

Original Article

A meta-analysis of modern neuro-stimulation modalities-Advances in neuro-stimulation techniques

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ABSTRACT

Background: Chronic pain is a debilitating condition that affects about 3% of the population globally. Conventionally, pharmacologic approaches, psychotherapy, and surgery have been used in the management of chronic refractory pain. However, over the past decades, advances in neurotechnology have enabled modern novel techniques of neurostimulation, such as spinal cord stimulation (SCS) and dorsal root ganglion (DRG), to be used in the management of chronic neuropathic pain that does not respond to conventional management. This review, therefore, aims to establish the efficacy of these two novel technologies in the management of chronic neuropathic pain compared to conventional medical management (CMM) techniques.

Methods: A systematic search was conducted on three electronic databases, PubMed, Science Direct, and CENTRAL, for all relevant articles to the study topic. After a detailed review by two independent reviewers, only the articles that met the inclusion criteria were included. The Review Manager 5.4 software was utilized to conduct a meta-analysis of the outcomes of pain reduction.

Results: Our online search yielded 345 articles; however, only eight studies were included in the analysis according to our inclusion criteria. The results from our pooled analysis indicated that SCS and dorsal root stimulation both resulted in a significant reduction in the rating of chronic pain mean difference (MD) (-4.73; 95% confidence interval [CI] [-4.76, -4.71] $P < 0.00001$) and MD (-1.09; 95% CI [-1.29, -0.90] $P < 0.00001$), respectively. Similarly, for the studies that reported percentage change in pain rating, the pooled analysis showed that SCS resulted in a higher percentage reduction in pain rating compared to CMM MD (69.47; 95% CI [64.31, 74.64] $P < 0.00001$).

Conclusion: Based on the results of our analysis, we conclude that advances in neurostimulation techniques, such as SCS and DRG stimulation, have resulted in better management of chronic neuropathic pain compared to conventional pain management techniques.

Keywords: Chronic neuropathic pain, Dorsal root ganglion stimulation, Spinal cord stimulation

INTRODUCTION

Neuropathic pain is a type of chronic pain that results when a lesion has affected the somatosensory system, and thus, the patient feels pain in the absence of a stimulus, enhanced pain in response to noxious stimuli, and pain in response to innocuous stimuli.^[10] Furthermore, the patient feels spontaneous symptoms such as tingling (paresthesia), hyperalgesia, burning, and allodynia.^[11]

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Recently, global evidence has shown that the clinical diagnosis of neuropathic pain is estimated to be about 2–3% globally, with different screening tools being developed and validated to be used in the screening of the pain.^[2] Furthermore, it is suggested that a multidisciplinary team should be involved in the management of pain in patients with neuropathic pain. Furthermore, with advancements in medicine, different pharmacologic therapies that are complemented by different nonpharmacologic approaches, such as psychotherapy and physiotherapy, have been developed.^[8] Psychotherapy is paramount in the management of these patients since most of the patients with treatment-resistant chronic pain have high rates of underlying psychological distress.^[25]

The conventional management of chronic intractable pain varies across different types of pains and the underlying pathology. For instance, in oncology, in which the prevalence of refractory pain in patients with advanced malignancies is very high, the conventional methods of pain management include radiology and palliative surgery, in addition to strong opioid use.^[12] Furthermore, in patients with refractory angina, empirical evidence has shown that escalating the conventional medical therapy from 1st line to 3rd line may not necessarily result in efficient pain relief and analgesia due to the reversible ischemia, which is the underlying pathology. Due to the limitations of conventional medical management (CMM) in pain, for instance, in angina, different professional and pain organizations have recommended alternative pain management regimens and approaches to improve the quality of life and analgesia of the patients.^[4] For example, in 2019, the European Society of Cardiology recommended chronic total occlusion percutaneous coronary intervention for the management of angina patients.^[4] Similarly, in other types of chronic refractory pain-associated pathologies, more emphasis has been placed on the use of alternative forms of pain management, such as neuromodulation, specifically spinal cord stimulation (SCS) and dorsal root ganglion (DRG) stimulation.^[15]

SCS is a novel and established treatment modality for different chronic illnesses, such as chronic leg pain and chronic back pain.^[17] The traditional SCS has had tremendous improvements in patient analgesia, whereas other approaches have failed.^[24] Furthermore, even with improved analgesia in patients with refractory pain, pain specialists still aim to achieve optimum analgesia and patient outcomes, and thus, various attempts have been made to improve the efficacy of SCS, leading to the development of other novel stimulation approaches.^[18] Examples of these situation approaches include differential target multiplexed SCS and DRG stimulation (DRGS), which affect the life of patients with chronic refractory pain.^[6] DRGS was developed to aid in managing pain in areas of the body that would not be routinely affected by SCS since in the body, a single DRG gets sensory information from a specific discrete region of the body. It

was initially approved by the Food and Drug Authority to be used in the management of complex regional pain syndrome of the lower limbs.^[7] However, over the years, DRGS has shown promising results in the management of other painful pathologies, such as diabetic neuropathy and groin pain.^[20]

DRGS and SCS are among the widely applied neuromodulation technologies used in the management of chronic refractory pain. This systematic review and meta-analysis, therefore, aim to establish the efficacy of these two novel neuromodulation techniques in the management of chronic refractory pain. Furthermore, the review will also achieve the following objectives:

1. Establish the efficacy of DRGS in reducing pain rating in patients with chronic refractory pain
2. Establish the efficacy of SCS in the management of chronic refractory pain
3. Synthesize the findings and make appropriate recommendations regarding the applications of these two neuromodulation techniques in the management of chronic refractory pain.

