quality.

Table 8 illustrates the characteristics of prevalence of diagnostic accuracy studies considered for inclusion. There were 2 studies utilizing a single block with 75% pain relief (41,42) and one study utilizing 90% pain relief (27). Among studies utilizing dual blocks, there was one study with 70% relief as the cutoff threshold (35), 4 studies with 75% relief as the cutoff threshold (28,34,93,101), and 3 studies with 80% pain relief as the cutoff threshold (25,26,89). Table 9 shows the characteristics of studies assessing the factors influencing a diagnosis.

Table 7. *Assessment of methodological quality of diagnostic accuracy studies utilizing quality appraisal of diagnostic reliability checklist.*

	Bokov et al (25)	Manchikanti et al (26)	Pang et al (27)	Maigne et al (34)	Irwin et al (35)	DePalma et al (28)	Schwarzer et al (41)	Maigne & Planchon (42)	Mitchell et al (89)	Liliang et al (93)	Liliang et al (101)
1. Was the test evaluated in a spectrum of subjects representative of patients who would normally receive the test in clinical practice?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Was the test performed by examiners representative of those who would normally perform the test in practice?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Were raters blinded to the reference standard for the target disorder being evaluated?	N	N	N	N	N	N	N	N	N	N	N
4. Were raters blinded to the findings of other raters during the study?	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
5. Were raters blinded to their own prior outcomes of the test under evaluation?	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
6. Were raters blinded to clinical information that may have influenced the test outcome?	Y	Y	Y	U	N	N	U	U	N	N	N
7. Were raters blinded to additional cues, not intended to form part of the diagnostic test procedure?	N	N	N	N	N	N	N	N	N	N	N
8. Was the order in which raters examined subjects varied?	N	N	N	N	N	N	N	U	N	N	N
9. Were appropriate statistical measures of agreement used?	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
10. Was the application and interpretation of the test appropriate?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
11. Was the time interval between measurements suitable in relation to the stability of the variable being measured?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
12. If there were dropouts from the study, was this less than 20% of the sample.	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
TOTAL	8/12	8/12	8/12	8/12	8/12	8/12	8/12	8/12	8/12	8/12	8/12

Y = Yes; N = No; U = Unclear; N/A = Not Applicable

Source: Lucas NP, Macaskill P, Irwing L, Bogduk N. The development of a quality appraisal tool for studies of diagnostic reliability (QAREL). *J Clin Epidemiol* 2010; 63:854-861 (16).

Table 8. *Summary characteristics of studies utilizing ≥ 50% relief for single and dual blocks.*

Study	Participants/Intervention	Outcome Measures	Result(s)/Comments
Schwarzer et al (41) Single block	43 consecutive patients with chronic low back pain maximal below L5/S1 were investigated. Intraarticular injection of 1 mL of 2% lignocaine	Criterion standard: 75% pain relief A positive response was classed as definite if there was a 75% or greater reduction of pain over the sacroiliac joint and buttock.	Prevalence = 30% Well performed study, but with a single block which may result in lesser prevalence with a certain false-positive rate with dual blocks.
Maigne & Planchon (42) Single block	This was a prospective series of 40 patients with persistent low back pain after technically successful fusion who received a sacroiliac anesthetic block under fluoroscopic control. Intraarticular injection with 2 mL of 2% lidocaine	Criterion standard: 75% or more pain relief post-injection	Prevalence = 35% The study was a single block study with a 35% prevalence. Further, this study showed that a past history of posterior iliac bone graft harvesting had no significant value.
Pang et al (27) Single block	In this prospective evaluation, 104 consecutive adult patients who underwent spinal pain mapping were examined and analyzed. They found in this group a total of 87% of the patients with a diagnosed pain source and 13% without a source. In this evaluation, sacroiliac joint pain was identified in 10% of the patients from the total sample. Intraarticular injection with 2 mL of 2% lidocaine	Criterion standard: 90% pain relief	Prevalence = 10% of total sample Even though this is a well-performed study in a large number of patients, it is not known the number of patients included for sacroiliac joint pain, thus we do not know the true prevalence of sacroiliac joint pain even with a single block.
DePalma et al (28) Dual blocks	31 of 156 patients undergoing diagnostic procedures including discography and dual diagnostic facet joint blocks received intraarticular sacroiliac joint injections to evaluate the source of chronic low back pain based on age. A screening block was performed with 1% lidocaine and a confirmatory block was performed with 0.5% bupivacaine. Intraarticular injection of 0.5 mL of anesthetic, 1% lidocaine for first block with 0.5% bupivacaine for the second	Criterion standard: At least 75% pain relief for 2 hours for lidocaine and 8 hours for bupivacaine	Prevalence = 18.2% False-positive rate = NA This is a large study leading to multiple publications of subcategory assessment. This study showed a prevalence of 18.2%; however, the authors have not calculated the false-positive rate in this study.
Maigne et al (34) Dual blocks	54 patients aged 18-75 with chronic unilateral LBP with or without radiation to the posterior thigh for > 50 days (median 4.2 months). Patients had failed epidural or lumbar facet injections. Successful blockade of the sacroiliac joint in 54 patients. A screening block was done with 2% lidocaine and a confirmatory block was performed with bupivacaine 0.5%. Greater than 75% relief was considered a positive block.	Criterion standard: At least 75% relief was considered a positive block	Prevalence = 18.5% False-positive rate = 20% The study questions the accuracy of some of the presumed sacroiliac pain provocation tests.
Irwin et al (35) Dual blocks	158 patients underwent sacroiliac joint injections with average duration of symptoms being 34 months. Patients failed conservative modalities prior to injection therapy. The fluoroscopically guided contrast medium-enhanced sacroiliac joint injections were performed initially with 2 mL of 2% lidocaine for the first injection, followed by 2 mL of 0.25% bupivacaine, a local anesthetic, for the confirmatory injection. A patient was required to have at least 70% reduction of familiar painful symptoms after the initial injection for 3 or 4 hours for a positive response.	Criterion standard: At least 70% reduction of familiar painful symptoms after the initial injection for 3 or 4 hours for positive response	Prevalence = 26.6% Estimated false-positive rate = 53.8% The largest study to date utilizing dual blocks yielding prevalence of 26.6% with an estimated false-positive rate of 53.8%.

Table 8 (cont.). *Summary characteristics of studies utilizing ≥ 50% relief for single and dual blocks.*

