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# The efficacy of conventional radiofrequency denervation in patients with chronic low back pain originating from the facet joints: a meta-analysis of randomized controlled trials

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**Abstract**

**BACKGROUND CONTEXT:** Radiofrequency denervation is commonly used for the treatment of chronic facet joint pain that has been refractory to more conservative treatments, although the evidence supporting this treatment has been controversial.

**PURPOSE:** We aimed to elucidate the precise effects of radiofrequency denervation in patients with low back pain originating from the facet joints relative to those obtained using control treatments, with particular attention to consistency in the denervation protocol.

**STUDY DESIGN/SETTING:** A meta-analysis of randomized controlled trials was carried out.

**PATIENT SAMPLE:** Adult patients undergoing radiofrequency denervation or control treatments (sham or epidural block) for facet joint disease of the lumbar spine comprised the patient sample.

**OUTCOME MEASURES:** Visual analog scale (VAS) pain scores were measured and stratified by response of diagnostic block procedures.

**METHOD:** We searched PubMed, Embase, Web of Science, and the Cochrane Database for randomized controlled trials regarding radiofrequency denervation and control treatments for back pain. Changes in VAS pain scores of the radiofrequency group were compared with those of the control group as well as the minimal clinically important difference (MCID) for back pain VAS. Meta-regression model was developed to evaluate the effect of radiofrequency treatment according to responses of diagnostic block while controlling for other variables. We then calculated mean differences and 95% confidence intervals (CIs) using random-effects models.

**RESULTS:** We included data from seven trials involving 454 patients who had undergone radiofrequency denervation (231 patients) and control treatments such as sham or epidural block procedures (223 patients). The radiofrequency group exhibited significantly greater improvements in back pain score when compared with the control group for 1-year follow-up. Although the average improvement in VAS scores exceeded the MCID, the lower limit of the 95% CI encompassed the MCID. A subgroup of patients who responded very well to diagnostic block procedures demonstrated significant improvements in back

FDA device/drug status. Not applicable.

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pain relative to the control group at all times. When placed into our meta-regression model, the response to diagnostic block procedure was responsible for a statistically significant portion of treatment effect. Studies published over the last two decades revealed that radiofrequency denervation reduced back pain significantly in patients with facet joint disease compared with the MCID and control treatments.
**CONCLUSIONS:** Conventional radiofrequency denervation resulted in significant reductions in low back pain originating from the facet joints in patients showing the best response to diagnostic block over the first 12 months when compared with sham procedures or epidural nerve blocks. 

*Keywords:* Back pain; Denervation; Facet joint; Medial branch; Radiofrequency; Rhizotomy; Zygapophyseal joint

## Introduction

Low back pain can originate from the lumbar facet joints, the sacroiliac joint, the intervertebral discs, and the coccyx [1]. Lumbar zygapophyseal (facet) joint arthropathy is a known source of spine pain, with prevalence rates between 15% and 45% in patients who experience low back pain [2–4]. Each facet joint is innervated by two medial branches of the primary dorsal rami of the spinal nerves [5]. Standard treatment modalities for lumbar zygapophyseal joint pain include intra-articular steroid injections and radiofrequency denervation of the medial branches innervating the joints [3].

Radiofrequency procedures, first introduced in 1975 [6], involve the application of current from an active electrode to a dispersive ground plate. The body's tissue completes the circuit, creating an electrical field. This electrical field and the resulting ionic motion lead to the dissipation of frictional heat in the local tissue [7]. Radiofrequency denervation ("rhizotomy") is commonly used for the treatment of chronic facet joint pain that has been refractory to other conservative treatments, and may be performed for more sustained relief, but the evidence supporting both of these uses is conflicting [3,5,8].

Some investigators have contended that there is strong evidence for long-term pain relief following radiofrequency denervation [9]. Two systematic review and meta-analyses concluded that facet joint radiofrequency denervation may be more effective for pain control than corticosteroid injections [10,11]. However, other investigators have objected to the conclusion of this meta-analysis, arguing that only one of the included studies actually showed the superiority of radiofrequency denervation, and this superiority was based on a non-validated outcome assessment instrument [12]. Other investigators have addressed that their study results have been widely referenced and often used to substantiate the claim that lumbar radiofrequency facet denervation procedures are ineffective [13]. Moreover, in one study, the authors failed to establish the facet joint as the generator of low back pain, which may have been responsible for the low success rates observed [14]. Because of such contradictory results, the efficacy of radiofrequency denervation of facet joint nerves in managing chronic low back pain remains controversial.

There are three prerequisites to determining whether radiofrequency denervation is effective in the treatment of lumbar facet joint pain. First, the structure responsible for the generation of the pain at or near the articular facets joints must be identified [15]. Second, the electrode tip must be located at the precise location and section of the nerve supplying the joint [15]. Third, the denervation protocol must be well-documented and consistent, and the patients who have undergone the procedure must be carefully selected.

We therefore sought to evaluate more precisely the effects of radiofrequency denervation compared with sham procedures or epidural steroid injections on low back pain in patients with facet joint disease, placing emphasis on the use of a consistent denervation protocol.

## Materials and methods

### *Search strategy and selection criteria*

We undertook a systematic review and meta-analysis of relevant randomized controlled trials regarding radiofrequency denervation and control treatments for patients with low back pain originating from the facet joints. Analyses were stratified in accordance with important differences in trial characteristics in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. We searched PubMed, Embase, Web of Science, and the Cochrane Database for randomized controlled trials from inception to October 12, 2016, using the following search terms: "radiofrequency", "lumbar", together with "facet" or "zygapophyseal." In addition, the reference lists of searched papers were screened for eligible studies. We excluded experiments and case reports and used only the largest study when there were overlapping study populations. There were no language restrictions on study eligibility.

Trials were included if they enrolled individuals with low back pain suspected to originate from the facet joints, and if such patients had been randomly assigned to treatment with either radiofrequency denervation (using conventional methods and well-documented protocols) or control treatments such as sham procedures or epidural steroid injections with or without the use of local anesthetic drugs. Trials in which specific endpoints were not reported were excluded only from the pooled analyses of the specific endpoints. For trials in which there were three or more arms, the relevant pairwise comparisons were assessed separately.

### *Data extraction*

We created a meta-analysis database of the selected studies using the following categories: study author, year of publication, study design, study period, number of patients, patient age, patient gender, denervation protocol, and inclusion criteria according to the patient's response to diagnostic nerve block procedures. Visual analog scale (VAS) ratings of back pain were serially evaluated to determine clinical outcomes, as these were most commonly used for evaluation in the studies reviewed. Mean VAS scores and standard deviations (SDs) at baseline and follow-up were extracted. Papers reporting only mean differences (MDs) of VAS and SD between baseline and follow-up states were also included. All disagreements were resolved via consensus, and there was complete agreement regarding the abstracted results in the final dataset.

