Systematic Review

Systematic Review and Meta-Analysis of Effectiveness of Therapeutic Sacroiliac Joint Injections

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Background: The sacroiliac joint is one of the proven causes of low back and lower extremity pain, ranging from 10% to 25% in patients with persistent axial low back pain without disc herniation, discogenic pain, or radiculitis. Despite the difficulty of diagnosis, multiple therapeutic modalities including surgical and nonsurgical interventions have been utilized. Among the interventional modalities, intraarticular injections are commonly utilized.

Objective: To evaluate the therapeutic effectiveness of intraarticular injections in the sacroiliac joint.

Study Design: A systematic review and meta-analysis of randomized controlled trials (RCTs) and observational studies of the therapeutic effectiveness of intraarticular injections of the sacroiliac joint utilizing the Preferred Reporting Items For Systematic Reviews And Meta-Analyses (PRISMA) checklist.

Methods: The available literature on therapeutic sacroiliac joint intraarticular injections was reviewed. The quality assessment criteria utilized were the Cochrane review criteria to assess risk of bias, the Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment (IPM-QRB) for randomized therapeutic trials, and the Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM-QRBNR) for nonrandomized studies. The level of evidence was based on best evidence synthesis with modified grading of qualitative evidence from Level I to Level V. Data collection was performed including literature published from 1966 through December 2022, as well as manual searches of the bibliographies of known articles.

Outcome Measures: Primary outcome measures include pain relief and improvement in functional status at 3 months for a single intervention. Only the studies performed under fluoroscopic guidance, with at least 3 months of follow-up were included. Duration of relief was categorized as short-term (< 6 months) and long-term (> 6 months).

Results: Based on the qualitative and quantitative analyses with a single-arm meta-analysis and the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system of appraisal, and the inclusion of 11 RCTs (5 positive, 6 negative) and 3 observational studies (2 positive, one negative), the evidence was Level III or fair in managing low back pain of sacroiliac joint origin with sacroiliac joint injections.

Limitations: This systematic review and meta-analysis are limited by lack of eligible studies, inconsistencies among the available studies, variations in techniques, variable diagnostic standards for inclusion criteria, and finally, the inability to correlate the results and perform an optimal systematic review and meta-analysis.

Conclusion: The present systematic review and meta-analysis show an inability to perform conventional dual-arm analysis, whereas a single-arm meta-analysis demonstrated a difference of approximately 3 points on the Numeric Rating Scale (NRS) and 8 points on the Oswestry Disability

Index (ODI). However, there were no studies that considered ≥ 50% relief as the criterion standard. Overall, the qualitative and quantitative evidence combined shows Level III or fair evidence for therapeutic sacroiliac joint injections for managing low back pain of sacroiliac joint origin.

Key words: Chronic low back pain, sacroiliac joint pain, sacroiliac joint dysfunction, sacroiliitis, sacroiliac joint injection, sacroiliac joint nerve blocks, radiofrequency ablation, conventional radiofrequency, pulsed radiofrequency

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Extensive published literature shows low back pain as the major source of disability with a disproportionate toll on health care and the economy of the United States and the world (1). Published health care spending patterns in the United States from 1996 to 2016 (2,3), showed that in 2013 the estimated spending for managing low back and neck pain was $87.6 billion (2), which increased to $134.5 billion in 2016, an increase of 53.5%. Further, national health care spending in the United States continues to increase and escalated in 2020 due to the COVID-19 pandemic, with an increase of 9.7% to reach $4.1 trillion in 2020 compared to a rate which was already considered fast at a 4.3% increase in 2019 (4,5). There has been a significant decline in services and an increase in provider expenses in 2020; however, increasing health care expenditures had already been discussed as having dire consequences before the COVID-19 pandemic (6-11). Consequently, utilization patterns have been carefully looked at and multiple measures have been expanded to provide evidence-based and value-based care with multiple studies, guidelines, and policies being put forward (8-20).

The sacroiliac joint is a common cause of low back and lower extremity pain, in addition to discs, nerve roots, and facet joints. However, faced with the difficulty of universal acceptance of diagnostic accuracy, discussions continue in reference to the diagnostic and therapeutic value of intraarticular injections (21-25). Difficulty with the successful diagnosis of sacroiliac joint dysfunction has been described due to the involvement of multiple structures generating similar pain patterns as well as the very nature of a multifaceted process. Similarly, the literature on therapeutic interventions continues to be limited, though emerging.

Along with multiple other interventional techniques, discussions continue in reference to effectiveness, indications and medical necessity, selection of patients for therapeutic interventions, and finally, utilization patterns (8-29). Further, these issues are not limited to interventional techniques alone, but also to opioids with multiple questions related to the Centers for Disease Control and Prevention (CDC) guidelines, federal regulations, and the ill effects of restricting opioids with an escalating fourth wave resulting in an opioid paradox with increasing opioid-related deaths despite decreasing opioid utilization patterns (10).

Recent analyses have demonstrated the utilization patterns of various types of interventional techniques, including those of sacroiliac joint injections. Analysis of utilization patterns based on the COVID-19 pandemic showed an 18.7% decrease in chronic pain interventions in the Medicare population from 2019 to 2020 (12). The results also showed vast differences between utilization patterns from 2000 to 2010 with an annualized increase of 10.2% per 100,000 in the Medicare population compared to an annualized decrease of 0.4% from 2010 to 2019, and a 19.2% decrease from 2019 to 2020 due to COVID-19. An analysis of sacroiliac joint utilization patterns from 2000 to 2020 (13) showed the effect of the COVID-19 pandemic with a significant decrease of 19.2% in intraarticular injections from 2019 to 2020 per 100,000 in the Medicare population. These decreases in intraarticular injections were accompanied by a 5.3% decrease in fusion, but a 23.3% increase in arthrodesis from 2019 to 2020 per 100,000 in the Medicare population.

Overall, the results show an annual increase of 0.9% per 100,000 Medicare population for intraarticular injections, a 35.4% annual increase for sacroiliac joint arthrodesis, and an increase of 15.5% for sacroiliac joint fusion from 2010 to 2019 (13). This analysis was not separated for diagnostic and therapeutic facet joint intraarticular injections and trends in expenditures were not assessed for sacroiliac joint injections.

Consequently, this systematic review with a meta-analysis of randomized controlled trials (RCTs) and observational studies was undertaken to evaluate the effectiveness of therapeutic sacroiliac joint intraarticular injections.

Methods

This systematic review and meta-analysis of therapeutic intraarticular injections performed utilizing the

process described by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (30). In the performance of this analysis, multiple other reviews were also utilized (31-33).

The objective of this systematic review and meta-analysis, therefore, was to assess the efficacy and effectiveness of therapeutic intraarticular injections in the sacroiliac joint for managing chronic low back pain.

Eligibility Criteria

Studies included RCTs (placebo-control and active-control), and observational studies (prospective evaluations, retrospective evaluations, and case series). However, individual case reports were not included.

Therapeutic intraarticular injections of the sacroiliac joint were included when performed under radiologic imaging (fluoroscopy, computed tomography [CT], or magnetic resonance imaging [MRI]). The ultrasound-guided interventions were also included in a separate category. Interventions performed blindly without any guidance were excluded.

The studies included were ones that patients had chronic low back pain for at least 3 months; had an inadequate response or lack of response to conservative therapies, including nonsteroidal anti-inflammatory drugs (NSAIDs), exercise regimens, physical therapy, and other conservative therapies; and at least 6 months of follow-up. The studies with a diagnosis based on controlled local anesthetic blocks were preferred; however, studies based on a clinical diagnosis were also included.

Information Sources

The literature search was comprehensive for RCTs and all types of observational studies published from all countries and in all languages.

Searches were performed from the following without language restrictions: PubMed from 1966 www.ncbi.nlm.nih.gov/pubmed; Cochrane library www.thecochranelibrary.com, Google scholar https://scholar.google.com, US National Guideline Clearinghouse (NGC) www.guideline.gov/; clinical trials www.clinicaltrials.gov, previous systematic reviews and cross references; and other sources, including nonindexed journals and abstracts. The search period was from 1966 through December 2022.