Study	Participants/Intervention	Outcome Measures	Result(s)/Comments
Liliang et al (93) Dual blocks	52 of the 130 patients who underwent lumbar or lumbosacral fusion were evaluated for sacroiliac joint pain with positive findings with 3 of the provocative tests for sacroiliac joint pain. They were selected to receive dual diagnostic blocks. Among the 52 patients, 20 were considered to have sacroiliac joint pain on the basis of 2 positive responses to diagnostic blocks with 75% as the criterion standard. Intraarticular injection with either lidocaine (2%) for initial block, followed by bupivacaine (0.5%) for subsequent block, 1 mL, mixed with 40 mg of triamcinolone acetonide	Criterion standard: At least 75% pain relief for 1 to 4 hours following the sacroiliac joint blocks	Prevalence = 40% False-positive rate = 26% With 75% pain relief, the results appear to be highly appropriate in highly select population.
Liliang et al (101) Dual blocks	In this prospective assessment, 150 patients were evaluated for sacroiliac joint pain with pain of at least 3 months without radiculopathy. Dual sacroiliac joint blocks were performed for the diagnosis of sacroiliac joint pain. Patients who had 2 or more consecutive positive responses to the sacroiliac joint blocks were considered to have sacroiliac joint pain. A positive response was defined as 75% or greater reduction of pain for 1 to 8 hours after the blocks. Patients without 75% relief for 1 to 8 hours were considered not to have sacroiliac joint pain.	Criterion standard: At least 75% pain relief lasting for 1 to 8 hours	Prevalence: 26% False-positive rate: NA
Bokov et al (25) Dual blocks	In this study a total of 83 patients with axial pain and noncompressive syndromes resistant to repeated course of conservative treatment were assessed. Dual blocks were performed with intraarticular injection of lidocaine 2% for the initial block followed by bupivacaine 0.5% for the second block in patients who were positive to the first block.	Criterion standard: At least 80% pain relief	Prevalence = 7.2% This is one of the studies assessing overall contribution of structures to chronic low back pain without radicular pain yielding a low prevalence of sacroiliac joint pain.
Manchikanti et al (26) Dual blocks	120 patients (age 18-90) presenting to the clinic with > 6 months of low back pain and no structural basis for the pain by radiographic imaging. 20 patients were evaluated for SI joint pain. All patients had facet blocks. Those not responding who fit the criteria had double injection sacroiliac joint blocks. The screening block was done with 2% lidocaine and the confirmatory block was performed using 0.5% bupivacaine.	Criterion standard: At least 80% pain relief with ability to perform previously painful movements with concordant relief based on the local anesthetic injected	Prevalence = 10% False-positive rate = 22% The study illustrates a low proportion of sacroiliac joint pain in 10% of the patients with suspected sacroiliac joint pain.
Mitchell et al (89) Dual blocks	This retrospective study included assessment of 1,060 patients with complete data available, with chronic pain over the sacroiliac joint region utilized in a consecutive series of sacroiliac joint injections over a 3½ year period. The fluoroscopically guided contrast medium sacroiliac joint injections were performed utilizing 1.5 mL of 0.5% bupivacaine or 1.5 mL of 2% lidocaine for control blocks. A second comparative block in positive patients was employed at least 2 weeks after the initial diagnostic injection. A positive response was considered as at least 80% pain relief lasting longer than 2 hours.	At least 80% reduction of pain lasting over 2 hours.	Prevalence = NA False-positive rate = 12.5% Sensitivity = 98.3% (95% CI, 95.80% to 99.54%) Specificity = 34.6% (95% CI, 21.97% to 49.09%) Overall accuracy of diagnostic blocks 87.03% Of 1,060 patients receiving the first diagnostic block, 680 or 64% recorded a positive result; however, only 293 patients underwent control blocks of which 271 had a positive result and 22 had a negative result yielding positive results in 237 in the positive group and 4 of 22 in the negative group.

NA = Not available

Table 9. *Summary characteristics of studies influencing the diagnosis of sacroiliac joint pain.*

Study	Participants/Intervention	Outcome Measures	Result(s)/Comments
Dreyfuss et al (81)	This prospective study included 85 patients based on historical data with 12 tests performed by 2 examiners. 90% or more relief was considered a positive response, and less than 90% relief was considered a negative response. Intraarticular injection of 1.5 mL of 2% lignocaine and 0.5 mL of Celestone® Soluspan® (betamethasone) unless a firm endpoint was reached before this volume.	90% or more relief was considered a positive response, and less than 90% relief was considered a negative response.	The results showed fairly high proportion of patients with sacroiliac joint pain due to strict selection criteria. However, there were no historical features with any of the 12 sacroiliac joint tests and any combination of these 12 tests demonstrating worthwhile diagnostic value.
Slipman et al (82)	50 consecutive patients meeting a pre-established criteria from a chronic spine practice. Intraarticular injection of 1 mL of betamethasone sodium phosphate and acetate suspension, 60 mg per mL, 3 mL of 1% lidocaine hydrochloride, or 3 mL of 2% lidocaine hydrochloride. Among the patients with positive response, there were 27 patients with negative scans and 4 patients with positive scans.	A reduction of the VAS rating by at least 80% was considered a positive response to sacroiliac joint block.	This study shows low sensitivity and high specificity of nuclear imaging in the evaluation of sacroiliac joint syndrome.
Laslett et al (83)	Prospective evaluation of 48 patients satisfying inclusion criteria from a total of 62 patients agreeing to participate and were evaluated. Patients with buttock pain, with or without lumbar or lower extremity symptoms were included. Intraarticular injection of 1 mL of 2% lignocaine. All patients underwent provocation testing.	At least 80% pain relief	The authors concluded that composites of provocation sacroiliac joint tests are of value in clinical diagnosis of symptomatic sacroiliac joint pain when 3 or more of the 6 tests were positive, with the greatest applicability when 4 tests were positive. When none of the provocation tests provoked familiar pain, the sacroiliac joint can be ruled out a s a source of current low back pain.
Young et al (84)	A prospective evaluation of 81 patients with chronic lumbopelvic pain to evaluate the correlation of the clinical examination characteristics with 3 sources of chronic low back pain with diagnostic injections as criterion standard. 57 patients were suspected to have sacroiliac joint pain. Intraarticular injection with 1.5 mL of lidocaine	At least 80% pain relief post injection	The authors illustrate the positive correlation with strongest relationships between sacroiliac joint pain and 3 or more positive pain provocation tests.
DePalma et al (37)	Retrospective evaluation of 27 motor vehicle collision-induced chronic low back pain patients undergoing multiple types of diagnostic interventions Intraarticular injection of 0.5 mL of anesthetic, 1% lidocaine for first block with 0.5% bupivacaine for the second	Diagnostic blockade of sacroiliac joints was deemed positive if the patient's index pain was relieved by 75% or greater after injection of each anesthetic	This is a small study with a subcategory analysis of patients involved in motor vehicle coalition showing the same prevalence as overall prevalence of 18.2%.
van der Wurff et al (88)	Total number of 140 patients with chronic low back pain visiting a pain clinic in the Netherlands; 60 patients entered the study. The fluoroscopically guided contrast medium-enhanced sacroiliac joint injections were performed initially with 2 mL of 2% lidocaine and then with 0.25% bupivacaine.	A reduction in the patient's characteristic pain of 50% or more on the VAS remaining for at least one hour for lidocaine or 4 hours for bupivacaine was considered as positive. When a patient showed a VAS reduction after both intraarticular sacroiliac joint blocks, this was considered a positive response. Any other outcome was considered a negative response.	Well-performed study in a large proportion of patients with a weakness of 50% pain relief, thus maybe resulting in higher prevalence rate of 38%.

Table 9 (cont.). *Summary characteristics of studies influencing the diagnosis of sacroiliac joint pain.*

Study	Participants/Intervention	Outcome Measures	Result(s)/Comments
Laslett et al (87)	48 patients received an initial sacroiliac joint diagnostic injection, derived from 62 patients with buttock pain with or without lumbar or lower extremity symptoms. Intraarticular injection of less than 1.5 mL of local anesthetic lidocaine for initial block followed by bupivacaine for the confirmatory block	At least 80% reduction in pain for the duration of anesthetic effect	The authors show the prevalence of 25.6% in a select group of patients with clinical reasoning in addition to provocation testing being superior to provocation testing alone.

