

The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain

A PRISMA-compliant meta-analysis

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Abstract

Background: Cooled radiofrequency procedure is a novel minimally invasive surgical technique and has been occasionally utilized in managing chronic sacroiliac joint (SIJ) pain. A meta-analysis was conducted to systematically assess the efficacy and safety of using cooled radiofrequency in treating patients with chronic SIJ pain in terms of pain and disability relief, patients' satisfaction degree as well as complications.

Methods: Studies of using cooled radiofrequency procedure in managing SIJ pain were retrieved from Medline and Web of Science according to inclusion and exclusion criteria. Quality evaluation was conducted using Cochrane collaboration tool for randomized controlled trials and MINORS quality assessment for noncomparative trials. Statistics were managed using Review Manager 5.3.

Results: Totally 7 studies with 240 eligible patients were enrolled. The overall pooled results demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29–4.33, $P < .001$] and 3.78 (95% CIs: 3.31–4.25, $P < .001$) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22–24.17, $P < .001$) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00–0.05, $P < .001$). Only mild complications were observed in the 7 studies, including transient hip pain, soreness, and numbness.

Conclusion: Cooled radiofrequency procedure can significantly relieve pain and disability with no severe complications, and majority of patients are satisfied with this technique. Thus, it is safe and effective to use this procedure in managing patients with chronic SIJ pain. More high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings.

Limitations: The sample size of the included studies was small and various heterogeneity existed.

Abbreviations: CIs = confidence intervals, GPE = Global Perceived Effect, MD = mean difference, NRS = Numerical Rating Scale, ODI = Oswestry Disability Index, OR = odds ratio, PSN = posterior sacral network, RCT = randomized controlled trials, SD = standard deviation, SIJ = sacroiliac joint, VAS = Visual Analog Scale.

Keywords: cooled radiofrequency, meta-analysis, sacroiliac joint pain

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1. Introduction

Sacroiliac joint (SIJ) pain is a condition in which pain is caused by the SIJ that connects the sacrum and the pelvis, and its prevalence is between 18% and 30%.^[1] Although many patients suffer from such disease, a detailed etiology of SIJ pain has not been well described. Trauma, parturition, and lumbar spinal fusion are all likely risk factors in the development of chronic SIJ pain,^[2] and approximately 40% of low back pain in patients with prior lumbar fusion originates from SIJ.^[3,4]

Currently, there is no reliably effective treatment for SIJ pain. Available therapies often begin with conservative strategies for acute cases, including physiotherapy, chiropractic, and nonsteroidal anti-inflammatory drugs.^[5] In chronic cases, corticosteroids injections or SIJ fusion are performed.^[6,7] However, the former cannot maintain long-term effect and the latter is not sufficiently effective to relieve pain and disability.^[8,9] Conventional radiofrequency denervation is often regarded as an alternative minimally invasive therapeutic option for chronic SIJ pain. However, the degree of success varies,^[10,11] because the probes of conventional radiofrequency can only yield small tissue lesions thereby having low chance of successfully finding and denervating nerves that have complex and variable localizations.^[12,13]

Cooled radiofrequency is a novel minimally invasive treatment option targeting nerves that are causing pain. Internally cooled radiofrequency probes can yield larger tissue lesions than those created by conventional radiofrequency probes. Consequently, it can help to achieve better or equal outcomes compared with conventional radiofrequency.^[14–16] Using cooled radiofrequency in managing SIJ pain was firstly described by Leonardo et al in 2008.^[17] After that, this novel procedure was performed by several other groups. However, the complications and degree of pain and disability relief have not been well assessed.

A meta-analysis was performed to systematically evaluate the efficacy and safety of using cooled radiofrequency in treating patients with chronic SIJ pain in the present study.

2. Methods

2.1. Study design and measurements

Our research complies with the principles of Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA). As this is an analysis of previously published articles, participant-informed consent and ethical approval are not required.

The Numerical Rating Scale (NRS) and the Visual Analog Scale (VAS) are used to measure pain intensity. The Oswestry Disability Index (ODI) is used to measure disability degree caused by low back pain. The Global Perceived Effect (GPE) is used to determine whether cooled radiofrequency procedure can improve patients' condition according to an affirmative response to the following 3 questions: My pain has improved/worsened/stayed the same since my last visit. The treatment I received improved/did not improve my ability to perform daily activities. I am satisfied/not satisfied with the treatment I received and would recommend it to others.