Search Strategy

The search strategy emphasized low back pain treated with sacroiliac joint interventions in which the title included chronic low back pain or chronic pain, or sacroiliac joint pain, or lumbosciatic pain, or post-laminectomy or lumbar surgery syndrome, sacroiliac joint injection, medial branch block, sacroiliac joint nerve block or intraarticular injection or radiofrequency neurotomy or radiofrequency ablation. The search strategy was as follows:

PubMed search strategy ((((((joint, sacroiliac [MeSH Terms]) OR (Sacrococcygeal joint[Title/Abstract])) OR (Sacroiliac joint[Title/Abstract])) OR (Sacroiliac[Title/Abstract])) OR (Sacroiliac joint injection[Title/Abstract])) OR (Sacroiliac joint block[Title/Abstract])) OR (Sacroiliac joint radiofrequency [Title/Abstract])) OR (Sacroiliac nerve neurotomy[Title/Abstract])), or (Sacroiliitis[Title/Abstract]) Filters: Clinical Trial, Meta-Analysis, Observational Study, Randomized Controlled Trial, Review, Systematic Review, Humans, Adult: 19+ years

All intraarticular injection studies with a 3-month follow-up were included. The studies with an appropriate diagnosis established by dual diagnostic blocks were preferred. Studies with a single diagnostic block or clinical diagnosis were also included. Studies without an appropriate diagnosis, systematic reviews, or non-systematic reviews, and case reports, were excluded.

Data Selection

Two review authors independently (RNJ, VP), established the search criteria, searched the literature, and extracted data from the selected studies. Disagreements between the 2 review authors were resolved by a third author (MRS). All conflicts of interest between reviewers who have authorship of this article were resolved by assigning the dispute to other reviewers.

Study of Risk of Bias and Methodologic Quality Assessment

RCTs were assessed for their quality or risk of bias methodologically with Cochrane review criteria (Appendix Table 1) (34) and Interventional Pain Management Techniques–Quality Appraisal of Reliability and Risk of Bias Assessment (IPM-QRB) (Appendix Table 2) (35). Nonrandomized studies were evaluated utilizing Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM-QRBNR), as shown in Appendix Table 3 (36).

Risk of Bias of Individual Studies

Trials that met the inclusion criteria and scored at least 9 of 13 using Cochrane review criteria (34) were

considered to be high quality, while trials scoring 5–8 were considered to be moderate quality. Trials that scored less than 5 were considered to be low quality.

Trials meeting the inclusion criteria were also assessed with IPM-QRB criteria (35). Studies scoring 32–48 were considered to be high quality, those scoring 16–31 were considered to be moderate quality and those that scored below 16 were considered to be low quality.

Based on IPM-QRBNR criteria (36), nonrandomized studies meeting the inclusion criteria but scoring less than 16 were considered to be low-quality, studies scoring from 16 to 31 were considered to be moderate quality; and studies scoring from 32 to 48 were considered to be high-quality.

Methodological quality of the trials was assessed by 2 authors (RNJ, MRS), independently in an unblinded manner. If a discrepancy occurred, a third author (LM) was involved to resolve the conflict. When an issue of conflict of interest was raised in reviewing the manuscript (regarding authorship), the involved authors were not allowed to review those manuscripts for quality assessment.

Analysis of Evidence

Analysis of the evidence was performed by 2 authors NNK and EK, and any disagreements between them was resolved MRS.

Outcome Measures

An outcome was considered clinically significant if there was a reduction of 3 points on the Visual Analog Scale (VAS) or Numeric Rating Scale (NRS), or at least a 50% reduction in pain and improvement in the functional status. A positive study was considered to be clinically significant and effective when the primary outcome was statistically significant at a P value ≤ 0.05.

Primary outcome measures include pain relief and improvement in functional status at 3 months for a single intervention. Only the studies performed under CT or fluoroscopic guidance, with at least 3 months of follow-up were included. Duration of relief was categorized as short-term (< 6 months) and long-term (> 6 months).

Evidence Assessment

The evidence was analyzed utilizing qualitative and quantitative evidence synthesis.

Qualitative Analysis

The qualitative analysis of the evidence was performed based on best-evidence synthesis, modified, and collated using multiple criteria, including Cochrane Review criteria and United States Preventive Services Task Force (USPSTF) criteria as illustrated in Table 1 (37). The analysis was conducted using 5 levels of evidence ranging from strong to opinion- or consensus-based.

Quantitative Analysis

Quantitative analysis was performed utilizing conventional dual-arm meta-analysis and a single-arm meta-analysis.

Single-Arm Meta-Analysis

For single-arm meta-analysis, software Comprehensive Meta-Analysis software version 3.0 was used (Biostat Inc., Englewood, NJ). For pain and functionality improvement data, the studies were reported as the mean differences with 95% CIs. Data were plotted using Forest plots to evaluate treatment effects. Heterogeneity was interpreted through I^2 statistics.

Table 1. *Qualitative modified approach to grading of evidence of therapeutic effectiveness studies.*

Level I	Strong	Evidence obtained from multiple relevant high-quality randomized controlled trials
Level II	Moderate	Evidence obtained from at least one relevant high-quality randomized controlled trial or multiple relevant moderate or low-quality randomized controlled trials
Level III	Fair	Evidence obtained from at least one relevant moderate or low-quality randomized trial or Evidence obtained from at least one relevant high-quality non-randomized trial or observational study with multiple moderate or low-quality observational studies
Level IV	Limited	Evidence obtained from multiple moderate or low-quality relevant observational studies
Level V	Consensus based	Opinion or consensus of large group of clinicians and/or scientists

Modified from: Manchikanti L, et al. A modified approach to grading of evidence. Pain Physician 2014; 17:E319-E325 (37).

Summary of Evidence

The overall analysis was conducted based on qualitative and quantitative analyses. Further, the results of best evidence as per grading were utilized. The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system of appraisal was used for determining the body of evidence (38). The clinical relevance and pragmatism of all studies were assessed utilizing the GRADE criteria (39).

Results

Study Selection

Figure 1 shows the flow diagram of the study selection using the PRISMA study selection process.

Based on the search criteria, from 17 articles, 14 articles (40-50,52-54) met the inclusion criteria. One study was excluded due to lack of availability of appropriate data for analysis and it included multiple arms in the study (55). Two studies were of injection of platelet rich plasma (PRP). Consequently, there were 11 RCTs (40-50) and 3 observational studies (52-54). Table 2 shows studies excluded from consideration from inclusion (55-94).

Methodologic Quality and Risk of Bias Assessment

Tables 3 and 4 show the methodologic quality assessment and risk of bias of the 11 RCTs utilizing the Cochrane review criteria and the IPM-QRB criteria respectively (40-50). Assessment by the Cochrane