2.1.2 Meta-Analysis

Even though there were 11 studies evaluating diagnostic accuracy meeting the inclusion criteria and all of them were considered to be high quality, each study utilized a variable technique without homogeneity in the overall selection of patients, performance of the procedure, and assessment. Consequently, a meta-analysis was not feasible.

2.1.3 Analysis of Evidence

The evidence was synthesized based on the relief criteria when sacroiliac joint injections were performed. Table 10 shows the results of prevalence data of sacroiliac joint pain by controlled diagnostic blocks and false-positive rates with a single block when available.

The evidence for diagnostic accuracy assessing the prevalence of sacroiliac joint pain based on controlled diagnostic blocks is Level II, with at least 70% pain relief as the criterion standard with a variable prevalence of 10% to 40.4% with a false-positive rate of 22% or 26%. The prevalence in large studies of 158 patients (35) and 150 patients (101) was 26%.

The evidence for single blocks supported by 4 studies (27,41,42,89) with at least a 75% pain relief criterion standard is Level III with variable prevalence of 10% to 64% with a relatively small number of patients included in 3 studies with lower prevalence and a large study yielding 64% prevalence, with internal inconsistency.

The study by Mitchell et al (89) shows the necessity of diagnostic blocks. It also shows a low false-negative rate of only 4 of 22 patients who were negative for the first block who were then positive for the second block.

2.2 Therapeutic Sacroiliac Joint Interventions

Figure 1 shows a flow diagram of the study selection of therapeutic intervention trials and studies in addition to diagnostic accuracy studies. There were 68 studies considered for inclusion (89,99-165). Of these, 6 RCTs (113,117,119,121,130,158) and 8 observational studies (99,101,108,131,149,152,153,165) assessing the various types of nonoperative intervention therapies in managing sacroiliac joint pain met inclusion criteria. The remaining studies were excluded with description of select studies as shown in Table 11.

There were 6 randomized trials (113,117,119,121,130,158) of which 2 evaluated intraarticular injections (119,130), 2 evaluated periarticular injections (113,121), and 2 evaluated neurolytic procedures (117,158).

There were 8 observational studies (99,101,108,131,149,152,153,165), of which 3 evaluated intraarticular injections (99,101,108), one evaluated blockade of the nerve supply (108), and 5 evaluated neurolytic procedures (131,149,152,153,165).

2.2.1 Methodological Quality Assessment

A methodological quality assessment of the RCTs meeting inclusion criteria was carried out utilizing Cochrane review criteria and IPM - QRB for randomized trials as shown in Tables 12 and 13; IPM – QRBNR for nonrandomized studies as shown in Table 14.

Utilizing Cochrane review criteria, studies meeting the inclusion criteria with at least 8 of 12 criteria were considered high quality and 4 to 7 were considered moderate quality. Those meeting criteria of less than 4 were considered as low quality and were excluded.

Based on IPM - QRB criteria for randomized trials and IPM - QRBNR for observational studies, the studies meeting the inclusion criteria that scored less than 16 were considered as low quality and were excluded; manuscripts meeting scores ranging from 16 to 31 were considered as moderate quality; and those above 32 were considered as high quality.

All 6 trials were considered high quality based on Co-

Table 10. *Data of prevalence of sacroiliac joint pain by controlled diagnostic blocks.*

Study	% Relief Used	Methodological Criteria Score	Number of Patients	Prevalence Estimates	False-Positive Rate
SINGLE BLOCK STUDIES					
Schwarzer et al (41)	75%	9/12	43	30%	---
Maigne & Planchon (42)	75%	8/12	40	35%	---
Pang et al (27)	90%	8/12	NA	10%	---
Mitchell et al (89)	80%	8/12	1,060	64%	---
DUAL BLOCKS STUDIES					
Irwin et al (35)	70%	9/12	158	26.6%	NA
DePalma et al (28)	75%	8/12	31	18.2%	NA
Maigne et al (34)	75%	9/12	54	18.5%	20%
Liliang et al (93)	75%	8/12	52	40.4%	26%
Liliang et al (101)	75%	8/12	150	26%	NA
Bokov et al (25)	80%	8/12	NA	7.2%	NA
Manchikanti et al (26)	80%	8/12	20	10%	22%
Mitchell et al (89)	80%	8/12	271	NA	12.5%

NA = Not available

Table 11. *Description of select randomized trials and observational studies excluded from methodological quality assessment*

Manuscript Author(s)	Reason for Exclusion
Standford & Burnham (89)	This study evaluated whether it was useful to repeat sacroiliac joint provocative tests post-block in 34 patients.
Dreyfuss et al (90)	Evaluated the ability of single site, single depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex.
Dreyfuss et al (91)	Evaluated the ability of multi-site, multi-depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex.
Kennedy et al (100)	This was a review article evaluating sacroiliac and lumbar zygapophyseal joint corticosteroid injections without original data.
Gupta (103)	Described an alternative method using a double needle technique for performing difficult sacroiliac joint injections.
Hart et al (104)	Described short-term follow-up of sacroiliac joint steroid injections after spinal fusion.
Sadreddini et al (107)	This study evaluated non-image-guided sacroiliac joint injections.
Murakami et al (109)	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.
Maugars et al (110)	The study evaluated effectiveness of corticosteroid injections of the sacroiliac joint in patients with zero negative spondyloarthropathy.
Maugars et al (111)	The study assessed the efficacy of sacroiliac joint corticosteroid injections in spondyloarthropathies in a randomized, double-blind design.
Dussault et al (112)	This was a retrospective study evaluating fluoroscopically guided sacroiliac joint injections.
Chakraverty & Dias (114)	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.
Stone & Bartynski (115)	Review article describing the treatment of facet and sacroiliac joint arthropathy with steroid injections and radiofrequency ablation.
Fritz et al (116)	This study evaluated MRI-guided steroid injections of the sacroiliac joints in children with refractory enthesitis-related arthritis.

Table 11 (cont). *Description of select randomized trials and observational studies excluded from methodological quality assessment*

Manuscript Author(s)	Reason for Exclusion
Cohen & Abdi (118)	The study evaluated lateral branch radiofrequency denervation as a treatment for sacroiliac joint pain in 18 patients.
Lee et al (120)	This is a small study assessing botulinum toxin compared to a mixture of steroid and local anesthetic as a treatment for sacroiliac joint pain with a total of 39 patients with less than 25 patients in each group for observational study.
Günaydin et al (122)	Small observational study evaluating MRI-guided sacroiliac joint injections for spondyloarthropathy.
Slipman et al (125)	Retrospective evaluation of therapeutic sacroiliac joint injections in 31 patients.
Braun et al (126)	This was an evaluation of 30 patients with ankylosing spondylitis or undifferentiated spondyloarthropathy with sacroiliitis.
Bollow et al (127)	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.
Visser et al (132)	The authors studied 51 patients using a single blinded randomized controlled design to assess the short-term therapeutic efficacy of physiotherapy, manual therapy, and intraarticular injection with local anesthetic and corticosteroids. This was a single-blinded study with 15 patients in physical therapy, 18 patients in manual therapy, and 18 patients in intraarticular injection group with short-term follow-up of 6 and 12 weeks.
Buchowski et al (138)	The authors evaluated functional and radiographic outcomes of sacroiliac arthrodesis in 20 patients. Diagnoses were made using intraarticular sacroiliac joint injections under fluoroscopic guidance.
Amoretti et al (134)	This manuscript described computed axial tomography-guided fixation of sacroiliac joint disruption.
Büker et al (142)	This study assessed a total of 72 patients; however, there were only 22 patients in the fusion group and 50 patients in the non-fusion group, even though follow-up was of long-term, basically showing patients in the non-fusion group were superior to the fusion group.
Speldewinde (154)	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.
Ferrante et al (155)	The authors studied 33 patients who underwent 50 intraarticular sacroiliac joint radiofrequency denervation procedures.
Vallejo et al (156)	This study only included 22 patients receiving radiofrequency neurotomy.
Burnham & Yasui (157)	The authors evaluated an alternate method of radiofrequency neurotomy (bipolar lateral branch denervation) of the sacroiliac joint in a pilot study of 9 patients.
Buijs et al (159)	The 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.
Kapural et al (160)	This study evaluated the records of 27 patients with sacroiliac joint pain who underwent cooled radiofrequency denervation of L5-S3.
Yin et al (161)	Retrospective evaluation of sensory stimulation-guided sacroiliac joint radiofrequency neurotomy.
Karaman et al (162)	The study evaluated the effectiveness of cooled radiofrequency in a total of 15 patients in a non-randomized observational study.