2.2. Literature selection criteria

Literature screening was performed by 2 authors independently of each other based on the inclusion and exclusion criteria. Whether an article could be included was decided by the 2 authors. Disagreement was resolved by discussion or the judgment of a third author. Primary screening was conducted

Table 1

Search criteria.

1.	Cooled radiofrequency
2.	Cooled radiofrequency ablation
3.	Cooled RF
4.	C-RFA
5.	Lateral branch neurotomy
6.	1 OR 2 OR 3 OR 4 OR 5
7.	Sacroiliac region pain
8.	Sacral lateral branch nerves
9.	sacroiliac joint pain
10.	pain from sacroiliitis
11.	lower back pain (mesh)
12.	7 OR 8 OR 9 OR 10 OR 11
13.	6 AND 12
14.	Limit 13 to English
15.	Limit 14 to clinical trial

by reading the titles and abstracts, and then full text was read to further evaluate whether an article was eligible.

The literature search was conducted in Medline and Web of Science from January of 1975 to May of 2017. It was not performed to contact study authors to identify additional studies. The search terms included cooled radiofrequency, sacroiliac region pain, and low back pain (Table 1).

2.3. Inclusion criteria

Among studies obtained by search terms, only studies meeting the following inclusion criteria were the candidates of our research: Participants in the studies were patients with chronic SIJ pain. Participants in the studies were treated by cooled radiofrequency procedure. Participants in the studies were followed at least 3 months. At least one of the following items was reported before and after treatment in the studies, NRS, VAS, ODI, GPE, and complications. Studies were presented as peer-reviewed full-text articles and were published in English.

2.4. Exclusion criteria

Among the candidates meeting inclusion criteria, studies had to be deleted if they met the following exclusion criteria: Articles were duplicative in the 2 databases. Scores of NRS, VAS, ODI, or GPE could not be obtained. If a single cohort was described in multiple articles, only the most recent one was included. Flow diagram of literature searching and screening is shown in Fig. 1.

2.5. Data extraction

Characteristics of articles were extracted by 2 authors independently of each other in terms of participants, interventions, comparisons, outcomes, and study design along with length of follow-up. As the data were from peer-reviewed publications, data confirmation from investigators was not performed exclusively.

The mean and standard deviation (SD) of NRS, VAS, and ODI scores measured before and after treatment were extracted, and the number of positive events measured by GPE after treatment was also extracted. Complications were described one by one. If the mean and SD of each measure were not presented in the articles and could not be calculated, we contacted the author for the absent data. We successfully contacted Andrea et al^[14] for the mean and SD of NRS and ODI scores.