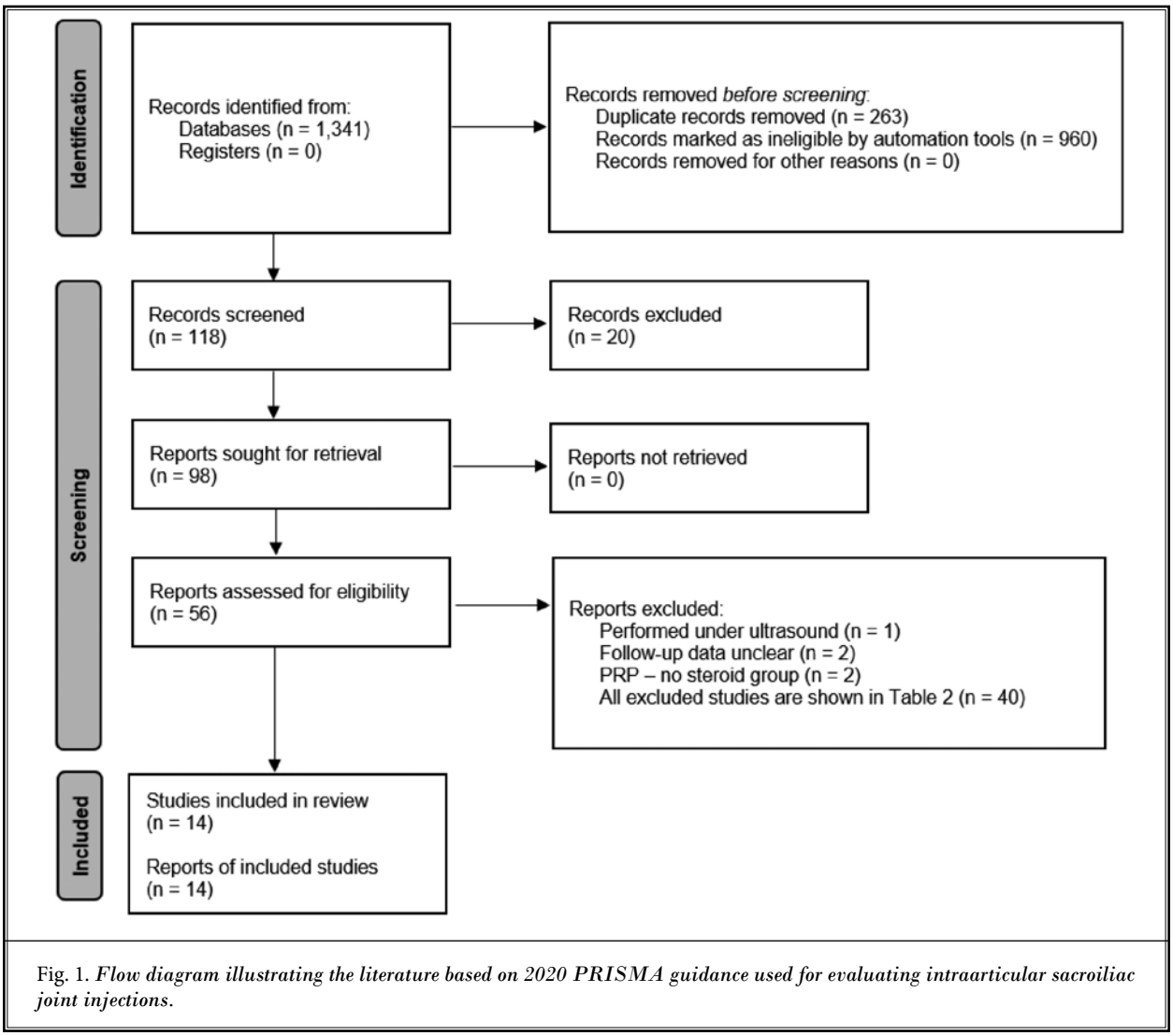

Fig. 1. *Flow diagram illustrating the literature based on 2020 PRISMA guidance used for evaluating intraarticular sacroiliac joint injections.*

Table 2. *Studies excluded for various reasons from inclusion.*

Author, Year	Title	Study Selection Criteria
Young et al, 2022 (55)	A Retrospective Analysis of Sacroiliac Joint Pain Interventions: Intraarticular Steroid Injection and Lateral Branch Radiofrequency Neurotomy	Persistent pain
Cánovas Martinez et al, 2016 (56)	Sacroiliac Joint Pain: Prospective Randomized, Experimental and Comparative Study of Thermal Radiofrequency with Sacroiliac Joint Block	Intraarticular injection was one of the 3 groups. Only abstract available, the full text is not in English.
Finlayson et al, 2017 (57)	A Randomized Comparison Between Ultrasound- and Fluoroscopy-Guided Sacral Lateral Branch Blocks	Lateral blocks
Hong et al, 2018 (58)	A Prospective Randomized Noninferiority Trial Comparing Upper and Lower One-Third Joint Approaches for Sacroiliac Joint Injections	Intraarticular but no follow-up. Only post procedure pain reported.
Luukkainen et al, 1999 (59)	Periarticular Corticosteroid Treatment of the Sacroiliac Joint in Patients with Seronegative Spondyloarthropathy	Periarticular injection
Luukkainen et al, 2002 (60)	Efficacy of Periarticular Corticosteroid Treatment of the Sacroiliac Joint in Non-Spondyloarthropathic Patients with Chronic Low Back Pain in the Region of the Sacroiliac Joint.	Periarticular injection
Maugars et al, 1996 (61)	Assessment of the Efficacy of Sacroiliac Corticosteroid Injections in Spondyloarthropathies: A Double-Blind Study	No diagnosis with clinical maneuvers or block, No chronic pain at least for 3 months
Pulisetti & Ebraheim, 1999 (62)	CT-Guided Sacroiliac Joint Injections	No short term or long-term therapeutic effect studied
Dussault et al, 2000 (63)	Fluoroscopy-Guided Sacroiliac Joint Injections	Retrospective study with only 24 patients.
Hansen, 2003 (64)	Is Fluoroscopy Necessary for Sacroiliac Joint Injections?	Study evaluating the success rate of blind needle placement into sacroiliac joint without fluoroscopy. No therapeutic effect reported.
Chou et al, 2004 (65)	Inciting Events Initiating Injection-Proven Sacroiliac Joint Syndrome	A study evaluating events leading to sacroiliac joint syndrome. No therapeutic effect reported.
Liliang et al, 2009 (66)	The Therapeutic Efficacy of Sacroiliac Joint Blocks with Triamcinolone Acetonide in the Treatment of Sacroiliac Joint Dysfunction without Spondyloarthropathy.	The study had only 39 patients with confirmed SI joint dysfunction with two diagnostic blocks.
Hartung et al, 2010 (67)	Ultrasound-Guided Sacroiliac Joint Injection in Patients With Established Sacroiliitis: Precise IA Injection Verified By mri Scanning Does Not Predict Clinical Outcome	Study included only 14 patients. Studied precision of ultrasound guided intraarticular injections with an MRI.
Liliang et al, 2014 (68)	Modified Fluoroscopy-Guided Sacroiliac Joint Injection: A Technical Report	The study of alternative SI joint injection technique in 34 patients and 50 SI joints. No therapeutic follow-up.
Park et al, 2015 (69)	Radiologic Analysis and Clinical Study of the Upper One-Third Joint Technique for Fluoroscopically Guided Sacroiliac Joint Injection	An MRI analysis study. No therapeutic follow-up.
Kurosawa et al, 2015 (70)	Referred Pain Location Depends on the Affected Section of the Sacroiliac Joint	The study aimed at determining location of pain from SI joint. No therapeutic follow-up.
Althoff et al, 2015 (71)	CT-Guided Corticosteroid Injection of the Sacroiliac Joints: Quality Assurance and Standardized Prospective Evaluation of Long-Term Effectiveness Over Six Months	This study includes only 29 patients
Navani & Gupta, 2015 (72)	Role of Intra-Articular Platelet-Rich Plasma in Sacroiliac Joint Pain	This study includes only 10 patients
Scholten et al, 2015 (73)	Short-Term Efficacy of Sacroiliac Joint Corticosteroid Injection Based on Arthrographic Contrast Patterns	This study assessed therapeutic effect only at 2 and 8 weeks after the injection. No 3I longer follow up reported
Khuba et al, 2016 (74)	Fluoroscopic Sacroiliac Joint Injection: Is Oblique Angulation Really Necessary?	No short term or long-term therapeutic effect studies
Kasliwal & Kasliwal, 2016 (75)	Fluoroscopy-Guided Sacroiliac Joint Injection: Description of a Modified Technique	The study describes a modified technique of SI joint injection. Study only has 30 patients.
Kurosawa et al, 2017 (76)	Fluoroscopy-Guided Sacroiliac Intraarticular Injection via the Middle Portion of the Joint	No short term or long-term therapeutic effect studied