### *Statistical analysis*

The pooled results were analyzed by calculating the effect size based on the MD and SD using Comprehensive Meta-Analysis Version 3 (Biostat, Englewood, NJ, USA). For the pooled effects, MD and 95% confidence intervals (CIs) were calculated for continuous variables according to the consistency of measurement units. Changes in VAS scores of low back pain were compared with its minimal clinically important difference (MCID), defined as the smallest difference perceived by the average patient. When the magnitude of the treatment effect equaled or exceeded the MCID and 95% CIs, we considered the treatment to have substantially improved clinical outcomes [16].We used a reference MCID of 3 for VAS scores of back pain in the present study, based on previous findings [17].

We stratified included patients according to responses of diagnostic block on a four-step Likert scale: no pain relief: 0%–30% improvement; moderate pain relief: 30%–50% improvement; good pain relief: 50%–80% improvement; and pain free: 80%–100% improvement [18]. We performed subgroup analysis depending on the response of diagnostic block. When significant effect was identified indicating a real difference in effectiveness of the radiofrequency treatment by the difference in response of diagnostic block, a meta-regression was used to formally investigate the cause using Comprehensive Meta-Analysis Version 3. Equivocal (≥50% pain relief) and best (≥80% pain relief) response of diagnostic block were used as a moderator and we fit a random-effects meta-regression model to consider the unexplained between-studies variance and the proportion of variance explained by model.

The studies in the meta-analysis were weighted by the inverse of the variance, which included both within- and between-study errors. To assess heterogeneity in the results of individual studies, we used the Cochran Q test and Higgins $I^2$ statistic ($I^2$>50% was used as a threshold to indicate significant heterogeneity). Random-effects or fixed-effects models were used depending on the heterogeneity of the specific studies included in the analysis. We assessed publication bias via visual inspection of funnel plots and calculation of two-tailed p-values for Egger intercepts. Sensitivity analysis was performed via single elimination of each study to ascertain if the results of our analysis were strongly influenced by any single study, and to determine any associated changes in statistical results. All tests were two-sided, and p-values less than .05 were deemed significant.

## Results

An initial literature search using the aforementioned subject headings identified 170 studies in PubMed, 204 studies in Embase, 193 studies in Web of Science, and 39 studies in the Cochrane Central Register of Controlled Trials. Among these 606 studies, 280 articles were duplicates and were thus excluded. Among the 326 remaining papers, 122 were review articles, case reports, letters, or experiments, and were also excluded from this analysis. Ninety-four studies included patients with conditions other than facet joint disease, such as herniated disc, stenosis, or spondylolisthesis. An additional 52 studies dealt with radiofrequency treatment for failed back surgery syndrome. The remaining 58 studies were subjected to a full-text review, following which 51 further studies were excluded. The reasons for the exclusion of these articles were as follows: single treatment arm (n=21); no description of SD, mean, or number of patients (n=13); comparison of radiofrequency treatment protocols (n=9); and pulsed radiofrequency treatment (n=8). Finally, a total of seven studies were included in the present meta-analysis. The details of the selection process are shown in Fig. 1.

Table 1 lists the characteristics of the individual trials included in the meta-analysis. Seven trials enrolled patients undergoing radiofrequency facet joint denervation (231 patients) or control treatments such as sham procedures or epidural nerve block (223 patients) [15,19–24]. There were no significant differences in mean age, gender, or baseline VAS scores between the radiofrequency denervation and control groups. All patients had been diagnosed with back pain originating from the facet joints based on symptoms and radiologic evaluation. All studies included in the present meta-analysis enrolled only those patients who responded positively to diagnostic nerve block procedures as follows: "equivocal responder" [19], "at least 50% pain relief" [20,22], "good response" [19], "alleviated by 80%" [24], "significant relief" [15], and "good relief or free of pain" [23]. All patients of the radiofrequency denervation group underwent conventional radiofrequency treatment, and the temperature of the electrode tip was raised to 80°C–85°C for 60–120 seconds (Table 1).

All included studies were randomized controlled trials of high quality. In the Civelek et al. [21] study, the SD of the mean VAS score was not clearly described. We therefore measured the SD from Fig. 2 of the paper. The study [21] enrolled patients without performing diagnostic block to prevent its possible false-positive effects.

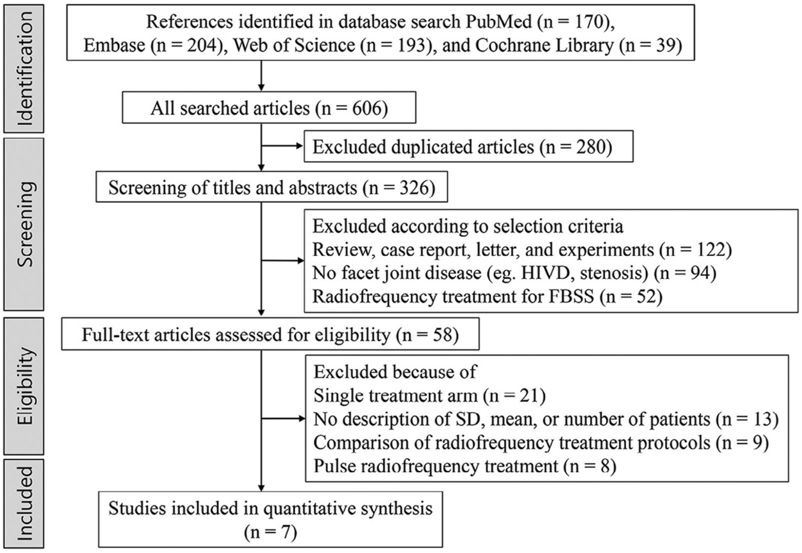


Fig. 1. Flow chart for the selection of relevant studies. FBSS, failed back surgery syndrome; SD, standard deviation.

### *Results of individual studies and synthesis of results*

At the 1- to 3-month follow-up, the MD in back pain improvement was 0.51 (95% CI, –0.45 to 1.47), indicating no statistically significant difference between radiofrequency treatment and controls although there was a trend toward high rates with radiofrequency denervation (Fig. 2). However, at the 6- and 12-month follow-up points, the radiofrequency group displayed substantially greater improvements in back pain scores when compared with the control group, and the MD in VAS scores between the radiofrequency and control groups was 1.52 (95% CI, 0.16–2.89) at 6-month follow-up and 3.55 (95% CI, 0.51–6.59) at the 12-month follow-up. Overall effect size across levels of time point, VAS of the radiofrequency denervation group improved 1.01 point (95% CI, 0.25–1.77) more than that of the control group for 1-year follow-up.