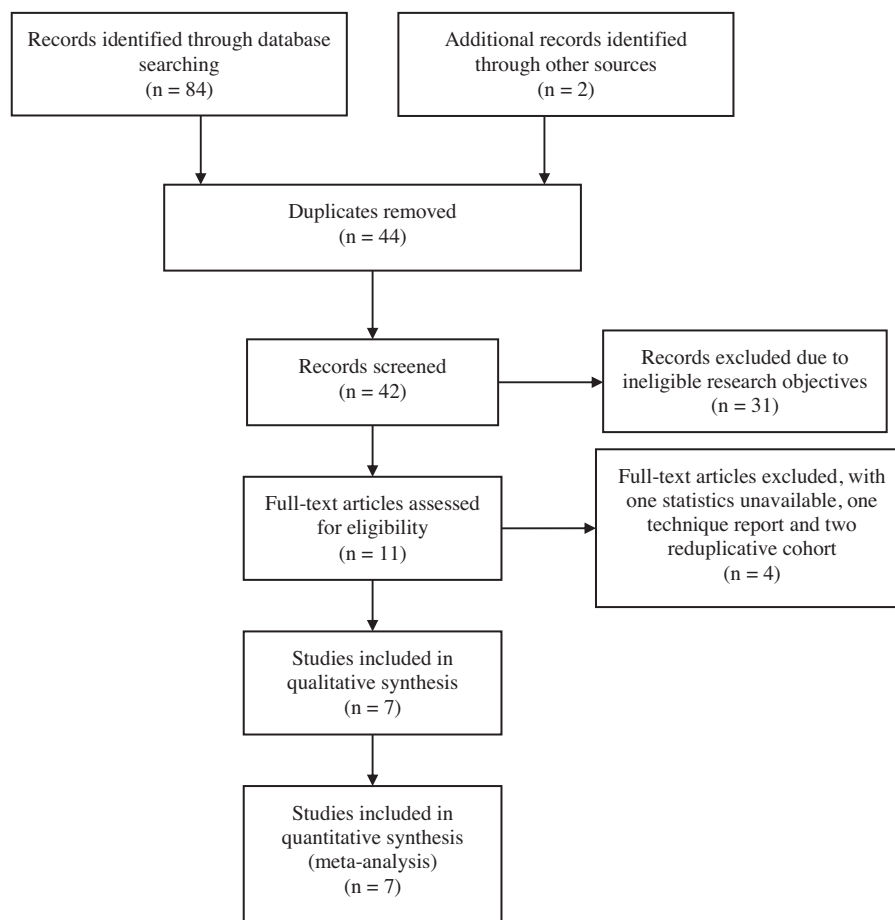


Figure 1. After searching and screening, 7 eligible articles were included in our analysis.

2.6. Statistical analysis

Data were handled using Review Manager 5.3 (The Cochrane Collaboration, Oxford, UK). A quality evaluation was conducted using Cochrane collaboration tool for randomized controlled trials (RCTs) in items of random, allocation concealment, blinding of participants and outcome assessment, incomplete outcome data, and selective reporting.^[18] The quality of noncomparative studies was evaluated based on MINORS quality assessments with scores ranging from 0 to 16.^[19] Zero represents lowest quality and 16 represents highest quality. Publication bias was evaluated by funnel plot.

Changes in continuous outcomes were expressed as the mean difference (MD) with 95% confidence intervals (CIs) such as the scores of NRS, VAS, and ODI. Changes in discontinuous outcomes were expressed as odds ratio (OR) with 95% CIs such as GPE. A 95% CIs reflects a significant level of 0.05. In order to calculate the overall MD and overall OR of all eligible studies, the MD and OR in individual studies were weighted by the inverse of the sum of the between- and within-study variances and Mantel-Haenszel method, respectively. Forest plots were used to graphically display the MD and 95% CIs for each measure.^[20]

Evidence of heterogeneity was evaluated using the χ^2 test and its impact on the meta-analysis was assessed by the I^2 statistic. A $P < .10$ was taken to reflect the presence of significant heterogeneity. The significant level for all other tests was 2-sided at 0.05. I^2 values of 25%, 50%, and 75% were regarded as low,

moderate, and high heterogeneity, respectively.^[21] When significant heterogeneity was found ($P < .10$ or $I^2 > 50\%$), a random-effect model was used; Otherwise, a fixed-effect model was chosen.

Sensitivity analysis was performed by deleting the studies one by one to confirm the stability of the outcomes. Whether one study had a significant impact on the pooled effect was determined by the following strategy: after 1 study was deleted, the point estimate of the pooled effect was out of the 95% CIs of the total pooled effect. No formal test was conducted for purpose of subgroup comparisons.

3. Results

3.1. Literature screening

Eighty-four peer-reviewed articles were identified primarily using search criteria in Table 1, and 2 peer-reviewed articles were identified via references of other articles. A total of 79 articles were excluded according to the inclusion and exclusion criteria. Among excluded studies, 44 were duplicates, 31 were not associated with cooled radiofrequency, 2 were duplicative cohort, 1 was technique report, and 1 was with unavailable data (the MD and SD of the NRS score were not reported and we failed to obtain the original data from corresponding author). Finally, a total of 7 articles with 240 enrolled participants were included^[14,17,22-26] (Fig. 1).