Table 2 cont. *Studies excluded for various reasons from inclusion.*

Author, Year	Title	Study Selection Criteria
Ko et al, 2017 (77)	Case Series of Ultrasound-Guided Platelet-Rich Plasma Injections for Sacroiliac Joint Dysfunction	4 case reports
Taheri et al, 2018 (78)	Sacroiliac Joint Intraarticular Injection in True Anteroposterior View: Description of a New C-Arm Guided Method	No short term or long term therapeutic effect studied
Schneider et al, 2018 (79)	Does Immediate Pain Relief After an Injection into the Sacroiliac Joint with Anesthetic and Corticosteroid Predict Subsequent Relief?	Only 4-week follow-up. Study included only 29 patients.
Suleiman et al, 2018 (80)	Fluoroscopic-Guided Sacroiliac, Joint Injections for Treatment of Chronic Axial Low Back Pain in a Tertiary Hospital in Nigeria: A Preliminary Study	Study included only 26 patients.
Kurosawa et al, 2020 (81)	Criteria for Identifying Technically Difficult Cases when Performing Sacroiliac Intraarticular Injections Based on the Grade of Sacroiliac Arthrogram	No short term or long-term therapeutic effect studied
Fouad et al, 2021 (82)	The Success Rate of Ultrasound-Guided Sacroiliac Joint Steroid Injections in Sacroiliitis: Are We Getting Better?	No short term or long-term therapeutic effect studied. Study only included 34 patients.
Schneider et al, 2020 (83)	Pain and Functional Outcomes After Sacroiliac Joint Injection with Anesthetic and Corticosteroid at Six Months, Stratified by Anesthetic Response and Physical Exam Maneuvers	This study includes only 34 patients
Cohen et al, 2022 (84)	Multicenter Study Evaluating Factors Associated with Treatment Outcome for Low Back Pain Injections	Nonrandomized trial, SI joint only followed at 1 month
Nam et al, 2022 (85)	Efficacy and Safety of Intra-articular Sacroiliac Glucocorticoid Injections in Ankylosing Spondylitis	Pain scores were collected within one to two weeks of the intervention. No long-term follow-up. Patients with Ankylosing spondylosis.
Kokar et al, 2021 (86)	The Role of Sacroiliac Joint Steroid Injections in the Treatment of Axial Spondyloarthritis	This study includes only 43 patients, otherwise studies efficacy at 6 months.
Khayyat et al, 2022 (87)	Ultrasound Guided Corticosteroids Sacroiliac Joint Injections (SIJIS) in the Management of Active Sacroiliitis: A Real-Life Prospective Experience	This study includes only 26 patients.
Karabacakoglu et al, 2022 (88)	Fluoroscopy-Guided Intraarticular Corticosteroid Injection into the Sacroiliac Joints in Patients with Ankylosing Spondylitis	This study includes only 22 patients, outcome evaluated only at 1 month.
Schneider et al, 2020 (89)	Validity of Physical Exam Maneuvers in the Diagnosis of Sacroiliac Joint Pathology	Only diagnostic block, no follow up
Mekhail et al, 2021 (90)	Diagnosis of Sacroiliac Joint Pain: Predictive Value of Three Diagnostic Clinical Tests	Only diagnostic block, no follow up.
Laslett et al, 2003 (91)	Diagnosing Painful Sacroiliac Joints: A Validity Study of a McKenzie Evaluation and Sacroiliac Provocation Tests	Only diagnostic block, no follow up.
Elgafy et al, 2001 (92)	Computed Tomography Findings in Patients with Sacroiliac Pain	Only diagnostic block, no follow up.
Maigne et al, 1996 (93)	Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain	Only diagnostic block, no follow up.
Rosenberg et al, 2000 (94)	Computerized Tomographic Localization of Clinically-Guided Sacroiliac Joint Injections	Only diagnostic block, no follow up.

review criteria showed 9 trials as high-quality (40,42-47,49,50) scoring at least 9 of 13, while 2 trials (41,48) scored between 5 and 8, thus were said to be studies of moderate quality. However, based on the IPM-QRB instrument, 5 of 11 trials scored high with scores of above 32 of 48 (40,43,46,47,49). The remaining 6 trials showed moderate quality with scores above 16 (41,42,44,45,48,50).

Table 5 shows the results of utilizing IPM-QRBNR criteria for 3 observational studies (52-54). it shows there were no trials of high-quality. Two studies (52,54) scored between 16 and 31, thus were considered to be moderate quality, with one study (53) determined as low-quality with a score of 14.

Study Characteristics

Tables 6 and 7 show characteristics of the RCTs and observational studies.

Placebo-controlled Trials

There were no placebo-controlled trials available meeting the selection criteria.

Table 3. *Methodological quality assessment of randomized trials utilizing Cochrane review criteria.*

	Kim et al (40)	Jee et al (41)	Soneji et al (43)	Singla et al (44)	Dutta et al (45)	Cohen et al (46)	Salman et al (47)	Bessar et al (48)	AboElfadl et al (49)	Chen et al (50)	Visser et al (42)
Randomization adequate	Y	Y	Y	Y	Y	Y	Y	Y	Y	U	Y
Concealed treatment allocation	N	N	Y	Y	Y	Y	Y	N	Y	U	Y
Patient blinded	Y	N	N	N	N	Y	Y	N	Y	Y	N
Care provider blinded	N	N	N	Y	N	N	N	N	N	Y	N
Outcome assessor blinded	Y	N	Y	Y	Y	Y	Y	N	Y	Y	Y
Drop-out rate described	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
All randomized participants analyzed in the group	Y	N	Y	Y	Y	N	Y	N	N	N	Y
Reports of the study free of suggestion of selective outcome reporting	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Groups similar at baseline regarding most important prognostic indicators	Y	Y	Y	Y	Y	Y	Y	y	Y	Y	Y
Co-interventions avoided or similar	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Compliance acceptable in all groups	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y
Time of outcome assessment in all groups similar	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Are other sources of potential bias unlikely?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
SCORE	11/13	8/13	11/13	12/13	10/13	11/13	12/13	8/13	11/13	9/13	11/13

Y = yes; N = no; U = undecided

Source: Furlan AD, et al; Editorial Board of the Cochrane Back, Neck Group. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group. Spine (Phila Pa 1976) 2015; 40:1660-1673 (37).

Table 4. *Methodological quality assessment of randomized trials utilizing ASIPP IPM – QRB.*

		Kim et al (40)	Jee et al (41)	Soneji et al (43)	Singla et al (44)	Dutta et al (45)	Cohen et al (46)	Salman et al (47)	Bessar et al (48)	AboElfadl et al (49)	Chen et al (50)	Visser et al (42)
I.	TRIAL DESIGN AND GUIDANCE REPORTING											
1.	CONSORT or SPIRIT	2	2	3	3	0	3	2	2	3	3	2
II.	DESIGN FACTORS											
2.	Type and Design of Trial	2	2	2	2	2	2	2	2	2	2	2
3.	Setting/Physician	2	1	2	1	2	2	2	1	1	1	1
4.	Imaging	3	2	3	1	3	3	3	3	3	3	3
5.	Sample Size	1	3	1	0	0	3	1	0	2	0	0
6.	Statistical Methodology	1	1	1	1	1	1	1	1	1	1	1

Table 4 cont. *Methodological quality assessment of randomized trials utilizing ASIPP IPM – QRB.*

		Kim et al (40)	Jee et al (41)	Soneji et al (43)	Singla et al (44)	Dutta et al (45)	Cohen et al (46)	Salman et al (47)	Bessar et al (48)	AboElfadl et al (49)	Chen et al (50)	Visser et al (42)
III.	PATIENT FACTORS											
7.	Inclusiveness of Population											
	• For facet or sacroiliac joint interventions:	2	2	0	0	1	1	1	0	2	1	0
8.	Duration of Pain	1	1	1	1	1	0	2	0	2	0	0
9.	Previous Treatments	0	0	2	0	2	0	0	2	2	2	0
10.	Duration of Follow-up with Appropriate Interventions	2	0	1	1	2	1	2	2	2	2	1
IV.	OUTCOMES											
11.	Outcomes Assessment Criteria for Significant Improvement	2	2	2	2	2	2	2	2	1	2	0
12.	Analysis of all Randomized Participants in the Groups	1	1	2	2	2	1	2	1	1	1	2
13.	Description of Drop Out Rate	2	2	2	2	0	0	2	1	1	0	0
14.	Similarity of Groups at Baseline for Important Prognostic Indicators	2	2	2	2	2	2	2	2	2	2	2
15.	Role of Co-Interventions	1	1	1	1	1	1	1	1	1	1	1
V.	RANDOMIZATION											
16.	Method of Randomization	2	2	2	2	2	2	2	2	2	0	2
VI.	ALLOCATION CONCEALMENT											
17.	Concealed Treatment Allocation	1	0	2	2	2	2	2	0	2	0	2
VII.	BLINDING											
18.	Patient Blinding	1	0	0	0	0	1	1	0	1	1	0
19.	Care Provider Blinding	0	0	0	1	0	0	0	0	0	1	0
20.	Outcome Assessor Blinding	1	0	1	1	1	1	1	0	1	1	1
VIII.	CONFLICTS OF INTEREST											
21.	Funding and Sponsorship	2	2	2	2	2	3	2	2	2	2	2
22.	Conflicts of Interest	2	2	0	0	3	2	3	2	3	3	3
TOTAL		33/48	28/48	32/48	27/48	31/48	33/48	36/48	26/48	37/48	29/48	25/48

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 (35).