To evaluate the actual effect of VAS changes following radiofrequency denervation, mean values of pain improvement were calculated at each time point. The VAS change for patients of the radiofrequency denervation group was 3.38 (95% CI, 1.37–5.40) at the 1- to 3-month follow-up, 3.33 (95% CI, 1.37–5.29) at the 6-month follow-up, and 5.65 (95% CI, 5.48–5.82) at the 12-month follow-up (Fig. 3). Although the average improvement in VAS scores exceeded the MCID (3 points on a 10-point scale), the lower limit of the 95% CI encompassed the MCID. At the 12-month follow-up alone, both the mean change of VAS and its 95% CI exceeded the MCID of VAS.

### *Treatment effect of radiofrequency denervation in the best responder to diagnostic block*

Patients who responded to diagnostic nerve block with "near complete," "significant relief,, or "more than 80% relief" of pain were classified as best responders [18]. The "best responders" excluded the patients who responded to diagnostic nerve block with an "equivocal response" or "more than 50% relief" of pain. At all time points, pain improvement in the

Table 1
Characteristics of included trials

| Study | Sx period (mo) | Response of diagnostic block | Radiofrequency denervation group | | | | Control group | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | No | Protocol | Mean age (SD) | Male | No | Method | Mean age (SD) | Male |
| Gallagher, 1994 [19] (equivocal responder) | ≥3 | "Equivocal response" | 6 | 80°C, 90 s | N/D | N/D | 5 | Sham | N/D | N/D |
| Gallagher, 1994 [19] (good responder) | ≥3 | "Good response" | 18 | 80°C, 90 s | N/D | N/D | 12 | Sham | N/D | N/D |
| van Kleef, 1999 [20] | ≥12 | ≥50% Relief | 15 | 80°C, 60 s | 46.5 (7.4) | 5 | 16 | Sham | 41.4 (7.5) | 6 |
| Leclaire, 2001 [15] | ≥3 | "Significant relief" | 36 | 80°C, 90 s | 46.7 (9.3) | 12 | 34 | Sham | 46.4 (9.8) | 13 |
| Civelek, 2012 [21] | ≥ 1.5 | Not performed | 50 | 80°C, 120 s | 51.8 (17.0) | 15 | 50 | Epi | 56.5 (17.1) | 15 |
| Lakemeier, 2013 [22] | ≥ 24 | ≥ 50% Relief | 26 | 80°C, 90 s | 57.6 (12.8) | 9 | 26 | Epi | 56.3 (10.8) | 13 |
| Moussa, 2016 [23] | ≥ 3 | "Complete or near complete" | 40 | 85°C, 90 s | 56.5 (14.0) | 23 | 40 | Sham | 55.9 (14.0) | 21 |
| Zhou, 2016 [24] | ≥ 6 | ≥80% Relief | 40 | 80°C, 90 s | 56.5 (8.7) | 5 | 40 | Epi | 54.6 (7.5) | 6 |
| Total | | | 231 | | | | 223 | | | |

Sx, symptom; SD, standard deviation; N/D, not described; Epi, epidural block.

| Study name | Difference in means | Standard error | Variance | Lower limit | Upper limit | Z-Value | p-Value |
|---|---|---|---|---|---|---|---|
| **1- to 3-month follow-up** | | | | | | | |
| Gallagher, 1994 (equivocal responder) | -2.700 | 0.350 | 0.123 | -3.386 | -2.014 | -7.712 | 0.000 |
| Gallagher, 1994 (best responder) | 1.200 | 0.264 | 0.070 | 0.682 | 1.718 | 4.543 | 0.000 |
| van Kleef, 1999 | 2.100 | 0.775 | 0.601 | 0.580 | 3.620 | 2.708 | 0.007 |
| Leclaire, 2001 | -0.770 | 0.625 | 0.391 | -1.995 | 0.455 | -1.232 | 0.218 |
| Civelek, 2012 | 0.900 | 0.096 | 0.009 | 0.712 | 1.088 | 9.367 | 0.000 |
| Moussa, 2016 | 0.600 | 0.235 | 0.055 | 0.139 | 1.061 | 2.553 | 0.011 |
| Zhou, 2016 | 2.300 | 0.253 | 0.064 | 1.805 | 2.795 | 9.101 | 0.000 |
| Total | 0.510 | 0.489 | 0.239 | -0.448 | 1.469 | 1.044 | 0.297 |
| **6-month follow-up** | | | | | | | |
| Gallagher, 1994 (equivocal responder) | -2.400 | 0.498 | 0.248 | -3.376 | -1.424 | -4.818 | 0.000 |
| Gallagher, 1994 (best responder) | 1.200 | 0.252 | 0.064 | 0.706 | 1.694 | 4.756 | 0.000 |
| Civelek, 2012 | 1.600 | 0.095 | 0.009 | 1.415 | 1.785 | 16.913 | 0.000 |
| Lakemeier, 2013 | 0.300 | 0.569 | 0.323 | -0.815 | 1.415 | 0.527 | 0.598 |
| Moussa, 2016 | 3.900 | 0.185 | 0.034 | 3.537 | 4.263 | 21.073 | 0.000 |
| Zhou, 2016 | 4.200 | 0.292 | 0.085 | 3.629 | 4.771 | 14.406 | 0.000 |
| Total | 1.524 | 0.698 | 0.487 | 0.156 | 2.892 | 2.184 | 0.029 |
| **12-month follow-up** | | | | | | | |
| Civelek, 2012 | 2.000 | 0.095 | 0.009 | 1.815 | 2.185 | 21.141 | 0.000 |
| Moussa, 2016 | 5.100 | 0.165 | 0.027 | 4.776 | 5.424 | 30.895 | 0.000 |
| Total | 3.547 | 1.550 | 2.402 | 0.509 | 6.585 | 2.288 | 0.022 |
| Overall | 1.013 | 0.388 | 0.150 | 0.253 | 1.774 | 2.613 | 0.009 |