Table 2**Characteristics of included studies.**

Study	Design	Participants	Interventions	Follow-up time, mo	Outcome measures	Comparisons
Leonardo 2008 ^[17]	Retrospective observational study	26 patients with SIJ. 23.1% male, mean age of 61 y	1. CRFD	3–4	ODI, VAS, GPE, Opioid use, complications	1. Before and after treatment
Steven 2008 ^[24]	Randomized placebo-controlled study	28 patients with SIJ 36% male, mean age of 51.9 y	1. CRFD (n=14) 2. Placebo	6	ODI, NRS, GPE, complications	1. Before and after treatment 2. Between treatment and control group
Haktan 2011 ^[25]	Prospective observational study	15 patients with SIJ 20% male, mean age of 47.1 y	1. CRFD	6	ODI, VAS, complications	1. Before and after treatment
Kok 2013 ^[22]	Retrospective observational study	20 patients with SIJ 30% male, mean age of 55.1 y	1. CRFD	24	NRS, GPE, complications	1. Before and after treatment
Nilesh 2016 ^[23]	Randomized, blinded, placebo-controlled study	51 patients with SIJ 32% male, mean age of 56 y	1. CRFD (n=34) 2. Placebo (n=17)	12	ODI, NRS, SF-36, AqoL, complications	1. Before and after treatment 2. Between treatment and control group
Andrea 2017 ^[14]	Retrospective observational study	22 patients with SIJ 38.1% male, mean age of 60.2 y	1. CRFD	12	ODI, NRS, complications	1. Before and after treatment
Wolfgang 2017 ^[26]	Retrospective observational study	109 patients with SIJ 31.9% male, unknown mean age	1. CRFD	6 (n=53), 12 (n=59)	VAS, Opioid use, complications	1. Before and after treatment

CRFD = cooled radiofrequency denervation, SIJ = sacroiliac joint.

3.2. Characteristics of studies

The included studies were published between 2008 and 2017. Among them, 4 were retrospectively observational studies,^[14,17,22,26] 2 were RCTs,^[23,24] and 1 was prospectively

observational study.^[25] The study locations distributed in Turkey,^[25] Italy,^[14] Singapore,^[30] USA,^[17,23,24] and Austria.^[26] The number of participants varied from 15 to 109 and the follow-up time varied from 3 to 24 months in individual studies. Characteristics of the articles are presented in Table 2.

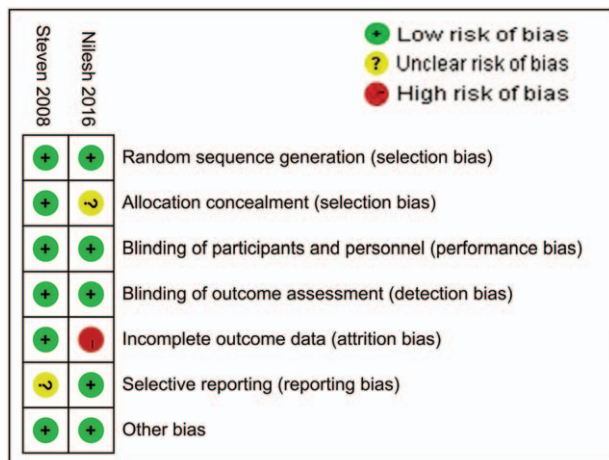


Figure 2. Risk of bias assessment for randomized controlled trials.

3.3. Risk of bias assessment

The 2 RCTs showed a low risk of bias (Fig. 2), and scores of the noncomparative studies ranged from 10 to 12 (Table 3). Publication bias for each measure is presented in Fig. 3. All the funnel plots were symmetrical, thus indicating no significant publication bias, although the number of included studies was small.

4. Outcomes of meta-analysis**4.1. Pain relief measured by NRS and VAS**

NRS scores were reported by 4 articles (n=81)^[14,22–24] with no significant heterogeneity ($\chi^2=5.58, P=.13, I^2=46\%$). The mean scores of NRS decreased after treatment in all of the 4 studies, with the MD varying from 2.7 to 4.3. The overall MD in pain intensity after treatment was 3.81 (95% CIs: 3.29–4.33, $P<.001$) as measured by the NRS, indicating that pain relieved significantly. The effect estimates and 95% CIs for individual

Table 3**The MINORS quality assessment of noncomparative studies.**

Items	Score				
	Leonardo 2008 ^[17]	Haktan 2011 ^[25]	Kok 2013 ^[22]	Andrea 2017 ^[14]	Wolfgang 2017 ^[26]
1. A clearly stated aim	2	2	2	2	2
2. Inclusion of consecutive patients	2	1	2	0	0
3. Prospective collection of data	0	2	0	0	0
4. Endpoints appropriate to the aim of study	2	2	2	2	2
5. Unbiased assessment of the study endpoint	2	2	2	2	2
6. Follow-up period appropriate to the aim of the study	1	1	2	2	2
7. Loss to follow-up less than 5%	2	2	2	2	2
8. Prospective calculation of the study size	0	0	0	0	0
Total score	11	12	12	10	10

*The items are scored 0 (not reported), 1 (reported but inadequate), or 2 (reported and adequate).