MATERIALS AND METHODS

Protocol and registration

This meta-analysis and systematic review were conducted using the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020. No protocol record was registered in any database.

Literature search

Two independent authors conducted a literature search using two search strategies for all articles published until April 2024. The first strategy is a well-outlined electronic search using a predetermined search criterion. The search utilized three databases: PubMed, ScienceDirect, and CENTRAL. This criterion utilized the Boolean expressions “AND” and “OR” to combine various keywords as follows: (neuromodulation) AND (“spinal cord stimulation” OR “dorsal root ganglion stimulation”) AND (“chronic pain” OR (“refractory pain”) OR (“intractable pain”)). The full search for PubMed was as follows: (“neuromodulate” [All Fields] OR “neuromodulating” [All Fields] OR “neuromodulation” [All Fields] OR “neuromodulations” [All Fields] OR “neuromodulative” [All Fields] OR “neurotransmitter agents” [Pharmacological Action] OR “neurotransmitter agents” [MeSH Terms] OR (“neurotransmitter” [All Fields] AND “agents” [All Fields]) OR “neurotransmitter agents” [All Fields] OR “neuromodulator” [All Fields] OR “neuromodulators” [All Fields]) AND (“Spinal cord stimulation” [All Fields] OR “Dorsal root ganglion stimulation” [All Fields]) AND (“Chronic pain” [All Fields] OR “Refractory pain” [All Fields] OR “intractable pain” [All

Fields)). Besides database search, the reviewers used a second search strategy, which involved manually scouring the lists of references of the various articles to obtain the studies that may not have been included in the study. Doing this ensured that all relevant articles were obtained.

Eligibility criteria

All articles retrieved from the three databases were assessed according to the predetermined eligibility criteria. If a study met the inclusion criteria below, it was selected and used in the review:

1. Population: Patient with chronic refractory pain
2. Intervention: Novel neurostimulation techniques such as SCS and DRGS
3. Comparison: CMM such as pharmacologic therapy and psychotherapy or placebo
4. Outcomes: The primary outcome is changes in the pain rating based on different rating scales
5. Study design: Randomized controlled trials are preferred and multiple cohort observational studies.

Studies were excluded from the review if they fell under the exclusion criteria below:

1. Population: Patients who do not have chronic refractory pain
2. Intervention: Patient who did not receive either SCS or DRGS
3. Comparison: Studies that did not have a comparative group or cohort
4. Outcomes: Studies that did not report outcomes in pain rating

5. Study design: Studies are designed as review articles, case reports, and letters to the editor.

Study selection and data extraction

The independent reviewers conducted the study selection in different phases. The phases entailed the removal of duplicate articles, screening of abstracts and titles, and, finally, screening of available full texts. For inclusion in the review, the independent authors first screened the articles' abstracts obtained after removing duplicates. If the study met the inclusion criteria, it was included in the study; however, if the reviews could not ascertain its eligibility, they proceeded to obtain the full text for screening. After completing the study selection, the reviewers used pilot-tested data extraction forms to extract all the relevant data from the included studies independently. Outcomes across all the time points were obtained for use in the analysis. The study data collected was Author ID (first author's last name and Publication year), the study setting, study design, the type of intervention, sample characteristics (age, sample size, and male-to-female ratio), and follow-up period, Table 1.

Statistical analysis

The statistical software RevMan 5.4 was used to perform a meta-analysis – a subgroup analysis according to time. Forest plots were then used to present the results. Outcomes of pain rating using different scales were presented as means and standard deviations, and thus, the mean changes in either Visual Analog Scales or numerical scale ratings were used in the analysis of the outcomes. In the studies in which the values

	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Deer et al., 2023						
Kapural et al., 2022						
Hara et al., 2022						
Petersen et al., 2021						
Koh et al., 2015						
Mol et al., 2023						
Piedade et al., 2023						

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
 Low

Figure 1: A risk of bias summary of the included studies. **: Records excluded based on title and abstract screening (n = 182). These exclusions were made due to non-relevance, inappropriate study design, or population mismatch with the study inclusion criteria.

Table 1: Characteristics of the included studies.