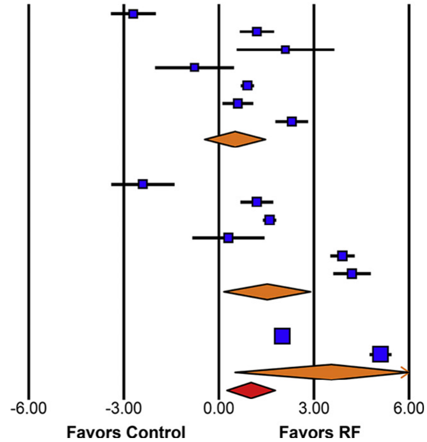


Fig. 2. Forest plots of back pain change in all included studies. Radiofrequency (RF) denervation was associated with significant decreases in back pain when compared with control treatments at the 6- and 12-month follow-up points. Overall effect size across levels of time point, visual analog scale (VAS) of the radiofrequency denervation group improved 1.01 point more than that of the control group for 1-year follow-up.

best responder group was better than that of the control group, as shown in Fig. 4. The best responder group reported significant decreases in VAS scores for back pain compared with the control group at the 1- to 3-month (MD, 0.98; 95% CI, 0.33–1.62), 6-month (MD, 2.72; 95% CI, 1.27–4.17), and 12-month (MD, 3.55; 95% CI, 0.51–6.59) follow-ups. In the best responder group, VAS scores decreased by 3.98 (95% CI, 2.29–5.67) at the 1- to 3-month follow-up, 4.55 (95% CI, 2.42–6.68) at the 6-month follow-up, and 5.65 (95% CI, 5.48–5.82) at the 12-month follow-up relative to baseline values in Fig. 5. The best responder group also showed significant decreases in clinical ratings of pain at the 12-month follow-up only.

To delineate the diagnostic accuracy of diagnostic block procedure, a meta-regression analysis was conducted (Appendix Fig. A1). When response of diagnostic block was inserted into a meta-regression model as a univariate independent variable, the best response of diagnostic block was significantly associated with pain improvement (coefficient, 2.87; 95% CI, 1.19–4.58; p=.001). Calculated equation was Y=−0.8156+2.8740×X, where Y is the MD and X is response of diagnostic block (if best responder=1; equivocal

| Study name | Mean | Standard error | Variance | Lower limit | Upper limit | Z-Value | p-Value | Relative weight |
|---|---|---|---|---|---|---|---|---|
| **1- to 3-month follow-up** | | | | | | | | |
| Gallagher, 1994 (Equivocal responder) | -1.00 | 0.19 | 0.04 | -1.38 | -0.62 | -5.21 | 0.00 | 14.37 |
| Gallagher, 1994 (Best responder) | 2.40 | 0.14 | 0.02 | 2.12 | 2.68 | 16.97 | 0.00 | 14.41 |
| van Kleef, 1999 | 4.90 | 0.54 | 0.29 | 3.84 | 5.96 | 9.04 | 0.00 | 13.89 |
| Leclaire, 2001 | -0.05 | 0.42 | 0.17 | -0.87 | 0.77 | -0.12 | 0.90 | 14.11 |
| Civelek, 2012 | 6.00 | 0.07 | 0.01 | 5.86 | 6.14 | 84.85 | 0.00 | 14.44 |
| Zhou, 2016 | 5.40 | 0.18 | 0.03 | 5.06 | 5.74 | 30.77 | 0.00 | 14.39 |
| Moussa, 2016 | 6.00 | 0.16 | 0.03 | 5.69 | 6.31 | 37.95 | 0.00 | 14.40 |
| Total | 3.38 | 1.03 | 1.06 | 1.37 | 5.40 | 3.29 | 0.00 | |
| **6-month follow-up** | | | | | | | | |
| Gallagher, 1994 (Equivocal responder) | 0.20 | 0.31 | 0.09 | -0.80 | 0.40 | -0.65 | 0.51 | 16.58 |
| Gallagher, 1994 (Best responder) | 1.40 | 0.15 | 0.02 | 1.11 | 1.69 | 9.43 | 0.00 | 16.78 |
| Civelek, 2012 | 5.70 | 0.07 | 0.01 | 5.56 | 5.84 | 79.03 | 0.00 | 16.83 |
| Lakemeier, 2013 | 1.90 | 0.42 | 0.18 | 1.07 | 2.73 | 4.49 | 0.00 | 16.35 |
| Zhou, 2016 | 5.10 | 0.22 | 0.05 | 4.67 | 5.53 | 23.04 | 0.00 | 16.70 |
| Moussa, 2016 | 6.00 | 0.17 | 0.03 | 5.66 | 6.34 | 34.50 | 0.00 | 16.76 |
| Total | 3.33 | 1.00 | 1.00 | 1.37 | 5.29 | 3.33 | 0.00 | |
| **12-month follow-up** | | | | | | | | |
| Civelek, 2012 | 5.60 | 0.07 | 0.01 | 5.46 | 5.74 | 77.64 | 0.00 | 74.75 |
| Moussa, 2016 | 5.80 | 0.16 | 0.03 | 5.49 | 6.11 | 36.68 | 0.00 | 25.25 |
| Total | 5.65 | 0.09 | 0.01 | 5.48 | 5.82 | 65.03 | 0.00 | |

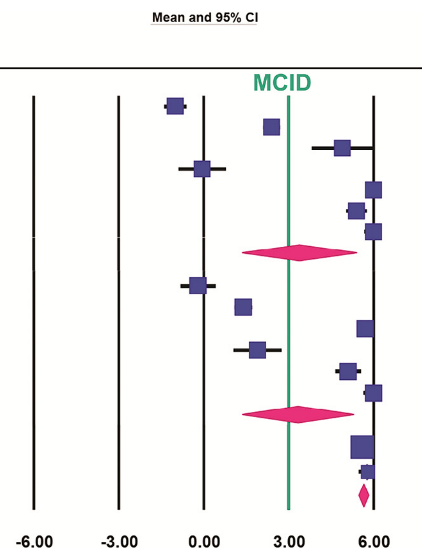


Fig. 3. Average improvement in back pain score for all included studies. At the 1- to 3-month and 6-month follow-ups, the lowest 95% CI did not exceed MCID, although the mean value exceeded the MCID for VAS scores. At the 12-month follow-up, ≥95% of the patients exhibited treatment effects that exceeded the MCID for VAS of back pain. CI, confidence interval; MCID, minimal clinically important difference; VAS, visual analog scale.