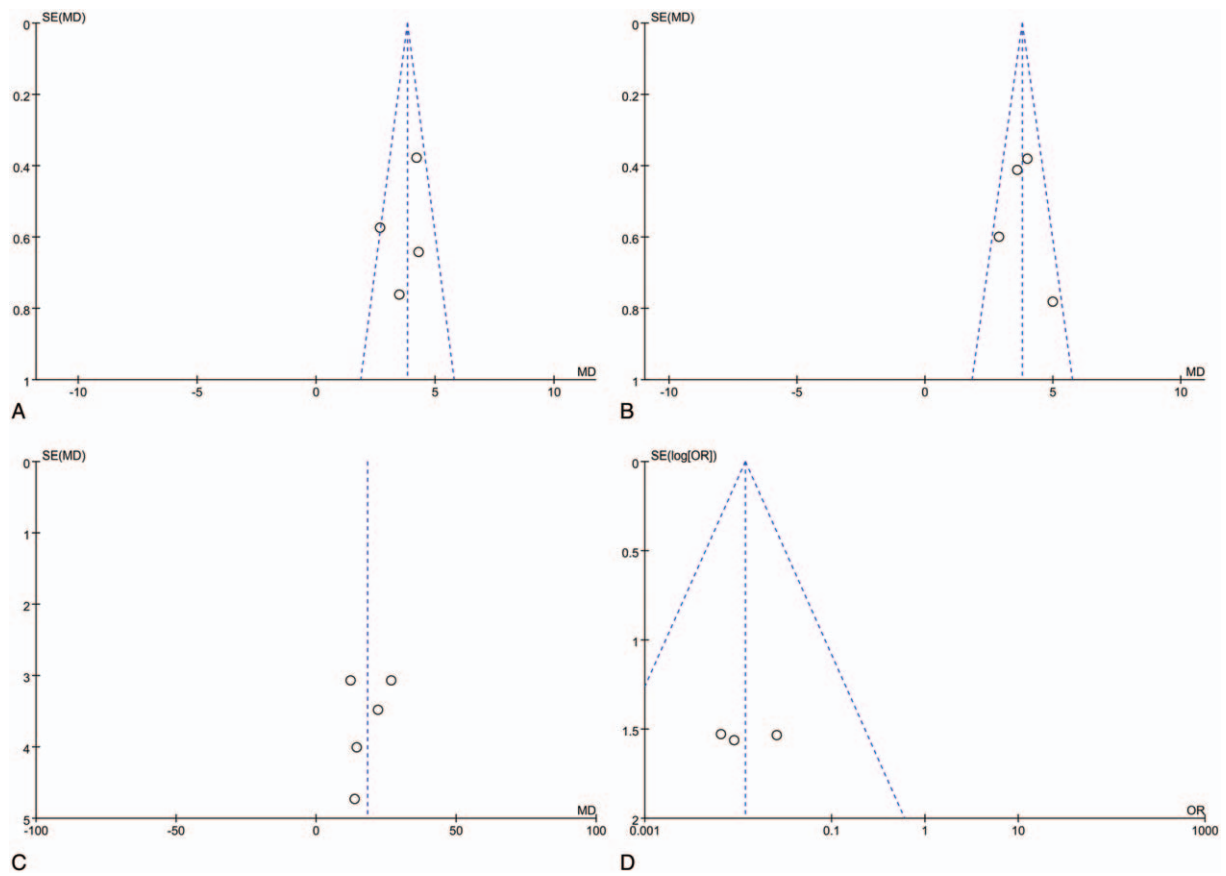


Figure 3. Publication bias assessed by funnel plot. A, B, C, and D were funnel plots of studies reporting NRS, VAS, ODI, and GPE, respectively. All the funnel plots were symmetrical thus indicating no significant publication bias.

studies as well as overall effect estimates and 95% CIs are shown in Fig. 4. Publication bias is presented in Fig. 3A.