Table 5. *Assessment of nonrandomized or observational studies utilizing IPM-QRBNR.*

		Borowsky & Fagen (52)	Hawkins & Schofferman (53)	Savran Sahin et al (54)
I.	STUDY DESIGN AND GUIDANCE REPORTING			
1.	STROBE or TREND GUIDANCE	3	0	0
II.	DESIGN FACTORS			
2.	Study Design and Type	1	0	0
3.	Setting/Physician	2	1	1
4.	Imaging	3	3	2
5.	Sample Size	1	1	0
6.	Statistical Methodology	2	0	2
III.	PATIENT FACTORS			
7.	Inclusiveness of Population	2	1	2
8.	Duration of Pain	0	0	0
9.	Previous Treatments	2	0	2
10.	Duration of Follow-up with Appropriate Interventions	2	1	3
IV.	OUTCOMES			
11.	Outcomes Assessment Criteria for Significant Improvement	2	2	2
12.	Description of Drop Out Rate	2	1	2
13.	Similarity of Groups at Baseline for Important Prognostic Indicators	2	0	0
14.	Role of Co-Interventions	2	1	2
V.	ASSIGNMENT			
15.	Method of Assignment of Participants	1	1	1
VI.	CONFLICTS OF INTEREST			
16.	Funding and Sponsorship	2	2	2
TOTAL		29/48	14/48	21/48

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 (36).

Active-controlled Trials

There were 11 randomized active-controlled trials (40-50). The comparators included prolotherapy (40), fluoroscopic guidance vs ultrasound guidance (41,43), intraarticular PRP (44), pulsed radiofrequency (45), landmark-guided procedures (46), radiofrequency ablation (47,49), comparison of fluoroscopic-guided vs CT-guided procedures (46), PRP injections (50), and physiotherapy (42).

Observational Studies

There were 3 observational studies (52-54), all of them utilizing a retrospective evaluation. Two of them had no control group (53,54); one study had a comparative group of combined intraarticular injection and periarticular injection (52).

Controlled Dual Diagnostic Blocks

There were no studies utilizing controlled dual diagnostic blocks.

Single Diagnostic Blocks with 75% or Above Percent Relief

Three trials utilized > 80% pain relief as the criterion standard (41,45,50).

Single Diagnostic > 50% Pain Relief

There were 3 studies utilizing single diagnostic block (40,47,49).

Clinical Diagnosis

All the remaining studies utilized clinical diagnosis for selection (42-44,46,48,52-54).

Qualitative Analysis

Of the 11 RCTs, 5 trials showed positive results (41-43,46,50). All other trials were negative (40,44,45,47-49).

Observational Studies

Among the observational studies, 2 of the 3 observational studies showed positive results (53,54) and

Table 6. Results of randomized trials 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.	Outcomes per Episode	Short-term ≤ 6 mos.	Long-Term		
								> 6 mos.	1 year	
Kim et al, 2010 (40) R, AC, F Quality Scores: Cochrane = 11/13 IPM-QRB = 33/48	50 Patients with SI joint pain >2 months, failed medical treatment Single diagnostic block with >50% pain relief.	Intraarticular steroid injection (levobupivacaine with triamcinolone) = 26 vs intraarticular prolotherapy (levobupivacaine plus 2.5 ml of 25% dextrose) =24 Repeated up to three injections every other week.	NA	Percentage of patients with >50% pain relief in steroid group = 27.2% vs 63.6% in prolotherapy group	Percentage of patients with >50% pain relief at 15 months in steroid group = 10.2% vs 58.7% in prolotherapy group	N	N	N	N	Negative study Negative results for intraarticular steroid therapy. Study reported that prolotherapy provided significantly longer pain relief in SI joint pain compared to intraarticular steroid injections. Clinical Relevance: Moderate Grade: No change
Jee et al, 2014 (41) R, AC, F Quality Scores: Cochrane = 8/13 IPM-QRB = 28/48	120 Patients with chronic low back pain >3 months without radiculopathy Single diagnostic block with >80% pain relief	Intraarticular injection performed under fluoroscopic guidance = 55 vs ultrasound guidance = 55 (Others were excluded for various causes)	Both groups had significant decrease in verbal numeric pain scale at 3 months compared to their baseline (combined baseline 6.49±0.87 vs 2.58±0.46 at 3 months). NO significant difference between the groups in pain reduction.	NA	NA	P	P	NA	NA	Positive trial Equal and significant relief with ultrasound and fluoroscopy guided intraarticular steroid injection Clinical Relevance: Moderate Grade: No change
Soneji et al, 2016 (43) R, AC, F Quality Scores: Cochrane =11/13 IPM-QRB = 32/48	40 Patients with clinical diagnosis of SI joint pain No diagnostic blocks	Intraarticular injection performed under fluoroscopy guidance = 20 vs ultrasound guidance =20	No significant difference between both groups. The mean pain NRS scores for fluoroscopy and ultrasound groups were 6.2(2.3) and 5.5(2.2) compared to their baseline scores of 6.7(1.3) and 6.6(2.0) respectively.	NA	NA	P	p	NA	NA	Positive trial Equal relief with fluoroscopy and ultrasound guidance. The overall pain relief at 3 months with either imaging guidance was small. Clinical Relevance: Low Grade: Downgraded

Table 6 continued. Results of randomized trials 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.	Outcomes per Episode	Short-term ≤ 6 mos.	Long-Term		
								> 6 mos.	1 year	
Singla et al, 2017 (44) R, AC, F Quality Scores: Cochrane = 12/13 IPM-QRB = 27/48	40 Patients with chronic low back pain >3 months and clinical diagnosis of unilateral SI joint pain No diagnostic blocks	Intraarticular injection of methylprednisolone plus lidocaine = 20 vs intraarticular injection of platelet rich plasma = 20	Reduction of pain VAS scores of ≥50% was seen in 25% of patients in steroid group compared to 90% in platelet rich plasma group	NA	NA	N	N	NA	NA	Negative trial Negative for intraarticular steroid injection. Study reports significantly more pain relief in intraarticular platelet rich plasma compared to intraarticular steroid injection Clinical Relevance: Low Grade: Downgraded
Dutta et al, 2018 (45) R, AC, F Quality Scores: Cochrane =10/13 IPM-QRB = 31/48	30 Patients with low back pain >3 months, not responsive to conservative therapy Single diagnostic block with 80% pain relief	Intraarticular depo-methylprednisolone injection = 15 vs Pulsed radiofrequency ablation = 15	Intraarticular Steroid group = 4.4 ± 0.98 vs PRF ablation group= 3.067 ± 0.88 (P= 0.0005)	Intraarticular steroid group = 5.400 ± 1.5 vs PRF ablation group= 3.200 ± 1.2 (P= 0.0002)	NA	N	N	N	NA	Negative trial Negative for intraarticular steroid injection group compared to pulsed radio frequency group Trial reported both intraarticular steroid injection and pulsed radiofrequency ablation were effective in pain relief at 3 and 6 months but pulsed radiofrequency was much more effective. Clinical Relevance: Moderate Grade: Same

Table 6 continued. Results of randomized trials 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.	Outcomes per Episode	Short-term ≤ 6 mos.	Long-Term > 6 mos.	Long-Term 1 year	
Cohen et al, 2019 (46) R, AC, F Quality Scores: Cochrane =11/13 IPM-QRB = 33/48	125 Patients with chronic low back pain >6 weeks and clinical diagnosis of sacroiliac joint pain No diagnostic blocks	Fluoroscopically guided = 64 (Group I) vs Landmark guided= 61 (Group II) Intraarticular steroid and local anesthetic injections	Fluoroscopy group mean change from baseline of -1.8 ± 2.1 points in Group I vs -0.9 ± 2.0 points in Group II	NA	NA	P	P	NA	NA	Weak positive trial Positive for fluoroscopically guided intraarticular injections Significant difference between the groups favoring fluoroscopically guided injections. Clinical Relevance: Low Grade: Downgraded
Salman et al, 2019 (47) R, AC, F Quality Scores: Cochrane = 12/13 IPM-QRB = 36/48	30 Patients with chronic low back pain >6 months Single positive diagnostic SI joint block with 50% relief criteria	intraarticular steroid injection = 15 vs Radiofrequency ablation (RFA)= 15	Percent of patients with >50% pain relief in steroid injection group = 0% vs RFA group = 60%	Percent of patients with >50% pain relief in RFA group = 53%	NA	N	N	N	NA	Negative trial RFA had better pain relief at both 3 months compared to steroid injection Clinical Relevance: Moderate Grade: Downgraded
Bessar et al, 2021 (48) R, AC, F Quality Scores: Cochrane = 8/13 IPM-QRB = 26/48	61 Patients with moderate to severe chronic low back pain with clinical diagnosis of SI joint pain and failed conservate therapies. No diagnostic blocks	Fluoroscopic guided steroid injection =29 vs CT guided group = 23 (Patients that were included in analysis)	Mean pain NRS scores of fluoroscopy-guided = 5.6±0.40 (P= 0.1) vs CT guided = 5.3±0.82	Mean pain NRS scores of fluoroscopy guided = 4.3±0.89 (P = 0.001) vs CT guided = 3.5±0.73	Mean pain NRS scores of fluoroscopy guided = 2.8±0.99 (P = <0.0001) vs CT guided = 1.6±0.65	N	N	N	P	Negative trial CT guided steroid injection more effective in pain relief compared to fluoroscopy guided in long term. Clinical Relevance: Low Grade: No change