| Study name | Difference in means | Standard error | Variance | Lower limit | Upper limit | Z-Value | p-Value |
|---|---|---|---|---|---|---|---|
| | Statistics for each study | | | | | | |
| **1-to 3-month follow-up** | | | | | | | |
| Gallagher, 1994 (best responder) | 1.200 | 0.264 | 0.070 | 0.682 | 1.718 | 4.543 | 0.000 |
| Leclaire, 2001 | -0.770 | 0.625 | 0.391 | -1.995 | 0.455 | -1.232 | 0.218 |
| Civelek, 2012 | 0.900 | 0.096 | 0.009 | 0.712 | 1.088 | 9.367 | 0.000 |
| Moussa, 2016 | 0.600 | 0.235 | 0.055 | 0.139 | 1.061 | 2.553 | 0.011 |
| Zhou, 2016 | 2.300 | 0.253 | 0.064 | 1.805 | 2.795 | 9.101 | 0.000 |
| Total | 0.981 | 0.325 | 0.106 | 0.343 | 1.618 | 3.015 | 0.003 |
| **6-month follow-up** | | | | | | | |
| Gallagher, 1994 (best responder) | 1.200 | 0.252 | 0.064 | 0.706 | 1.694 | 4.756 | 0.000 |
| Civelek, 2012 | 1.600 | 0.095 | 0.009 | 1.415 | 1.785 | 16.913 | 0.000 |
| Moussa, 2016 | 3.900 | 0.185 | 0.034 | 3.537 | 4.263 | 21.073 | 0.000 |
| Zhou, 2016 | 4.200 | 0.292 | 0.085 | 3.629 | 4.771 | 14.406 | 0.000 |
| Total | 2.718 | 0.735 | 0.541 | 1.277 | 4.159 | 3.697 | 0.000 |
| **12-month follow-up** | | | | | | | |
| Civelek, 2012 | 2.000 | 0.095 | 0.009 | 1.815 | 2.185 | 21.141 | 0.000 |
| Moussa, 2016 | 5.100 | 0.165 | 0.027 | 4.776 | 5.424 | 30.895 | 0.000 |
| Total | 3.547 | 1.550 | 2.402 | 0.509 | 6.585 | 2.288 | 0.022 |
| Overall | 1.346 | 0.292 | 0.085 | 0.773 | 1.918 | 4.608 | 0.000 |

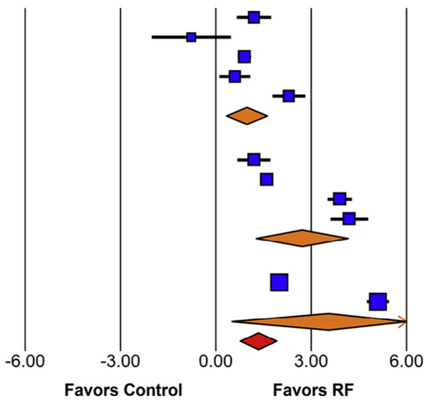


Fig. 4. Forest plots of back pain change in the best responders to diagnostic nerve block procedures. Significant improvement in back pain was observed in the radiofrequency (RF) denervation group when compared with control treatments at all time points. Overall effect size across levels of time point, visual analog scale (VAS) of the RF denervation group improved 1.34 point more than that of the control group for 1-year follow-up.

responder=0). In other words, equivocal responder group may accomplish better outcomes after control treatment than radiofrequency denervation (MD, −0.75; 95% CI, −2.75 to 1.24).

*Sensitivity analysis and publication bias*

To determine if an individual study was responsible for the presence or absence of an effect in each of the statistical tests, we performed a series of sensitivity analyses. Sensitivity analysis demonstrated that Gallagher et al.'s [19] study affect substantially the effect size. When Gallagher et al.'s [19] study was eliminated, a substantial difference in pain improvement was observed between the radiofrequency denervation and control groups at all time points (Fig. 6), and decreases in the lowest 95% CI of VAS scores exceeded the MCID. The mean decrease in VAS score for the best responder group was 4.52 (95% CI, 3.37–5.67) at the 1- to 3-month follow-up and 4.78 (95% CI, 3.83–5.73) at the 6-month follow-up (Fig. 7). These findings indicate that 95% of patients who had experienced more than 80% relief following diagnostic nerve block exhibited significant decreases in VAS ratings of pain following radiofrequency denervation, relative to the MCID and control treatments.

All funnel plots were symmetric, indicating an absence of significant publication bias within the studies (Appendix Fig. A2). The Egger test results for the comparison of interventions were −11.56 (p=.05), −10.24 (p=.33), −15.83 (p=.25), and −12.41 (p=.60) for the intervention comparison at the

| Study or Subgroup | Mean | Standard error | Variance | Lower limit | Upper limit | Z-Value | p-Value | Relative weight |
|---|---|---|---|---|---|---|---|---|
| | Statistics for each study | | | | | | | |
| **1- to 3-month follow-up** | | | | | | | | |
| Gallagher, 1994 (**Best responder**) | 2.40 | 0.14 | 0.02 | 2.12 | 2.68 | 16.97 | 0.00 | 20.16 |
| Leclaire, 2001 | -0.05 | 0.42 | 0.17 | -0.87 | 0.77 | -0.12 | 0.90 | 19.36 |
| Civelek, 2012 | 6.00 | 0.07 | 0.01 | 5.86 | 6.14 | 84.85 | 0.00 | 20.24 |
| Zhou, 2016 | 5.40 | 0.18 | 0.03 | 5.06 | 5.74 | 30.77 | 0.00 | 20.10 |
| Moussa, 2016 | 6.00 | 0.16 | 0.03 | 5.69 | 6.31 | 37.95 | 0.00 | 20.13 |
| **Total** | 3.98 | 0.86 | 0.74 | 2.29 | 5.67 | 4.62 | 0.00 | |
| **6-month follow-up** | | | | | | | | |
| Gallagher, 1994 (**Best responder**) | 1.40 | 0.15 | 0.02 | 1.11 | 1.69 | 9.43 | 0.00 | 25.02 |
| Civelek, 2012 | 5.70 | 0.07 | 0.01 | 5.56 | 5.84 | 79.03 | 0.00 | 25.11 |
| Zhou, 2016 | 5.10 | 0.22 | 0.05 | 4.67 | 5.53 | 23.04 | 0.00 | 24.88 |
| Moussa, 2016 | 6.00 | 0.17 | 0.03 | 5.66 | 6.34 | 34.50 | 0.00 | 24.98 |
| **Total** | 4.55 | 1.09 | 1.18 | 2.42 | 6.68 | 4.19 | 0.00 | |
| **12-month follow-up** | | | | | | | | |
| Civelek, 2012 | 5.60 | 0.07 | 0.01 | 5.46 | 5.74 | 77.64 | 0.00 | 74.75 |
| Moussa, 2016 | 5.80 | 0.16 | 0.03 | 5.49 | 6.11 | 36.68 | 0.00 | 25.25 |
| **Total** | 5.65 | 0.09 | 0.01 | 5.48 | 5.82 | 65.03 | 0.00 | |