VAS scores were reported by 3 articles (n = 150)^[17,25,26] with no significant heterogeneity ($\chi^2 = 5.13, P = .16, I^2 = 41\%$). In the article published by Wolfgang et al, patients were divided into 2 groups according to the follow-up time.^[26] Fifty-three participants were followed by 6 months and 56 were followed by 12 months. The MD and SD of VAS scores of the 2 subgroups were reported separately, so they were regarded as 2 cohorts instead of combined them together, as the cohorts were not reduplicative. The mean scores of VAS decreased after treatment in all of the 3 articles, with MD varying from 2.9 to 5.0. The overall MD in pain intensity after treatment was 3.78 (95% CIs: 3.31–4.25, $P < .001$) as measured by the VAS, indicating that pain relieved

significantly. The effect estimates and 95% CIs for individual studies as well as overall effect estimates and 95% CIs are shown in Fig. 5. Publication bias is presented in Fig. 3B.

4.2. Disability relief measured by ODI

ODI scores were reported by 5 articles (n = 103)^[14,17,23–25] with significant heterogeneity ($\chi^2 = 33.11, P < .001, I^2 = 72\%$). The mean scores of ODI decreased after treatment in all of the 5 articles, with the MD varying from 12.4 to 26.9. The overall MD of ODI scores was 18.20 (95% CIs: 12.22–24.17, $P < .001$), indicating that disability relieved significantly. The effect estimates and 95% CIs for individual studies as well as overall effect estimates and 95% CIs are shown in Fig. 6. Publication bias is presented in Fig. 3C.

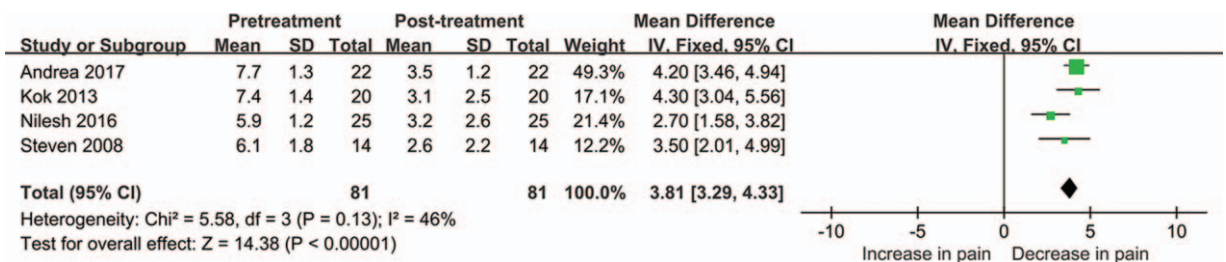


Figure 4. Forest plot of changes in NRS scores measured before and after treatment. The difference was statistically significant ($P < .001$), indicating that pain intensity decreased significantly after cooled radiofrequency procedure.

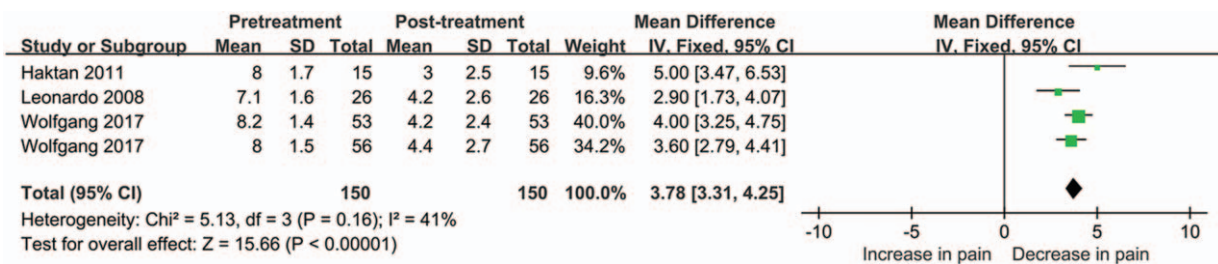


Figure 5. Forest plot of changes in VAS scores measured before and after treatment. The difference was statistically significant ($P < .001$), indicating that pain relieved significantly after cooled radiofrequency procedure.