Table 6 continued. Results of randomized trials 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.	Outcomes per Episode	Short-term ≤ 6 mos.	Long-Term		
								> 6 mos.	1 year	
AboElfadl et al, 2021 (49) R, AC, F Quality Scores: Cochrane = 11/13 IPM-QRB = 37/48	68 Patients with persistent SI joint arthritis with chronic pain>6 months Single diagnostic block with 50% relief criteria	Intraarticular methylprednisolone alone (C) = 30 vs Intraarticular Radiofrequency ablation + Methylprednisolone (RF) = 30	Median NRS pain scores of C group = 3.5 vs RF group median NRS = 2 (*P*= 0.015) from baseline of 9(4-10) and 8.5(6-10) respectively.	Median NRS pain scores of C group = 3.5 vs RF group median NRS = 1.5 (*P*= 0.015)	Median NRS pain scores of C group = 4 vs RF group median NRS = 2.5 (*P*= 0.025)	N	N	N	P	Negative trial Intraarticular radiofrequency plus methylprednisolone had significant lower NRS scores at 3,6,12 month follow up compared to intraarticular methylprednisolone alone. Clinical Relevance: Moderate Grade: No change
Chen et al, 2022 (50) R, AC, F Quality Scores: Cochrane = 9/13 IPM-QRB = 29/48	26 Patients with chronic unilateral low back pain Single diagnostic block with 80% relief criteria	Intraarticular steroid = 11 vs PRP injection = 15	Lower numeric pain rating scale (NPRS) score in steroid group than PRP group	Lower NPRS scores in steroid group than PRP group	NA	P	P	P	NA	Positive trial Positive for intraarticular steroid Steroid group had better pain relief at 3 and 6 months follow up compared to PRP group.
Visser et al, 2013 (42) R, AC, F Quality Scores: Cochrane =11/13 IPM-QRB = 25/48	51 Patients with clinical diagnosis of SI joint related leg pain and exclusion of discogenic, stenotic pain and spondyloarthropathies. No diagnostic blocks	Intraarticular injection = 18 vs Physiotherapy = 15 vs Manual therapy = 18	Success rate in intraarticular injection = 50% and in physical therapy = 20%, manual therapy = 72%. No differences were found between intra-articular injection and manual therapy (P = 0.17)	NA	NA	P	P	NA	NA	Positive trial Positive for manual therapy and intraarticular injection. Clinical Relevance: Low Grade: No change

R = Randomized; F = Fluoroscopy; AC = Active-control; P = Positive; N = Negative; NA = Not Applicable; IPM-QRB = Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment; CT = computed tomography; C = control; RF = radiofrequency; NRS = Numeric Rating Scale; PRP = platelet rich plasma

Table 7. *Results of 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.	Outcomes per Episode	Short-term ≤ 6 mos.	Long-Term		
								> 6 mos.	1 year	
Borowsky & Fagen, 2008 (52) Retrospective review of 2 case series Quality Scores: IPM-QRBNR= 29/48	120 Sequentially all patients who had undergone SI joint injection at a single practice. All patients had low back pain and failed conservative therapy. No diagnostic blocks	Intraarticular injection= 40 2 mL of bupivacaine and 40 mg of DepoMedrol vs Combined intraarticular plus periarticular injection with 2 mL each of bupivacaine and 40 mg intraarticular and same volume dosage	Rate of positive response (defined as a 50% or better improvement in VAS Score) for intraarticular was 12.5% VS 31.25% for combined intraarticular plus periarticular injection	NA	NA	N	N	NA	NA	Negative study Better results for Combined injection. Combined intraarticular injection and periarticular injection of anesthetic and steroid had statistically significant better response rate than intraarticular injection alone. Clinical Relevance: Low Grade: Same
Hawkins & Schofferman, 2009 (53) Retrospective Ies Quality Scores: IPM-QRBNR= 14/48	155 Patients who received SI joint injections and had at least 2 year follow up after the injections No diagnostic blocks	All patients who underwent one or more intraarticular injection of anesthetic and steroid No control group	NA	NA	Mean duration of follow up was 44 months The average duration of relief was 9.3 months per injection in patients who received 2 or more injections.	P	NA	P	P	Positive study Positive for intraarticular injection of local anesthetic and steroid. 77% of patients were positive responders after first injection (≥5 0% relief). On average, the relief lasted 9.3 months per injection in patients who received 2 or more injections. On average, the patients received 2.7 injections per patient. Clinical Relevance: Low Grade: No change

Table 7 cont. *Results of 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.	Outcomes per Episode	Short-term ≤ 6 mos.	Long-Term	
								> 6 mos. / 1 year	
Savran Sahin et al, 2015 (54) Retrospective case review Quality Scores: IPM-QRBNR= 21/48	67 Patients that underwent CT guided intraarticular steroid and local anesthetic injection between January 2009 and December 2013 were included in the study. No diagnostic blocks	CT guided intraarticular steroid and local anesthetic injection No control group	NA	Median VAS score for patients with low grade arthritis was 10 (0-65) while for high grade arthritis was 45 (28-82) with $P<0.05$	NA	P	P	NA / NA	Positive study The patients who underwent CT guided intraarticular steroid injection were assessed for grade of arthritis and were followed for therapeutic effect. In patients with high grade arthritis intraarticular steroid and local anesthetic injection is less effective at long term follow up compared to patients with low grade arthritis. Clinical Relevance: Low Grade: No change

P = Positive; N = Negative; NA = Not Applicable; IPM-QRBNR = Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies; CT = computed tomography; VAS = Visual Analog Scale

one observational study showed negative results (52).

Overall, the trials with negative results exceeded the trials with positive results. Active-controlled trials utilized various types of controls. The number of patients was 50 or more in 6 of the 11 RCTs (40-42,46,48,49) and all 3 of the observational studies (52-54).

Positivity related to the type of diagnostic block or clinical diagnosis had no correlation.

Quantitative Analysis

Related to high variability among the trials included, conventional dual-arm analysis was not feasible. Consequently, a single-arm analysis was performed (Fig. 2).

Figure 2A shows the results of a single-arm meta-analysis utilizing steroids with an sacroiliac joint injection. There were 8 trials (41-43,45-49) used to assess pain scores at 3 months using NRS. As shown in Fig. 2A, the pooled mean difference of functionality scores from the baseline to 3-month follow-up decreased 2.979 points (95% CI: -3.109 to -2.849, $P < 0.0001$).

Figure 2B shows the results of a single meta-analysis utilizing steroids with an sacroiliac joint injection. There were 4 trials (41,45,46,49) used to assess functionality scores at 3 months using the Oswestry Disability Index (ODI). As shown in Fig. 2B, the pooled mean difference of functionality scores from the baseline to 3-month follow-up decreased 18.057 points (95% CI: -19.215 to -16.899, $P < 0.0001$).

Pain and Functionality at 6 Months with Sacroiliac Joint Injection

Figure 3A shows the results of a single meta-analysis utilizing steroids with an sacroiliac joint injection. There were 3 trials (45,48,49) used to assess pain scores at 6 months using NRS. As shown in Fig. 3A, the pooled mean difference of pain scores from the baseline to 6-month follow-up decreased 3.069 points (95% CI: -3.353 to -2.784, $P < 0.0001$).

Figure 3B shows the results of a single meta-analysis utilizing steroids with an sacroiliac joint injection. There were 3 trials (45,48,49) used to assess functionality scores at 6 months using the ODI. As shown in Fig. 3B, the pooled mean difference of functionality scores from the baseline to 6-month follow-up decreased 5.240 points (95% CI: -7.298 to -3.181, $P < 0.0001$).