chrane scores of 8 or higher (113,117,119,121,130,158).

Of the 6 trials, 3 trials were considered high quality (117,119,158) based on IPM - QRB scores and 3 trials were considered moderate quality (113,121,130).

2.2.2 Study Characteristics

Table 15 illustrates the study characteristics of the included randomized trials and observational studies assessing intraarticular sacroiliac joint injections (99,101,108,119,130).

Table 16 illustrates the study characteristics of the included randomized trials and observational studies assessing periarticular sacroiliac joint injections (108,113,121).

Table 17 shows the results of randomized trials and observational studies assessing the effectiveness of radiofrequency lesioning of the sacroiliac joint (117,131,149,152,153,158,165).

2.2.3 Meta-Analysis

Due to the high variability among the trials without clinical homogeneity, a meta-analysis was not feasible.

Table 12. *Methodological quality assessment of randomized trials utilizing Cochrane review criteria.*

	Luukkainen et al (113)	Patel et al (117)	Kim et al (119)	Luukkainen et al (121)	Jee et al (130)	Cohen et al (158)
Randomization adequate	Y	Y	Y	Y	Y	Y
Concealed treatment allocation	N	Y	Y	N	N	Y
Patient blinded	Y	Y	Y	Y	N	Y
Care provider blinded	N	N	N	N	N	N
Outcome assessor blinded	Y	Y	Y	Y	N	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	10/12	11/12	11/12	10/12	8/12	11/12

Y = yes; N = no; U = undecided

Source: Furlan AD, Pennick V, Bombardier C, van Tulder Ml; 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 (53).

2.2.4 Study Characteristics

2.2.4.1 Intraarticular Injections

There were a total of 5 studies (Table 18) performed evaluating intraarticular injections (99,101,108,119,130). In an active-controlled trial, Jee et al (130) assessed the accuracy of ultrasound-guided versus fluoroscopically guided sacroiliac joint intraarticular injections for noninflammatory sacroiliac joint dysfunction; they also assessed its effectiveness. They allocated 60 patients to each group and analyzed 55 patients at the end of the study period. Effectiveness was shown in a significant proportion of patients at 12-week follow-up. The study by Kim et al (119) compared prolotherapy to steroid injections. The authors (119) 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 (99) reported positive results with intraarticular injections performed appropriately under fluoroscopy. Liliang et al (101) showed short-term effectiveness for intraarticular steroid injections. Borowsky and Fagen (108) compared 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 (111) in patients with spondyloarthropathy. In addition, Murakami et al (109), in a short-term follow-up, showed the superiority of periarticular injections over intraarticular injections.

2.2.4.2 Periarticular Injection

As shown in Table 19, periarticular injections were evaluated in 3 studies (108,113,121). The study by Borowsky and Fagen (108) retrospectively compared intraarticular injections to a combination of intraarticular and periarticular injections. Borowsky and Fagen (108) 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 (113,121). Both studies showed periarticular injection of local anesthetic with steroids to be superior, though only in a short-term follow-up. Murakami et al (109) also showed superiority for periarticular injections over intraarticular injections.

2.2.4.3 Conventional Radiofrequency Neurotomy

There were 4 studies assessing conventional radiofrequency neurotomy (131,149,152,153). The first

Table 13. *Methodological quality assessment of randomized trials utilizing ASIPP IPM – QRB.*

		Luukkainen et al (113)	Patel et al (117)	Kim et al (119)	Luukkainen et al (121)	Jee et al (130)	Cohen et al (158)
I.	TRIAL DESIGN AND GUIDANCE REPORTING						
1.	CONSORT or SPIRIT	1	2	2	0	2	3
II.	DESIGN FACTORS						
2.	Type and Design of Trial	2	2	2	2	2	2
3.	Setting/Physician	2	2	2	1	1	3
4.	Imaging	0	3	3	0	2	3
5.	Sample Size	1	2	1	0	3	2
6.	Statistical Methodology	1	1	1	1	1	1
III.	PATIENT FACTORS						
7.	Inclusiveness of Population						
	• For facet or sacroiliac joint interventions:	0	2	2	0	2	2
8.	Duration of Pain	1	2	1	1	1	2
9.	Previous Treatments	0	0	0	0	0	2
10.	Duration of Follow-up with Appropriate Interventions	0	2	2	0	0	1
IV.	OUTCOMES						
11.	Outcomes Assessment Criteria for Significant Improvement	1	4	2	2	2	4
12.	Analysis of all Randomized Participants in the Groups	1	1	1	1	1	1
13.	Description of Drop Out Rate	1	2	2	2	2	2
14.	Similarity of Groups at Baseline for Important Prognostic Indicators	1	1	2	2	2	2
15.	Role of Co-Interventions	0	1	1	1	1	1
V.	RANDOMIZATION						
16.	Method of Randomization	1	1	2	1	2	2
VI.	ALLOCATION CONCEALMENT						
17.	Concealed Treatment Allocation	1	2	1	0	0	2
VII.	BLINDING						
18.	Patient Blinding	1	1	1	1	0	1
19.	Care Provider Blinding	0	0	0	0	0	0
20.	Outcome Assessor Blinding	0	1	1	1	0	0
VIII.	CONFLICTS OF INTEREST						
21.	Funding and Sponsorship	0	1	2	2	2	3
22.	Conflicts of Interest	2	2	2	2	2	2
TOTAL		17	35	33	20	28	41

Source: Manchikanti L, et al. Assessment of methodologic quality of randomized trials of interventional techniques: Development of an interventional pain management specific instrument. *Pain Physician* 2014; 17:E263-E290 (54).

study by Cohen et al (131), as shown in Table 20, was a retrospective evaluation of 77 patients. The second study was by Cheng et al (152) comparing traditional radiofrequency neurotomy and cooled radiofrequency neurotomy. Cohen et al (131) showed positive results in their retrospective assessment of conventional radiofrequency with 52% of the patients showing at least a 50% improvement at 6 month follow-up. They also showed that the patients who underwent cooled radiofrequency showed superior improvement. Cheng et al (152) compared conventional radiofrequency with cooled radiofrequency. They reported a 50% improvement with conventional radiofrequency at 3 months and 40% improvement at 6-month follow-up. Similar