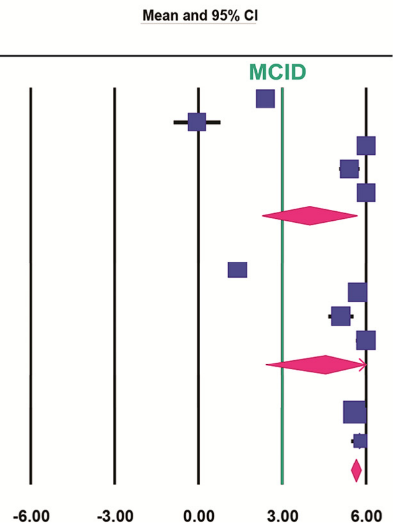


Fig. 5. Average improvement in back pain scores in the best responders to diagnostic block procedures. Mean values of pain improvement increased at all time points, although the results of the best responder were similar to those of the remaining patients.

| Study name | Difference in means | Standard error | Variance | Lower limit | Upper limit | Z-Value | p-Value |
|---|---|---|---|---|---|---|---|
| **1- to 3-month follow-up** | | | | | | | |
| van Kleef, 1999 | 2.100 | 0.775 | 0.601 | 0.580 | 3.620 | 2.708 | 0.007 |
| Leclaire, 2001 | -0.770 | 0.625 | 0.391 | -1.995 | 0.455 | -1.232 | 0.218 |
| Civelek, 2012 | 0.900 | 0.096 | 0.009 | 0.712 | 1.088 | 9.367 | 0.000 |
| Moussa, 2016 | 0.600 | 0.235 | 0.055 | 0.139 | 1.061 | 2.553 | 0.011 |
| Zhou, 2016 | 2.300 | 0.253 | 0.064 | 1.805 | 2.795 | 9.101 | 0.000 |
| Total | 1.049 | 0.388 | 0.151 | 0.288 | 1.810 | 2.701 | 0.007 |
| **6-month follow-up** | | | | | | | |
| Civelek, 2012 | 1.600 | 0.095 | 0.009 | 1.415 | 1.785 | 16.913 | 0.000 |
| Lakemeier, 2013 | 0.300 | 0.569 | 0.323 | -0.815 | 1.415 | 0.527 | 0.598 |
| Moussa, 2016 | 3.900 | 0.185 | 0.034 | 3.537 | 4.263 | 21.073 | 0.000 |
| Zhou, 2016 | 4.200 | 0.292 | 0.085 | 3.629 | 4.771 | 14.406 | 0.000 |
| Total | 2.545 | 0.822 | 0.676 | 0.934 | 4.157 | 3.095 | 0.002 |
| **12-month follow-up** | | | | | | | |
| Civelek, 2012 | 2.000 | 0.095 | 0.009 | 1.815 | 2.185 | 21.141 | 0.000 |
| Moussa, 2016 | 5.100 | 0.165 | 0.027 | 4.776 | 5.424 | 30.895 | 0.000 |
| Total | 3.547 | 1.550 | 2.402 | 0.509 | 6.585 | 2.288 | 0.022 |
| Overall | 1.430 | 0.342 | 0.117 | 0.759 | 2.101 | 4.176 | 0.000 |

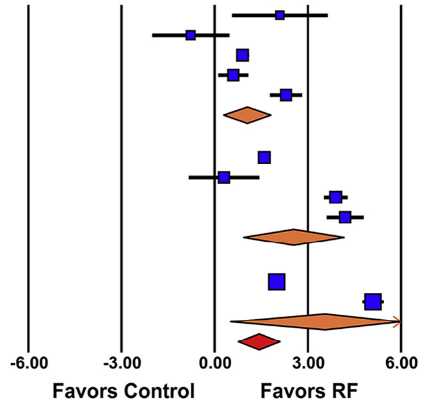


Fig. 6. Forest plots of back pain change for studies published over the last two decades (exclusion of Gallagher et al.'s study). Back pain improvement in the radiofrequency treatment group was significantly better than in the control group throughout the follow-up period. RF, radiofrequency.

3-month, 6-month follow-up points, average value of VAS at the 3-month follow-up, and average value of VAS at the 6-month follow-up, respectively. These results indicate that there was no substantial evidence of publication bias in the dataset.

## Discussion

In this meta-analysis of seven randomized controlled trials involving 454 patients, conventional radiofrequency denervation resulted in better back pain improvement than control procedures (sham or epidural block) for 1-year follow-up. The radiofrequency treatment accomplished much better outcomes in the best responder to diagnostic block and similar outcomes with control treatments in the equivocal responder. Average improvements in VAS scores for patients of the radiofrequency denervation group did not significantly exceed the MCID. However, this phenomenon occurred mainly owing to the influence of Gallagher et al.'s [19] study, according to the results of our sensitivity analysis. Upon exclusion of this study, we observed that radiofrequency denervation resulted in significant decreases in back pain scores relative to the MCID and control treatments throughout the follow-up period.

When comparing the radiofrequency treatment and control treatments, substantial differences in VAS change were

| Study name | Mean | Standard error | Variance | Lower limit | Upper limit | Z-Value | p-Value | Relative weight |
|---|---|---|---|---|---|---|---|---|
| **1- to 3-month follow-up** | | | | | | | | |
| van Kleef, 1999 | 4.90 | 0.54 | 0.29 | 3.84 | 5.96 | 9.04 | 0.00 | 17.96 |
| Leclaire, 2001 | -0.05 | 0.42 | 0.17 | -0.87 | 0.77 | -0.12 | 0.90 | 19.17 |
| Civelek, 2012 | 6.00 | 0.07 | 0.01 | 5.86 | 6.14 | 84.85 | 0.00 | 21.15 |
| Zhou, 2016 | 5.40 | 0.18 | 0.03 | 5.06 | 5.74 | 30.77 | 0.00 | 20.82 |
| Moussa, 2016 | 6.00 | 0.16 | 0.03 | 5.69 | 6.31 | 37.95 | 0.00 | 20.90 |
| Total | 4.52 | 0.59 | 0.34 | 3.37 | 5.67 | 7.71 | 0.00 | |
| **6-month follow-up** | | | | | | | | |
| Civelek, 2012 | 5.70 | 0.07 | 0.01 | 5.56 | 5.84 | 79.03 | 0.00 | 26.60 |
| Lakemeier, 2013 | 1.90 | 0.42 | 0.18 | 1.07 | 2.73 | 4.49 | 0.00 | 22.20 |
| Zhou, 2016 | 5.10 | 0.22 | 0.05 | 4.67 | 5.53 | 23.04 | 0.00 | 25.34 |
| Moussa, 2016 | 6.00 | 0.17 | 0.03 | 5.66 | 6.34 | 34.50 | 0.00 | 25.86 |
| Total | 4.78 | 0.48 | 0.23 | 3.83 | 5.73 | 9.90 | 0.00 | |
| **12-month follow-up** | | | | | | | | |
| Civelek, 2012 | 5.60 | 0.07 | 0.01 | 5.46 | 5.74 | 77.64 | 0.00 | 74.75 |
| Moussa, 2016 | 5.80 | 0.16 | 0.03 | 5.49 | 6.11 | 36.68 | 0.00 | 25.25 |
| Total | 5.65 | 0.09 | 0.01 | 5.48 | 5.82 | 65.03 | 0.00 | |