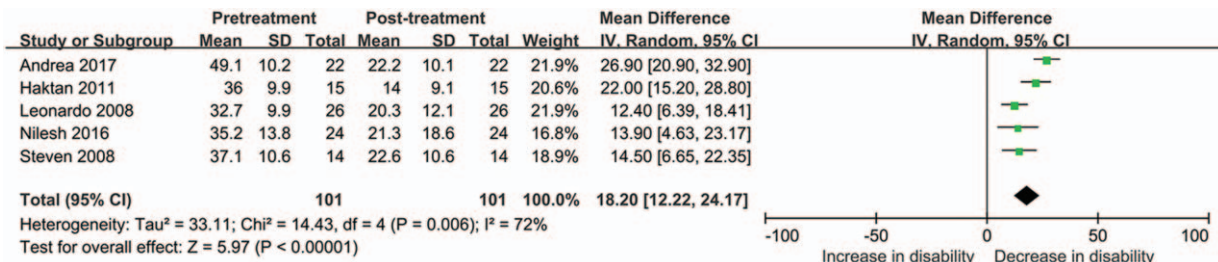


Figure 6. Forest plot of changes in ODI scores measured before and after treatment. The difference was statistically significant ($P < .001$), indicating that disability relieved significantly after cooled radiofrequency procedure.

4.3. Positive events of pain and disability relief as well as satisfaction degree measured by GPE

We supposed that no patient presented positive results before treatment. GPE was reported in 4 articles (n = 75)^[17,22,24,25] with no significant heterogeneity ($\chi^2 = 0.48, P = .92, I^2 = 0\%$). Seventy-two percent (n = 54) patients presented positive results as measured by GPE. The overall OR was 0.01 (95% CIs: 0.00–0.05, $P < .001$), indicating that patients' overall condition improved significantly. The effect estimates and 95% CIs in individual studies as well as overall effect estimates and 95% CIs are shown in Fig. 7. Publication bias is presented in Fig. 3D.

4.4. Complication

None of the 7 articles described any severe or moderate complications during and after the cooled radiofrequency procedure. Wolfgang et al reported that mild complications were spontaneously resolved without any sequelae.^[26] A small

proportion of subjects were described to be with soreness or numbness at the introducer sites in the first 1 to 2 weeks after treatment.^[22,23] Steven et al reported 1 patient with transient nonpainful buttock paresthesias that resolved without therapy.^[24] Andrea et al reported that 1 patient had transient leg pain that could be related to post-procedure neuritis and was resolved after 1-week treatment with oral steroids.^[14] The hip pain occurred in almost all of the patients and lasted about 5 days dissipated without any intervention other than simple analgesics in the study of Haktan et al.^[25] Leonardo described no complications being observed during or after treatment.^[17] In general, using cooled radiofrequency procedure is safe in managing SIJ.

4.5. Sensitivity analysis

After deleting articles one by one, all the point estimates of the pooled effect were in the 95% CIs of the total pooled effect. Thus, the sensitivity in the present article was low and the outcomes were credible and stable.

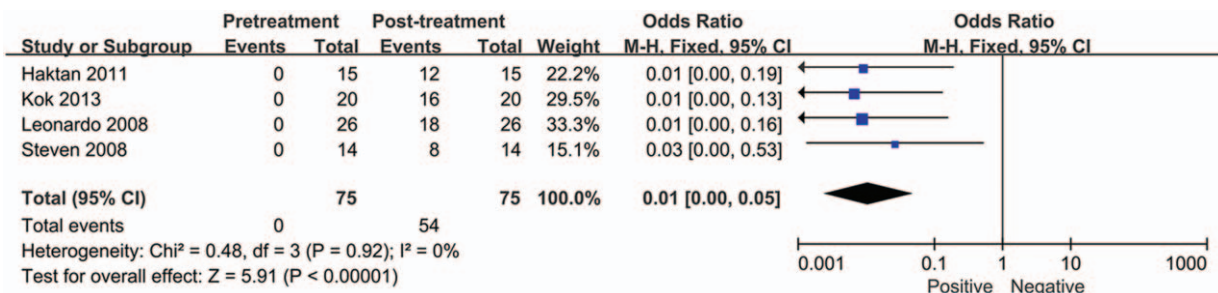


Figure 7. Forest plot of changes in outcomes of GPE measured before and after treatment. The difference was statistically significant ($P < .001$), indicating that cooled radiofrequency procedure can significantly improve patients' condition.