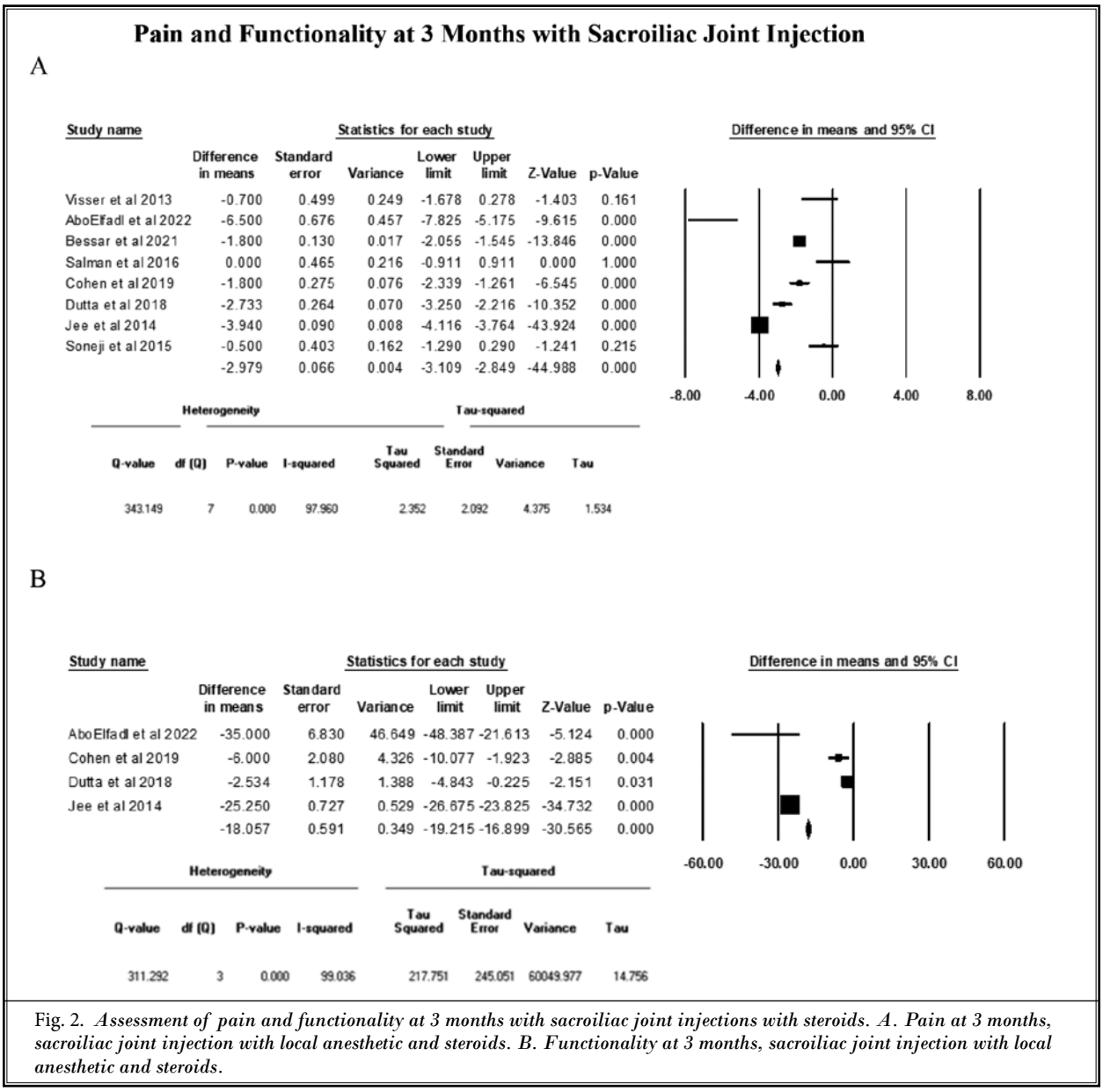

Fig. 2. *Assessment of pain and functionality at 3 months with sacroiliac joint injections with steroids. A. Pain at 3 months, sacroiliac joint injection with local anesthetic and steroids. B. Functionality at 3 months, sacroiliac joint injection with local anesthetic and steroids.*

Analysis of Evidence

Evidence was borderline based on the results from 5 of 11 RCTs which were positive (41-43,46,50) and 2 of the 3 observational studies also being positive (53,54), making a total of 7 of 14 studies positive. A single-arm meta-analysis showed strong results with a pain score reduction of 2.979 points based on 8 trials and an ODI score decrease of 18.057. These scores indicate Level II, or moderate, evidence. At the 6-month follow-up, the evidence was Level III, or fair. Even though pain relief was appropriate, functional status improvement was significantly less than at 3 months, with insignificant improvement.

Overall, the application of GRADE criteria did not change the evidence levels. Thus, the evidence is Level III for therapeutic intraarticular injections with local anesthetic and steroids based on quantitative and qualitative analysis with the application of GRADE criteria.

Discussion

The present systematic review and meta-analysis of sacroiliac joint injections for low back pain originat-

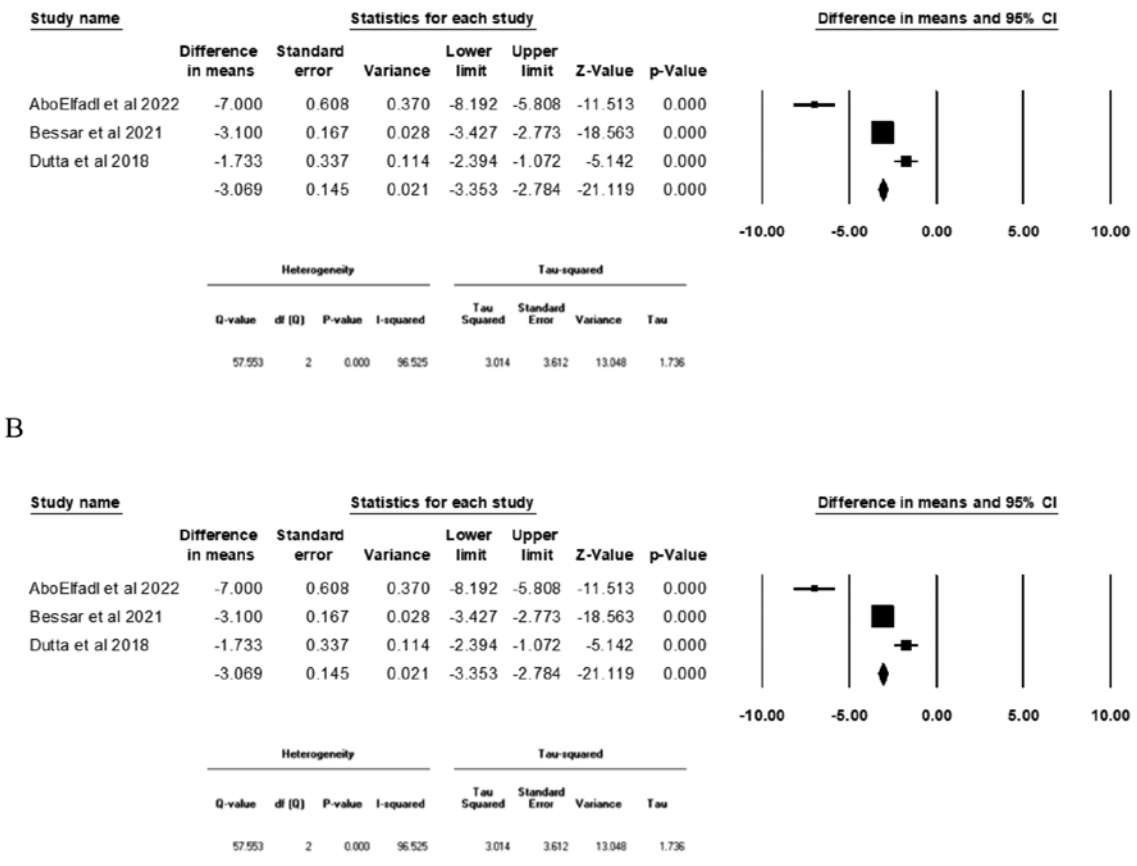

Fig. 3. *Pain and functionality at 6 months in patients receiving sacroiliac joint injections with steroids. A. Pain at 6 months, sacroiliac joint injection with local anesthetic and steroids. B. Functionality at 6 months, sacroiliac joint injection with local anesthetic and steroids.*

ing from the sacroiliac joints shows Level III, or fair, evidence based on relevant moderate and high quality RCTs and relevant observational studies. There were 11 RCTs and 3 observational studies studying intraarticular injections in chronic sacroiliac joint pain without spondyloarthropathy. However, there were no placebo-controlled trials, there were only active-controlled trials. Further, these studies are challenged by a lack of standardized patient selection, lack of uniform diagnostic blocks (i.e., only 3 studies used a single block with 50% relief (40,47,49) with 3 studies using 80% pain relief (41,45,50) and none of the studies using dual blocks.