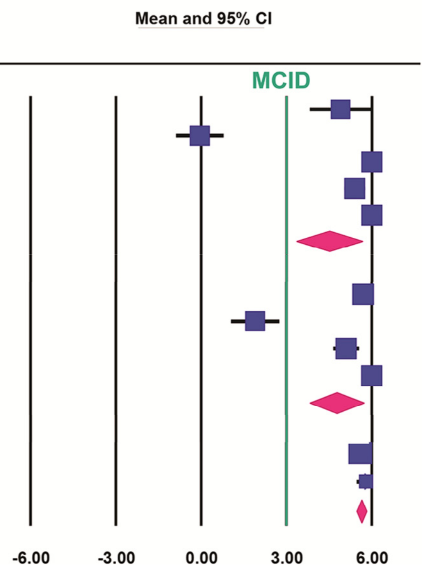


Fig. 7. Average improvement in back pain scores in papers published over the last two decades (exclusion of Gallagher et al.'s study). Both mean and lowest 95% confidence interval (CI) of pain improvement exceed the minimal clinically important difference (MCID) of 3 points throughout the 1-year follow-up.

revealed at the 6-month and 12-month follow-up points. Ninety-five percent of patients in the radiofrequency denervation group exhibited improvements in back pain, exceeding the MCID at the 12-month follow-up, indicating that the effect of radiofrequency treatment appears to increase over time. However, such findings may be due to the influence of Gallagher et al.'s study [19]. Where sensitivity analyses identify particular decisions or missing information that greatly influence the findings of the review, greater resources can be deployed to attempt to resolve uncertainties and obtain extra information [25]. Unfortunately, the paper was published in 1994, which prevented us from obtaining individual patient data. Considering technical advancements that have occurred since the publication of Gallagher et al.'s [19] study, our findings may suggest that all randomized controlled trials published over the last two decades indicate that conventional radiofrequency denervation is more effective in improving back pain than control treatments over the course of the first year, and that the majority of patients undergoing radiofrequency denervation exhibit improvements that meet or exceed the MCID.

Some investigators have insisted that the diagnostic nerve block is a valid, sensitive, and specific test for the diagnosis of zygapophyseal joint pain, and a valuable tool for confirming facetogenic pain [15,26]. However, it remains controversial whether false-positive responses occur with blocks, even with the use of imaging. Others have reported that a placebo response rate of 38% (false positives) has been demonstrated for uncontrolled lumbar facet joint blocks, along with a low positive predictive value of 31% [4,21,27,28]. In the present meta-analysis, the radiofrequency denervation group was divided into equivocal responder of diagnostic block and best responder. The best responder subgroup demonstrated consistently better improvement of low back pain than the control group, whereas the equivocal responder seemed to show worse than the control group. Our findings therefore suggest that diagnostic nerve block is an effective diagnostic tool before radiofrequency treatment to determine the potential outcome of denervation.

In aspect of effect continuance duration of radiofrequency treatments, Manchikanti et al. [9] contended that there is strong evidence for long-term pain relief from radiofrequency denervation. Another study further indicated that facet joint injections seemed to be more effective than radiofrequency denervation in the short term, although radiofrequency treatment had more satisfying results than facet joint injection by the midterm follow-up [21]. The authors of the aforementioned study concluded that the success rate seemed to be significantly higher in the radiofrequency denervation group. In contrast, other studies have reported that radiofrequency facet joint denervation used to manage chronic low back pain may offer some short-term improvement in functional disability at 4 weeks, no effect at 12 weeks, and no effect on pain at either 4 or 12 weeks [15]. In the present meta-analysis, we observed substantial decreases in back pain that exceeded the MCID, and that these decreases in VAS score were maintained throughout the 12-month follow-up. Our findings, which include data obtained for the 1-year follow-up, may help clinicians make a more informed decision when selecting between radiofrequency denervation and alternative treatments.

There are several limitations that need to be addressed regarding the present study. First, sensitivity analyses identified that Gallagher et al.'s [19] study significantly influenced the results. Because of the influence of this study, the overall results can be regarded with a low certainty. As the study was published in 1994, we were unable to resolve uncertainties. Although all papers published over the last two decades showed objective and non-contentious results, the results must be interpreted with an appropriate degree of caution because we could not verify the findings of the study. Second, as is the case for any meta-analysis, data were combined from different studies, each of which used its own protocol and definitions. We aimed to include only those studies with consistent denervation protocols and rhizotomy parameters (eg, temperature) across trials, and in which outcomes were defined in the same manner. Furthermore, patients who had undergone pulsed radiofrequency and repeated radiofrequency treatment were excluded to reduce heterogeneity. However, there is considerable variability among the studies in terms of rhizotomy duration (range, 60–120 seconds) and exact position of the electrode tip. If electrodes are directed perpendicularly onto a nerve, the nerve may not be encompassed by the lesion generated. Indeed, some clinical failures of radiofrequency denervation may be due to this phenomenon [29]. Although little description was included regarding the position of the electrode tip, we hypothesized that the interventions were successful. Third, this study evaluated only VAS as clinical outcomes, although 7 evaluation tools were used in the aforementioned studies. Although the Oswestry Disability Index (ODI) was used in four studies, two of them did not provide values of SD and the other two evaluated ODI score at seemingly different time points. The Roland-Morris questionnaire was used only in two studies, administered at seemingly different time points. The other evaluation tools were used only once. Although VAS is subjective and may have a bias, its reliability has already been proven in many studies [30–33]. Therefore, the present data are largely reliable despite the use of a single evaluation tool. Fourth, this study evaluated the efficacy of radiofrequency treatment for 1 year. Only one study, that is, Moussa et al. [23], reported 3-year follow-up results, whereas the others reported results of only 1-year follow-up or less. Moussa et al. [23] reported a reduction in the effect of radiofrequency denervation after 1-year follow-up. Finally, additional treatments such as analgesics or physiotherapy were administered in some studies [15,20,22,23]. The cointervention is a common confounding factor of clinical studies about pain. All included studies were randomized controlled trials, and they might try to control additional treatments so that their results were not substantially affected. The present study, although not the best, summarizes relatively the most reliable studies.