Table 14. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM - QRBNR.*

		Hawkins & Schofferman (99)	Cohen et al (131)	Liliang et al (101)	Borowsky & Fagen (108)	Schmidt et al (149)	Cheng et al (152)	Mitchell et al (153)	Stelzer et al (165)
I.	STUDY DESIGN AND GUIDANCE REPORTING								
1.	STROBE or TREND GUIDANCE	1	2	2	2	1	2	3	1
II.	DESIGN FACTORS								
2.	Study Design and Type	1	1	1	1	0	1	3	0
3.	Setting/Physician	2	2	2	2	2	2	2	2
4.	Imaging	3	3	3	3	3	3	3	3
5.	Sample Size	1	0	0	1	1	1	1	0
6.	Statistical Methodology	0	2	0	2	0	2	2	0
III.	PATIENT FACTORS								
7.	Inclusiveness of Population								
	• For facet or sacroiliac joint interventions:	2	2	2	0	2	2	4	2
8.	Duration of Pain	2	2	1	1	0	1	2	1
9.	Previous Treatments	0	1	2	2	0	2	2	0
10.	Duration of Follow-up with Appropriate Interventions	2	2	2	1	2	4	4	2
IV.	OUTCOMES								
11.	Outcomes Assessment Criteria for Significant Improvement	2	4	2	2	2	4	1	2
12.	Description of Drop Out Rate	2	2	2	2	2	2	2	2
13.	Similarity of Groups at Baseline for Important Prognostic Indicators	0	0	0	2	0	2	0	0
14.	Role of Co-Interventions	0	0	2	2	0	2	0	0
V.	ASSIGNMENT								
15.	Method of Assignment of Participants	1	1	0	0	1	1	3	1
VI.	CONFLICTS OF INTEREST								
16.	Funding and Sponsorship	2	2	2	2	2	2	3	2
TOTAL		21	26	23	25	18	33	35	18

Source: Manchikanti L, et al. Development of an interventional pain management specific instrument for methodologic quality assessment of nonrandomized studies of interventional techniques. *Pain Physicia*n 2014; 17:E291-E317 (55).

Table 15. *Study characteristics of the included randomized trials and observational studies assessing intraarticular sacroiliac injections.*

Study Study Characteristics Methodological Quality Scoring	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses
Hawkins & Schofferman, 2009 (99) NR, F Quality Score: IPM-QRBNR = 21/48	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.
Liliang et al, 2009 (101) NR, F Quality Score: IPM-QRBNR = 23/48	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 acetonide 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.
Kim et al, 2010 (119) R, F, AC Quality Scores: Cochrane = 11/12 IPM-QRB = 33/48	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.

Table 15 (cont.). *Study characteristics of the included randomized trials and observational studies assessing intraarticular sacroiliac injections.*

Study Study Characteristics Methodological Quality Scoring	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses
Borowsky & Fagen, 2008 (108) NR, F Quality Score: IPM-QRBNR = 25/48	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.
Jee et al, 2014 (130) R, F Quality Scores: Cochrane = 8/12 IPM-QRB = 28/48	120 patients were randomized in a single-blinded study with 60 patients allocated to receive controlled treatment with ultrasound guidance and 60 patients allocated to receive under fluoroscopy. The included patients were judged to be positive with diagnostic sacroiliac joint injections with criteria of greater than 80% pain relief, along with positive findings on at least 1 of 3 provocation tests for sacroiliac joint pain.	Intraarticular injection performed under fluoroscopic guidance	Intraarticular injection performed under fluoroscopy Fluoroscopy was utilized to confirm the positioning of ultrasound guidance.	Percent change in verbal numeric pain scale and ODI	2 weeks and 12 weeks	Both ultrasound guided and fluoroscopic guided treatments showed significant improvement from baseline at 12 weeks.	Randomized controlled trial; however, the study focused more on accuracy of ultrasound-guided injections rather than outcomes. The fluoroscopically guided sacroiliac joint group exhibited a greater accuracy of 98.2% compared to ultrasound-guided approach with 87%.

NR = Non-randomized; R = Randomized; F = Fluoroscopy; AC = Active-control; NRS = Numeric Rating Scale; ODI = Oswestry Disability Index; VAS = Visual Analog Scale; SF-36 BP = Short-form 36 bodily pain; Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB); Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR)

Table 16. *Study characteristics of the included randomized trials and observational studies assessing periarticular sacroiliac joint injections.*

Study Study Characteristics Methodological Quality Scoring	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses
Luukkainen et al, 2002 (113) R, B, AC Quality Scores: Cochrane = 11/12 IPM-QRB = 17/48	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.
Luukkainen et al, 1999 (121) R, B, AC Quality Scores: Cochrane = 10/12 IPM-QRB = 20/48	20 patients with zero negative spondyloarthropathy and clinical sacroiliitis Methylprednisolone 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.
Borowsky & Fagen, 2008 (108) NR, F Quality Score: IPM-QRBNR = 25/48	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.

R = Randomized; B = Blind; F = Fluoroscopy; AC = Active-control; NR = Non-randomized; VAS = Visual Analog Scale; Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB); Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR)

Table 17. *Study characteristics of the included randomized trials and observational studies assessing the effectiveness of radiofrequency lesioning of the sacroiliac joint.*

Study Study Characteristics Methodological Quality Scoring	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses
Cohen et al, 2008 (158) R, DB Quality Scores: Cochrane = 11/12 IPM-QRB = 41/48	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.
Patel et al, 2012 (117) R, DB, PC Quality Scores: Cochrane = 11/12 IPM-QRB = 35/48	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 patients 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 an 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.
Cohen et al, 2009 (131) NR, F Quality Score: IPM-QRBNR = 26/48	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.

Table 17. 9cont) *Study characteristics of the included randomized trials and observational studies assessing the effectiveness of radiofrequency lesioning of the sacroiliac joint.*

Study Study Characteristics Methodological Quality Scoring	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses
Stelzer et al, 2013 (165) NR, F Quality Score: IPM-QRBNR = 18/48	Cooled radiofrequency of lateral branch neurotomy was evaluated retrospectively in 126 patients with low back pain. Patients were selected based on findings of physical examination and positive response to an intraarticular sacroiliac joint block with 50% pain relief as the criterion standard.	None	Cooled radiofrequency neurotomy of L5 dorsal ramus and S1, S2, S3 lateral branches. Patients also received lidocaine and bupivacaine mixture for infiltration.	VAS, quality of life, medication usage, satisfaction	1 month, 4 months, and 20 months post procedure	The results showed 50% or greater reduction in VAS and improvement in quality of life in over 86% of the patients at 4 to 6 month follow-up, 71% at 6 to 12 month follow-up, and 48% after 12 month follow-up.	This is a retrospective study with 126 patients. This is a fairly large sample compared to randomized controlled trials and other reported studies. The results were promising with a significant proportion of patients showing improvement at the end of one year.
Schmidt et al, 2014 (149) Case series Quality Score: IPM-QRBNR = 18/48	A total of 60 patients received 77 radiofrequency treatments from 2 separate institutions, with 47 and 30 patients from each institution, for radiofrequency ablation with a multilesion probe. Patient selection included positive response to diagnostic intraarticular injections with bupivacaine and steroids with 50% criterion standard and findings of physical examination.	None	Radiofrequency ablation with a multilesion probe	Greater than 50% pain relief	6 weeks, 6 months, and 1 year	Of the 77 radiofrequency treatments in 60 patients, 55 treatments were considered as successful outcome at 6 weeks defined as greater than 50% pain relief. At 6 months, 54.5% and at one year, 15.6% of the patients were shown to be with significant pain relief.	This is a relatively small study for retrospective evaluation; however, appears to be the first one with a multilesion probe. The results were positive up to 6 months in almost 55% of the patients.