Steroids were used in varying doses, and there were different technical applications of the procedures, variability and use of imaging to guide the procedures, the type of assessment, and the post-injection duration of when assessing patient response. Finally, there appears to be significant risks of bias (23,25). Further, previous studies included sacroiliac joint injections for spondyloarthritis, which is not a common practice in interventional pain management. Furthermore, the American College of Rheumatology treatment guidelines for axial spondyloarthritis offer a conditional recommendation for sacroiliac joint injections based on 2 small RCTs that have a high risk of bias due to a lack of blinding, thereby resulting in low-quality evidence (95). Consequently, sacroiliac joint injections for axial spondyloarthritis are recommended only as an adjunct in acute pain relief, not as monotherapy (96,97).

Of the 11 RCTs meeting inclusion criteria, 5 were positive (41-43,46,50) and 6 were negative (40,44,45,47-49). The number of patients studied varied from a total

of 26 to 120. The total number of patients included in the 11 RCTs was 641. Of these, the number of patients included in positive studies was 362. Thus, the number of patients showing positive response in the sample of positive studies was 154 of 362. Considering the entire sample, the positive response was 154 of 641 patients studied — 42% of the sample of positive trials and 24% of the entire sample. A further limitation was that no meta-analysis could be performed based on the study design, etc. Among the observational studies, 3 observational studies included a total of 342 patients with 2 of the 3 studies involving 222 patients with positive results. All RCTs and observational studies were included in a single-arm meta-analysis. Three studies collected the data of 6 months or longer (48,49,53).

The results of this systematic review and meta-analysis are in agreement with some previous systematic reviews (22) and may differ with others (23). Overall, the evidence was inconclusive in the previous reviews, including the local coverage determinations (LCDs), which are also confirmed in this review. However, there seems to be some evidence emerging. More recently, another RCT was published with positive results, which was published after the analysis was performed for this review (98).

The literature is replete with assumptions and recommendations that systematic reviews and meta-analyses are performed to meet the goals of evidence-based medicine using the best available evidence and determining clinical care for an individual patient (28,29,31,35,99). Thus, systematic reviews and meta-analyses are expected to provide information from high-quality research. However, they may vary and do not guarantee high methodologic and reporting rigor in a large proportion of publications (28,29). Further, multiple limitations have been described, including the presence of multiple biases, which include place of publication bias, publication or multiple publication bias, citation bias, outcome reporting bias, and, finally, interpretation bias (29).

Of all the biases, interpretation bias has been criticized the most as a crucial and relevant issue related to systematic reviews in interventional pain management (29). Interpretation bias has been described as the bias referring to the abilities of reviewers and researchers to synthesize and objectively judge when weighing the results found in a study. It is a well-known fact that 2 researchers of different backgrounds or different viewpoints might look at the same result in a different way, leading to different conclusions based on their own backgrounds and viewpoints (100-102). This issue becomes most relevant when the data are debatable or qualitative, leading to conclusions either being overstated or being understated (102).

One of the most contentious issues described is the descriptions of pragmatic and real-world data, as well as application of GRADE criteria. In fact, Dal-Ré et al (39) described requirements for a genuinely pragmatic RCT, which should fulfill 2 fundamental features, including conduct of the study, which should resemble usual clinical practice, and the applicability of the results to multiple other settings, namely the real world, thus, not limited to the study site. Dal-Ré et al (39) described that some RCTs overly deviate from usual clinical care and pragmatism and many RCTs are classified as pragmatic for purposes of convenience so that the study becomes credible as representing the real-world evidence.

Recent systematic reviews of epidural steroids (28,29) and others (99) have highlighted this phenomenon. These reviews have focused extensively on the role of the placebo effect and inappropriate conversion of active-controlled trials into placebo-controlled trials yielding negative results (103). Systematic reviews published reviewing the role of the placebo effect in epidural injections (103) highlighted the placebo effect to be equivalent to active treatment, in some cases providing credence to some of the criticisms of placebo in interventional pain management. Further, this is seen in relation to the compliance of systematic reviews to various principles, specifically in the systematic analysis of findings of systematic reviews in post-lumbar surgery syndrome (104-108). In this review, there was high compliance in only one systematic review and moderate compliance in 2 systematic reviews. Further, one systematic review included in this analysis (104) showed negative results with a low compliance rate on the PRISMA checklist (30).

The advantages of this systematic review and meta-analysis are inclusion of all the available RCTs and observational studies, the exclusion of spondyloarthropathy studies, and performance of not only a systematic review, but also a meta-analysis with a single-arm analysis. However, the limitations of this systematic review include a significant paucity of relevant literature despite 11 eligible trials. Further, there was lack of placebo-controlled trials. Additionally, there is not a standardized technique and inclusion criteria is poor compared to the standard of practice and medical guidelines.

Conclusion

This systematic review with meta-analysis utilizing appropriate methodology with qualitative and quantitative evidence synthesis with single-arm analysis shows Level III or fair evidence regarding the effectiveness of therapeutic sacroiliac joint injections.

Author Contributions

The study was designed by RNJ, EK, NNK, RP, MRS, ADK, VP and LM.

Statistical analysis was performed by NNK, EK.

All authors contributed to preparation to the manuscript, reviewed, and approved the content with final version.

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Compliance with Ethics Guidelines

This article is based on previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

Data Availability

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

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Appendix Table 1. *Source of risk of bias and Cochrane Review rating system.*

Bias Domain	**Source of Bias**		**Possible Answers**
Selection	(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, preordered sealed envelopes, sequentially-ordered vials, telephone call to a central office, and preordered list of treatment assignments.	Yes/No/Unsure
		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.	
Selection	(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
Performance	(3) Was the patient blinded to the intervention?	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
Performance	(4) Was the care provider blinded to the intervention?	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
Detection	(5) Was the outcome assessor blinded to the intervention?	Adequacy of blinding should be assessed for each primary outcome separately. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or:	Yes/No/Unsure
		• 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., cointerventions, 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	
Attrition	(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 (N.B. these percentages are arbitrary, not supported by literature).	Yes/No/Unsure
Attrition	(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 noncompliance and cointerventions.	Yes/No/Unsure

Appendix Table 1 cont. *Source of risk of bias and Cochrane Review rating system.*

Bias Domain	**Source of Bias**		**Possible Answers**
Reporting	(8) Are reports of the study free of suggestion of selective outcome reporting?	All the results from all prespecified 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
Selection	(9) Were the groups similar at baseline regarding the most important prognostic indicators?	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
Performance	(10) Were cointerventions avoided or similar?	If there were no cointerventions or they were similar between the index and control groups.	Yes/No/Unsure
Performance	(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 for 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
Detection	(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 primary outcome measures.	Yes/No/Unsure
Other	(13) Are other sources of potential bias unlikely?	Other types of biases. For example: • When the outcome measures were not valid. There should be evidence from a previous or present scientific study that the primary outcome can be considered valid in the context of the present. • Industry-sponsored trials. The conflict of interest (COI) statement should explicitly state that the researchers have had full possession of the trial process from planning to reporting without funders with potential COI having any possibility to interfere in the process. If, for example, the statistical analyses have been done by a funder with a potential COI, usually "unsure" is scored.	Yes/No/Unsure

Adapted and Modified from: Furlan AD, et al; Editorial Board of the Cochrane Back, Neck Group. 2015 Updated method guideline for systematic reviews in the Cochrane Back and Neck Group. Spine (Phila Pa 1976) 2015; 40:1660-1673 (34).

Appendix Table 2. *Item checklist for assessment of randomized controlled trials 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
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

Appendix Table 2 cont. *Item checklist for assessment of randomized controlled trials of IPM techniques utilizing IPM – QRB.*

		Scoring
	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	
	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.	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	
	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	

Appendix Table 2 cont. *Item checklist for assessment of randomized controlled trials of IPM techniques utilizing IPM – QRB.*

		Scoring
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: 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 (35).

Appendix Table 3. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR*.

		Scoring
I.	STUDY DESIGN AND GUIDANCE REPORTING	
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
	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

Appendix Table 3 cont. *IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR*.

		Scoring
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
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

Appendix Table 3 cont. ***IPM checklist for assessment of nonrandomized or observational studies of IPM techniques utilizing IPM-QRBNR.***

		Scoring
	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 (36).