## Conclusion

Our findings indicate that conventional radiofrequency denervation resulted in significant reductions in low back pain originating from the facet joints in patients showing the best response to diagnostic block over the first 12 months when compared with sham procedures or epidural nerve blocks. Recent results may suggest that back pain decreases exceed the clinically important difference following radiofrequency denervation.

## Appendix

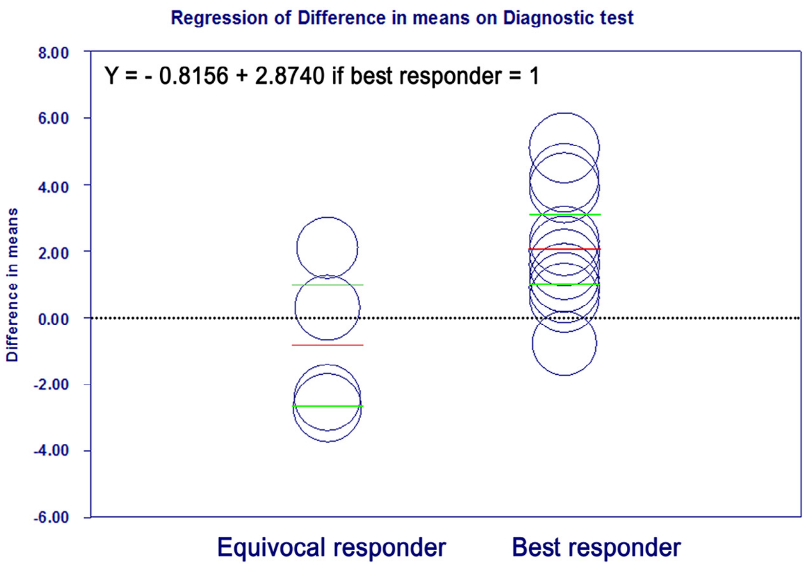


Fig. A1. Scatter plot of meta-regression model. Regression lines (red) and 95% confidence interval (CI) level (green) of equivocal and best responder are quite different from each other. The regression value of equivocal responder shows negative value, which means that control treatment results in better outcomes than radiofrequency treatment in the equivocal responder group.

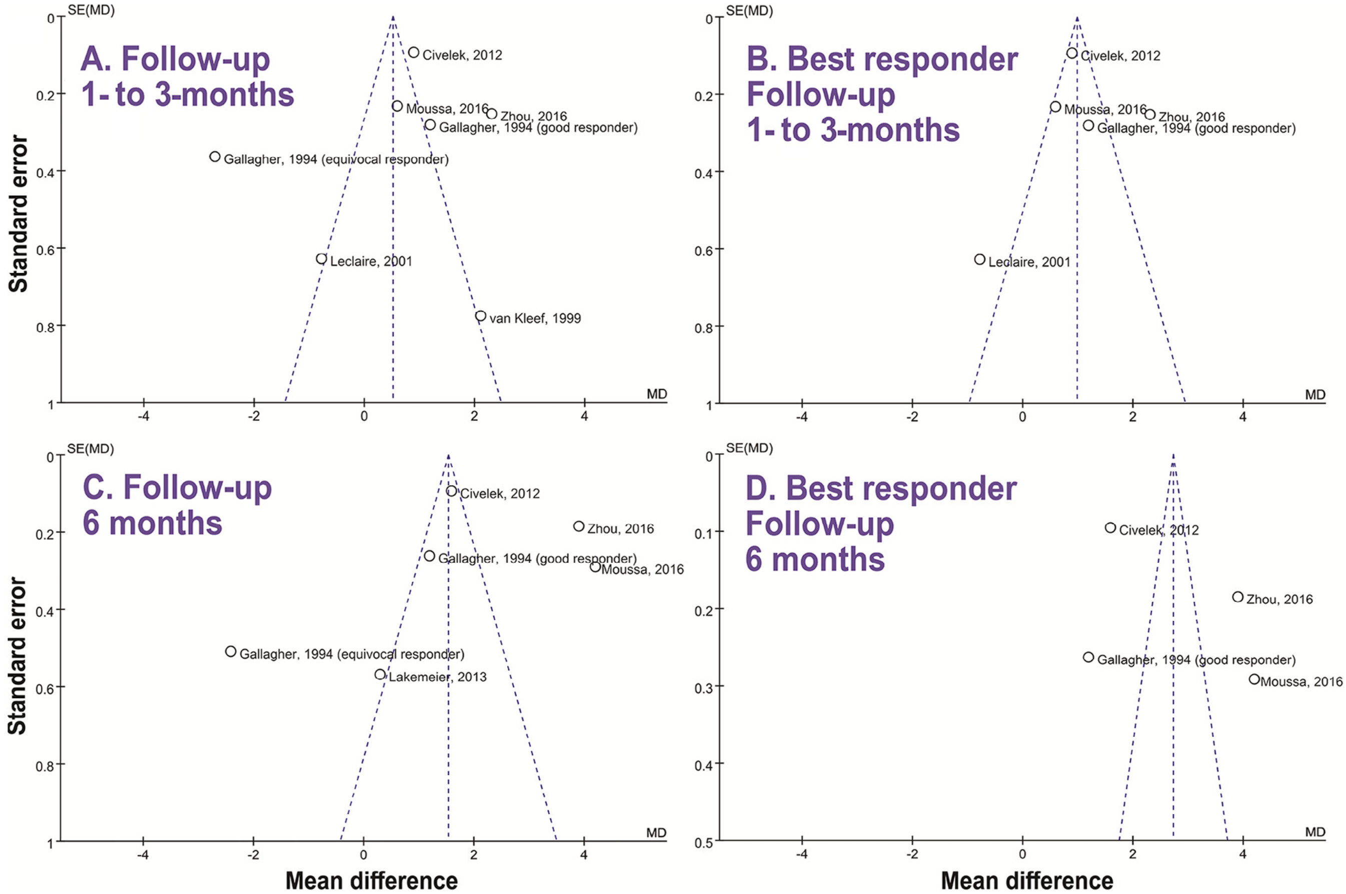


Fig. A2. Funnel plots of standard error by mean difference. All plots are generally symmetric about the mean effect, which may indicate an absence of substantial publication bias.

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