Table 17 (cont) . *Study characteristics of the included randomized trials and observational studies assessing the effectiveness of radiofrequency lesioning of the sacroiliac joint.*

Study Study Characteristics Methodological Quality Scoring	Number of Patients Selection Criteria	Control	Intervention	Outcome Measures	Time of Measurement	Results	Strengths Weaknesses
Cheng et al, 2013 (152) NR, F Quality Score: IPM-QRBNR = 33/48	This retrospective assessment included 88 patients with 30 patients receiving traditional radiofrequency ablation and 58 receiving cooled radiofrequency ablation. Patients were selected with at least 3 months of pain and at least 50% pain relief after 2 fluoroscopically guided sacroiliac joint blocks with local anesthetic and steroids.	None	Traditional radiofrequency neurotomy in 30 patients and cooled radiofrequency in 58 patients	NRS, pain relief of 50% or greater	3 and 6 months	Both traditional and cooled radiofrequency provided greater than 50% pain reduction for 3 to 6 months in the majority of the patients with no significant difference between the 2 techniques.	Relatively small sample size; however, they compared 2 techniques.
Mitchell et al, 2015 (153) PR, CH, NR, F Quality Score: IPM-QRBNR = 35/48	This prospective, observational, cohort of 215 patients received conventional radiofrequency neurotomy. Patients were selected with chronic sacroiliac joint pain with positive response to controlled, comparative local anesthetic blocks with a criterion standard of 80%.	None	Conventional radiofrequency neurotomy at L5 dorsal ramus and S1 to S4 lateral branches	NRS, opioid intake, return to work, patient satisfaction, Likert scale	6 to 49 months	Overall, 57% of patients reported pain relief with a mean reduction of 2.3 ± 2.1 NRS points noted at follow-up compared to baseline pain scores of 6.9 ± 1.7 to a follow-up average of 4.6 ± 2.7 pain scale points. 47% of the patients reported a reduction in their medication usage with 41 of 76 noting this decrease as extreme on a 5 point Likert scale. 66% of the patients were satisfied with the outcomes.	Relatively large prospective assessment with 215 patients with appropriate selection of patients with controlled diagnostic blocks and a long-term follow-up. Weakness includes a prospective cohort with no control group and weak outcome parameters.

R = Randomized; DB = Double-blind; PC = Placebo control; F = Fluoroscopy; NR = Non-randomized; PR = Prospective; CH = Cohort; NRS = Numeric Rating Scale; ODI = Oswestry Disability Index; VAS = Visual Analog Scale; SF-36 BP = Short-form 36 bodily pain; QOL = Quality of life; Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB); Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRB-NR)

Table 18. *Results of randomized trials 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	
Kim et al, 2010 (119) R, AC, F Quality Scores: Cochrane = 11/12 IPM-QRB = 33/48	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	N	N	Positive for prolotherapy
Jee et al, 2014 (130) R, F Quality Scores: Cochrane = 8/12 IPM-QRB = 28/48	120	Intraarticular injection performed under fluoroscopic guidance or ultrasound guidance	SI	NA	NA	P	NA	NA	Equal relief with ultrasound and fluoroscopy
Hawkins & Schofferman, 2009 (99) NR, F Quality Score: IPM-QRBNR = 21/48	155	Local anesthetic and steroids Number of injections = 1 to 4	77%	77%	77%	P	P	P	Positive study
Liliang et al, 2009 (101) NR, F Quality Score: IPM-QRBNR = 23/48	150	Local anesthetic and steroids Number of injections = 1 to 3	66.7%	NA	NA	P	NA	NA	Positive study
Borowsky & Fagen, 2008 (108) NR, F Quality Score: IPM-QRBNR = 25/48	120	Intraarticular or with extraarticular injection Number of injections = 1	12.5 % vs. 31.25%	NA	NA	N	N	N	Negative study

*Prolotherapy; R = Randomized; F = Fluoroscopy; AC = Active-control; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable; SI = Significant improvement; Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB); Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR)

Table 19. Results of randomized trials and observational studies of effectiveness of periarticular sacroiliac joint injections.

Study Characteristics Methodological Quality Scoring	Participants	Interventions	Results					Comment
			Pain Relief and Function			Short-term ≤ 6 mos.	Long-Term	
			3 mos.	6 mos.	12 mos.		> 6 mos.	1 year	
Luukkainen et al, 2002 (113) R, B Quality Scores: Cochrane = 11/12 IPM-QRB = 17/48	24 Steroid group = 13 Sodium chloride group = 11	Methylprednisolone with local anesthetic vs. sodium chloride solution Number of injections = 1	Significant improvement in steroid group	NA	NA	P	NA	NA	Small study showed effectiveness for steroid with local anesthetic
Luukkainen et al, 1999 (121) R, B Quality Scores: Cochrane = 10/12 IPM-QRB = 20/48	20 Steroid group = 10 Sodium chloride group = 10	Methylprednisolone with local anesthetic vs. sodium chloride solution Number of injections = 1	Significant improvement in steroid group	NA	NA	P	NA	NA	Small study showing effectiveness for steroid with local anesthetic
Borowsky and Fagen, 2008 (108) NR, F Quality Score: IPM-QRBNR = 25/48	120	Intraarticular and periarticular	12.5 % vs. 31.25%	NA	NA	N	NA	NA	A relatively large study showing lack of effectiveness of intraarticular and periarticular injections

R = Randomized; B = Blind; F = Fluoroscopy; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable; Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB); Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR)

results were obtained with cooled radiofrequency neurotomy.

In a case series, Schmidt et al (149) assessed results in 60 patients who had radiofrequency ablation with a multilesion probe. They showed positive results at 3 months in 71% of the patients and at 6 months in 55% of the patients; however, this improvement deteriorated to an effectiveness of 16% at 12 months.

Finally, the recent publication by Mitchell et al (153) of a prospective observational study with data collection over 5 years in a cohort of 215 patients who underwent conventional radiofrequency of the dorsal and lateral branches of S1-S3 and dorsal ramus of L5, showed effectiveness for conventional radiofrequency neurotomy. They selected patients using dual diagnostic blocks with at least 80% pain relief as the criterion standard. This high-quality study demonstrated an average pain reduction of 2.3 ± 2.1 NRS points following radiofrequency neurotomy with an average follow-up of 14.9 ± 10.9 months, ranging from 6 to 49 months. Overall, 57% of the patients reported pain relief, 47.5% of the patients reported reduction in their opioid usage, and 66% were satisfied with the outcome; however, they also reported that initial pain relief achieved from radiofrequency neurotomy was comparable to the published literature. Overall, even though they did not utilize robust outcomes with significant improvement of 50% or more, they did utilize appropriate study design and proper selection of patients with at least 80% pain relief with controlled diagnostic blocks. Thus, this study provides evidence for the effectiveness of conventional radiofrequency neurotomy with inclusion of a large number of patients.