5. Discussion

The pooled outcomes showed great positive results as measured by GPE and presented significant decrease of NRS, VAS, and ODI scores, indicating that cooled radiofrequency could significantly relieve pain and disability of patients with chronic SIJ pain. Importantly, there were no severe complications reported in any studies. Therefore, we suggest using this novel procedure in managing chronic SIJ pain. Previously, Vanelderen et al^[27] recommended cooled radiofrequency neurotomy for patients who failed or received only short-term effects from intra-articular injections. Simopoulos et al^[10] also provided evidence supporting using this procedure in managing SIJ pain. Our conclusion is consistent with theirs and the evidence of the present study is stronger than theirs.

In spite of the effectiveness reported by this article, placebo effects may exist in the observational studies. In order to eliminate such possibility, 2 RCTs^[23,24] were conducted and they revealed that such positive outcomes were not attributable to a placebo effect. Besides, Andrea et al demonstrated that cooled radiofrequency procedure afforded patients with greater and more durable analgesia and disability relief than conventional radiofrequency procedure for chronic SIJ pain.^[14]

Small-volume local anesthetic blocks test is the most commonly used method to diagnose the SIJ pain, and it was utilized in all the included studies. It should be noted that 1 difference exists in diagnostic criteria of SIJ pain, which may preclude direct comparison of outcomes. During diagnosis period, a cutoff threshold of at least 50% pain reduction after test block was chosen by some studies,^[14,17,22,26] while others regarded 75% pain reduction as the cutoff threshold.^[23–25] Although Cohen et al found no significant differences existing between radiofrequency denervation outcomes when they compared treatment efficacy between cutoff thresholds of 50% and 80%,^[15] this factor might still have mildly negative effect on the outcomes of individual studies.

Another variation is the difference in participant selection in individual studies. Although majority of the selection criteria were the same, few existing differences might still impact the outcomes. Patients with failed back surgery syndrome (n=6)^[24] and previous back surgery (n=4)^[14] were included in 2 studies, while patients with history of spinal surgery were excluded by Haktan et al.^[25] Previous back surgery may be a factor predicting of negative outcomes.^[15] In the present article, the mean decrease in VAS and ODI scores reported by Haktan et al^[25] was obviously higher than that reported by Steven et al^[24] (Figs. 5 and 6). Thus, appropriate patient selection appears to be an important factor in explaining the variation of outcomes among different studies.

The follow-up time varied from 3 to 24 months. Two of the included studies reported that there was no statistically significant difference on NRS, VAS, and ODI scores among follow-up periods and proved the durability of effectiveness in managing SIJ pain for selected patients.^[23,25] However, another study revealed that NRS and ODI scores rose in average at each follow-up time point,^[14] indicating that the efficacy decreased over time. Attention should be paid on this controversial outcome and follow-up time may also be a potential reason of various results.

The complex posterior sacral network (PSN) is formed by S1-S4 lateral branches as well as L4 and L5 dorsal rami, which contribute to SIJ innervation,^[28–31] while only Cohen et al reported blockade and lesion of the L4 dorsal rami.^[24] Besides, 2 studies analyzed SIJ innervation in cadavers and reported

different outcomes. Roberts et al studied 25 cadavers and reported that S5 contributed to the PSN only in 8% of the cadavers, while Cox et al studied 12 cadavers and reported that L5 contributed to the PSN in 75% of cadavers observed.^[30,31] It seems that a high degree of variability exists in the SIJ innervation, which may have significant implications for cooled radiofrequency denervation.

We acknowledge limitations of the literature and our review. First, although several relevant trials have been published, the number of participants was small and most of them were retrospective studies. Second, the heterogeneity of study populations in terms of history of lumbar surgery and the use of pain medication poses additional challenges in evaluating the individual therapeutic options. Third, the utilization of diversified measures further undermines consistent decision making. Despite these reservations, this meta-analysis provides strong evidence to support the application of cooled radiofrequency procedure.

In conclusion, although variations exist in the studies, our analysis shows that it is safe and effective to perform this procedure in managing chronic SIJ pain. More high-quality and large-scale RCT are required to validate our findings and more studies with long follow-up time are required to confirm the durability of the effectiveness.

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