2.2.4.4 Cooled Radiofrequency Neurotomy

Two RCTs (117,158) and 2 nonrandomized studies (152,165) evaluated the effectiveness of cooled radiofrequency neurotomy. Both RCTs used a placebo control design; however, there were multiple potential shortcomings with the control groups in both trials, even though the treatment group showed effectiveness with cooled radiofrequency neurotomy (Table 20). Further, among the 2 observational studies (152,165), one of them yielded effectiveness

Table 20. *Results of randomized trials and observational studies of effectiveness of radiofrequency lesioning of the sacroiliac 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, 2009 (131) NR, F Quality Score: IPM-QRBNR = 26/48	77	Conventional or cooled radiofrequency from L4/5 to S3/4	NA	52%	NA	P	P	NA	Effectiveness of conventional radiofrequency at 6 months.
Cheng et al, 2013 (152) NR, F Quality Score: IPM-QRBNR = 33/48	Total: 88 Traditional radiofrequency ablation = 30 Cooled radiofrequency ablation = 58	Traditional radiofrequency neurotomy and cooled radiofrequency	T = 50% C = 60%	T = 40% C = 40%	NA	P (T)	NA	NA	Effectiveness of cooled and traditional radiofrequency at 3 months with borderline effectiveness at 6 months with cooled radiofrequency neurotomy or conventional radiofrequency neurotomy.
Schmidt et al, 2014 (149) Case series Quality Score: IPM-QRBNR = 18/48	60	Radiofrequency ablation	71.4%	54.5%	45.6%	P	P	N	Effectiveness of cooled radiofrequency neurotomy at 6 months with declining relief at one year to 14% from 57% compared to the controlled group.
COOLED RADIOFREQUENCY NEUROTOMY									
Cohen et al, 2008 (158) R, DB, PC Quality Scores: Cochrane = 11/12 IPM-QRB = 41/48	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%	NA	P	P	N	Study showed effectiveness at 6 months
Patel et al, 2012 (117) R, DB, PC Quality Scores: Cochrane = 11/12 IPM-QRB = 35/48	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	P	P	NA	Study showed effectiveness in 47% at 3 months and 38% at 6 months.
Stelzer et al, 2013 (165) NR, F Quality Score: IPM-QRBNR = 18/48	126	Cooled radiofrequency neurotomy of L5 dorsal ramus and S1, S2, S3 lateral branches	86%	71%	48%	P	P	P	Study showed effectiveness at 6 months with reduction to 48% at one year

Table 20 (cont.). *Results of randomized trials and observational studies of effectiveness of radiofrequency lesioning of the sacroiliac 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.	Long-Term 1 year	
Cheng et al, 2013 (152) NR, F Quality Score: IPM-QRBNR = 33/48	Total: 88 Traditional radiofrequency ablation = 30 Cooled radiofrequency ablation = 58	Traditional radiofrequency neurotomy and cooled radiofrequency	T = 50% C = 60%	T = 40% C = 40%	NA	P (T)	NA	NA	Effectiveness of cooled and traditional radiofrequency at 3 months with borderline effectiveness at 6 months with cooled radiofrequency neurotomy or conventional radiofrequency neurotomy.
Mitchell et al, 2015 (153) PR, CH, NR Quality Score: IPM-QRBNR = 35/48	Total: 215	Conventional radiofrequency neurotomy from S1 to S1 with inclusion of L5 dorsal ramus	NA	NA	57%	NA	NA	P	Effectiveness of conventional radiofrequency neurotomy is demonstrated in a large proportion of patients with appropriate selection criteria and long-term follow-up period of 6 to 49 months.

R = Randomized; DB = Double-blind; PC = Placebo control; PR = Prospective; CH = Cohort; F = Fluoroscopy; NR = Non-randomized; P = Positive; N = Negative; NA = Not Applicable; RF = Radiofrequency; T = Treatment; C = Control; Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM – QRB); Interventional Pain Management Techniques - Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM – QRBNR)

(165) for cooled radiofrequency neurotomy. Stelzer et al (165) showed the results of 126 patients with cooled radiofrequency neurotomy with effectiveness for 6 months in 71% of patients which was reduced to 48% at 12 months. The second study by Cheng et al (152) compared traditional radiofrequency and cooled radiofrequency with no significant difference noted between both modalities at 6 months; only 40% of patients sustained relief at 6 months. However, the response rate was 60% in the cooled radiofrequency group at 3 months.

2.2.5 Analysis of Evidence

Based on a best evidence synthesis, there is Level II-III evidence for cooled radiofrequency neurotomy based on 2 high-quality RCTs of cooled radiofrequency neurotomy (117,158) and 2 observational studies (152,165).

The evidence is Level IV for intraarticular injections based on 2 RCTs (119,130); 3 observational studies (99,101,108) had contradictory evidence.

The evidence for periarticular sacroiliac joint injections is Level IV based on 2 RCTs (113,121) showing effectiveness at short-term follow-up and a large study of 120 patients showing a lack of effectiveness (108).

The evidence for conventional radiofrequency neurotomy is largely based on relatively small observational studies (131,149,153) resulting in Level III to IV evidence and only one large prospective cohort study (153).

3.0 Discussion

This systematic review of the diagnostic accuracy of sacroiliac joint interventions and their therapeutic effectiveness, utilizing rigorous criteria, showed Level II to III evidence for the diagnostic accuracy of sacroiliac intraarticular injections based on 2 large high quality diagnostic accuracy studies with at least 70% and 75% pain relief as the criterion standard with dual blocks (35,101), supported by multiple controlled block studies with 75% or 80% pain relief as the criterion standard (25,26,28,34,93). The evidence for single diagnostic blocks with 75% or 90% pain relief shows there was Level III to IV evidence for a single diagnostic block. The 2 large studies (35,101), which included 158 and 150 patients, showed a prevalence of 26%. The other dual-block studies showed prevalence varying from 7% to 40%. The false-positive rates were shown to be 20% to 26% with dual blocks. With single blocks, the prevalence was 10% to 35% with wide variability

and internal inconsistency. Among the therapeutic interventions, for cooled radiofrequency neurotomy, the evidence is Level III based on 2 small RCTs (117,158) and 2 observational studies (152,165). The evidence for intraarticular injections and periarticular injections is Level IV despite small RCTs. The evidence for conventional radiofrequency neurotomy is Level V based on observational studies only.

This systematic review included 10 diagnostic accuracy studies using either single or dual controlled diagnostic blocks (25-28,34,35,41,42,93,101). The threshold was strict in that each study had to meet at least 50% of the methodological quality assessment criteria. The rationale behind using double comparative blocks is to eliminate false-positive responders, which is important to establish accuracy. These results showed significant variability in the rate of prevalence ranging from 7.2% to 40.4% with the dual blocks and 10% to 35% with the single blocks. Two large studies utilizing over 150 patients (35,101) each showed a prevalence of 26%. The false-positive rate is derived from smaller studies of 20, 50, or 54 patients (26,34,93). Thus, there is internal inconsistency with the prevalence as well as false-positive rates.

In contrast to diagnostic sacroiliac joint blocks, there is a significant paucity of the literature regarding multiple therapeutic sacroiliac joint interventional modalities including intraarticular injections, periarticular injections, conventional radiofrequency neurotomy, and cooled radiofrequency neurotomy. In addition to this, various drugs and various needle localization procedures have been utilized. The greatest evidence is available for cooled radiofrequency neurotomy based on 2 small RCTs and 2 observational studies, yet, this is weak at just Level III. For periarticular injections and intraarticular injections, the evidence is Level IV, and for conventional radiofrequency neurotomy, the evidence is Level V. Both of the RCTs were high quality; however, they included a very small number of patients showing only modest results with 6-month follow-up. A total of 48 patients were studied for cooled radiofrequency neurotomy; 31 patients were studied in the control groups in the 2 studies combined. The results started deteriorating after 3 months. While Cohen et al (158) showed a 57% success rate in the treatment group at 6 month follow-up, Patel et al (117) showed success in only 38% of the patients and the blinding was appropriate only for 3 months. Consequently, the study by Patel et al (117) may be considered essentially ineffective, even though the results were better than placebo. Aydin et al (148), in a systematic review and meta-analysis of the role of radiofrequency ablation for sacroiliac joint pain, concluded that radiofrequency ablation was an effective treatment for sacroiliac joint pain at 3 and 6 months. In contrast, King et al (166) concluded that while some evidence of moderate quality exists on therapeutic procedures, it was insufficient to determine the indications and effectiveness of sacral lateral branch thermal radiofrequency neurotomy, and more research was required. The quality of the literature available on other modalities was limited and therefore insufficient to derive any conclusions of effectiveness.

There continues to be significant debate surrounding the accuracy of diagnostic tests, with some of the debate being contentious (6,29,43-50,166-172). The precision and reliability of controlled comparative local anesthetic blocks has been questioned (6,43-45,170-173). Debate surrounds the quality and quantity of pain relief, the value and validity of dual blocks, the reference standard employed, chronic opioid and other substance use and abuse, the effects of perioperative sedation,, and the role of placebo and nocebo effects (6,29,43-50,74,166-185). Despite the weak evidence of diagnostic blocks to identify the sacroiliac joint(s) as a pain generator, significant evidence is available in support of using controlled facet joint nerve blocks to diagnose facet joint pain in the lumbar and cervical regions (6,29,43). In fact, the authors of multiple Cochrane review publications, Rubinstein and van Tulder (29), have reported that there is moderate evidence for the validity and accuracy of diagnostic injections including sacroiliac joint injections. Despite these conclusions by the Cochrane review team and numerous publications since then, including those of systematic reviews, the criticism continues from various sources (45-51). In addition to Chou and Huffman in the United States (45), the CRD of the University of York from NIHR also provided negative opinions (47,50) of the systematic reviews utilized in the assessment by Rubinstein and van Tulder (29). However, contradictory to these opinions, CRD also provided variable opinions on other systematic reviews (48,49). The criticism of CRD and variable opinions contradict each other and also were not based on rigorous assessment of the quality of a systematic review.

For surgical interventions the reference standard is clearly available and established utilizing biopsy or autopsy in case of a death. In contrast, neither biopsy nor autopsy may be applied in interventional pain management. As an alternative, long-term clinical follow-up of

patients has been utilized extensively and appears to be the best means of establishing a reference standard for accuracy and prognostic value of controlled diagnostic blocks (6,64,167,168,178,186,187). In fact, Manchikanti et al (168), in assessing the role of controlled diagnostic blocks, showed 90% of the patients showing significant improvement at 2-year follow-up of therapeutic facet joint nerve blocks with a criterion standard of at least 80% pain relief for diagnostic blocks compared to 51% of the patients with a criterion standard of 50% pain relief for lumbar diagnostic facet joint nerve blocks managed with therapeutic medial branch blocks. These results were also echoed in multiple RCTs (64,186-188). However, weak evidence also has been presented in support of therapeutic management without diagnostic blocks or with single or dual diagnostic blocks (174). Further, stricter standards utilizing at least 80% pain relief as a criterion standard have yielded fewer false-positive results without a significancant prevalence of higher false-negative results (153).

The usefulness of a diagnostic test is judged based on its ability to distinguish between the reference condition and other disorders which might otherwise be misdiagnosed. In general, it is easy to differentiate healthy persons from severely affected ones with many available tests. However, the true pragmatic value of a test is only established in a study that closely resembles the patients with clinical symptoms and also management resembling clinical practice. Even though there is significant evidence for a criterion standard of 80% pain relief with ability to perform previously painful movements with dual blocks as the most accurate and desirable path, numerous studies have utilized less stringent criteria, thus, for this assessment the selection criteria were broadened. Further, this assessment also showed that even single blocks utilizing either 75% pain relief as the criterion standard or 90% pain relief as the criterion standard have shown reasonable prevalence rates of 10% with 90% pain relief (27) and 30% and 35% with 75% pain relief (41,42). Even though these prevalence rates are similar to some of the dual blocks with similar criterion standards, essentially the rate by Pang et al (27), they are lower than many of the dual block studies (28,34,35,93,101).

There are also arguments that noninvasive clinical testing may suffice, however, noninvasive clinical testing with physical examination with various maneuvers, laboratory assessment, and imaging continue to be considered as nonspecific, even though pain provocation tests advocated by some may point towards the necessity of performing diagnostic blockade if interventional management is foreseen. Abundant literature with multiple systematic reviews (32,33,38) have shown moderate evidence for the accuracy of provocative maneuvers.

There has been substantial controversy in reference to placebo and nocebo effects with injection therapy. In fact, some investigators have gone so far that they consider any local anesthetic injection as a placebo, which leads to inappropriate conclusions as local anesthetic injections also provide similar relief in multiple settings, both experimentally and clinically (188-194). In addition, injection of sodium chloride or dextrose solutions, considered as inactive or inert, into various structures have yielded results with multiple activities demonstrated in these structures (195-201). There is also significant evidence of the effectiveness of local anesthetics on a long-term basis (188-191,202-205). Further, experimental evidence has shown that local anesthetics provide prolonged analgesic effect with no additional benefit (204) with the addition of corticosteroids in neuropathic pain and no additional benefit (205) in lumbar disc herniation with the addition of corticosteroids in nerve root infiltration. Further, recent literature has highlighted numerous misunderstandings of placebo and nocebo as well as importance of consideration of placebo and nocebo in experimental studies along with necessity to avoid both placebo and nocebo (179-185). Finally, recently Ghahreman et al (206) and Gerdesmeyer et al (207) have shown a lack of effectiveness of true placebo and also designed protocols for performance of interventional studies.

The limitations of this systematic review include a continued paucity of literature with multiple inconsistencies not only in diagnostic accuracy studies, but also for therapeutic interventions. These deficiencies include a lack of high quality, replicative, and consistent literature with standardized techniques and diagnostic standards for inclusion criteria.

In summary, this comprehensive assessment evaluated the available literature and offers evidence for practical management with diagnostic and therapeutic interventions in managing sacroiliac joint pain.

4.0 Conclusion

The results of this systematic review show Level II to III evidence for the diagnostic accuracy of sacroiliac joint injections even though there were multiple studies available with internal inconsistencies.

For therapeutic modalities the evidence is Level III

in managing sacroiliac joint pain with cooled radiofrequency neurotomy. However, the evidence for conventional radiofrequency neurotomy, intraarticular steroid injections, and periarticular injections with steroids or botulinum toxin is limited to Level III or IV.

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Conflicts Of Interest

Dr. Manchikanti has provided limited consulting services to Semnur Pharmaceuticals, Incorporated, which is developing nonparticulate steroids.

Dr. Gupta has been paid honorarium for presenting at meetings and teaching on the interventional pain medicine cadaver courses and by pharmaceutical companies for presenting to health care professionals. Pharmaceutical companies and companies that manufacture equipments used in pain medicine have supported meetings organized by Dr S Gupta

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