Author ID.	Setting	Study design	Type of pain	Intervention group	Sample size	Age	Male: Female	Body mass index
Hara <i>et al.</i> , 2022. ^[11]	Norway	Randomized cross-over clinical trial	Chronic radicular pain	Spinal cord stimulation	21	50 (45–59)	NR	27.2 (24.3–29.8)
Deer <i>et al.</i> , 2023. ^[5]	United States of America	Multicenter randomized clinical trial	Refractory low back pain	Placebo	21	50 (45–59)	NR	27.2 (24.3–29.8)
				Spinal cord stimulation	162	58.1±13.0	66:96	NR
Piedade <i>et al.</i> , 2023. ^[23]	Germany	Nonrandomized clinical trial	Chronic neuropathic pain	Conventional medical management	103	59.1±12.4	51:52	NR
				Dorsal root ganglion stimulation	17	55.2 years	NR	NR
Kapural <i>et al.</i> , 2022. ^[13]	United States of America	Randomized clinical trial	Nonsurgical refractory pain	Control group	17	55.2 years	NR	NR
				Spinal cord stimulation	83	53	50:33	NR
Petersen <i>et al.</i> , 2021. ^[22]	United States of America	Randomized controlled trial	Painful diabetic neuropathy	Conventional medical management	76	58.50	30:46	NR
				Spinal cord stimulation	113	60.7±11.4	70:43	33.6±5.4
Koh <i>et al.</i> , 2015. ^[16]	Korea	Randomized controlled trial	Chronic lumbosacral pain	Conventional medical management	103	60.8±9.9	66:37	33.9±5.2
				Dorsal root ganglion stimulation	31	65.97±7.25	11:20	25.15±7.25
Kim <i>et al.</i> , 2017. ^[14]	Korea	Retrospective cohort study.	Chronic pain in herpes zoster patients	Control group	31	65.16±8.96	10:21	23.17±2.91
				Dorsal root ganglion stimulation	20	68.10±7.99	11:19	NR
Mol <i>et al.</i> , 2023. ^[19]	Netherlands	Randomized controlled trial.	Chronic inguinal pain	PRF of the dorsal root ganglion	22	70.41±10.25	6:16	NR
				Dorsal root ganglion stimulation	9	44±10	NR	NR
				Conventional medical management.	9	45±	NR	NR

NR: Not reported

Table 2: The methodological quality of the included observational studies.

Author ID	Selection	Comparability	Outcome	AHRQ standard
Kim <i>et al.</i> , 2017. ^[14]	3	2	2	Good

AHRQ: Agency for Healthcare Research and Quality

were presented in the tables, the values were obtained and used in the analysis software directly. However, in the studies in which the data were presented in graphs, an online software Plot Digitizer discussed by the Cochrane Collaboration was utilized to extract the values from the graphs manually.

The Cochrane Collaboration has previously described the procedure used. Furthermore, to analyze the mean changes for the studies that provided baseline values and values after intervention, an online calculator provided by the Statistics Kingdom was utilized to calculate the mean change and the

respective standard deviations.^[3] A 95% confidence interval for the meta-analysis and the heterogeneity across the studies were analyzed using the I^2 statistic. A low heterogeneity was assigned for $I^2 < 25\%$, moderate heterogeneity to $I^2 = 25\text{--}50\%$, high heterogeneity to $I^2 > 50\%$. A random effects model was selected for the meta-analysis, considering the expectations for high heterogeneity of the studies included. Fixed effect was used for homogenous outcomes. Open Meta Analyst software was used to calculate the proportion of adverse effects. We conducted a sensitivity analysis using the leave-one-out method to investigate the sources of heterogeneity. Publication bias was investigated using funnel plots; however, they are not adequately presented due to the small number of studies (<10 studies).

Quality appraisal

The quality appraisal of the studies was conducted using the Newcastle Ottawa Scale. This assessment scale assesses the methodological quality of the studies in three aspects: selection of participants, comparability, and reporting of outcomes. The overall quality of the studies is then assessed using the Agency for Healthcare Research and Quality standard. The quality appraisal summary is presented in Table 2. For the randomized clinical trials, the risk of bias 2 (ROB2) provided by the Cochrane

Collaboration was utilized to assess the ROB. The ROB of the various studies was performed using the ROB2 assessment scale provided by the Cochrane Collaboration. The ROB2 assessment tool has five domains, i.e., the randomization process, deviations from the intended intervention, selection of the reported results, and missing outcome data. A domain is assigned “low risk” if the criterion was met correctly, “some concerns” if the criterion was not addressed correctly, and “high risk” if there was no address to the specified criterion. The overall risk was assigned “low” if all the domains had low risk, “some concerns” if some domains were assigned some concern, and “high” if some domains had high risk. A summary of the ROB is presented in Figure 1.

RESULTS

The online search yielded 945 articles from the three databases. After a detailed analysis of the articles, 623 duplicates were excluded from the study. Two hundred twenty records were then screened according to the screening criteria of abstracts, and 140 articles were excluded based on the screening criteria. All the articles were obtained; thus, 140 were analyzed based on the predetermined eligibility criteria. After carefully examining the studies using the population, intervention, comparison, outcomes, and study designs

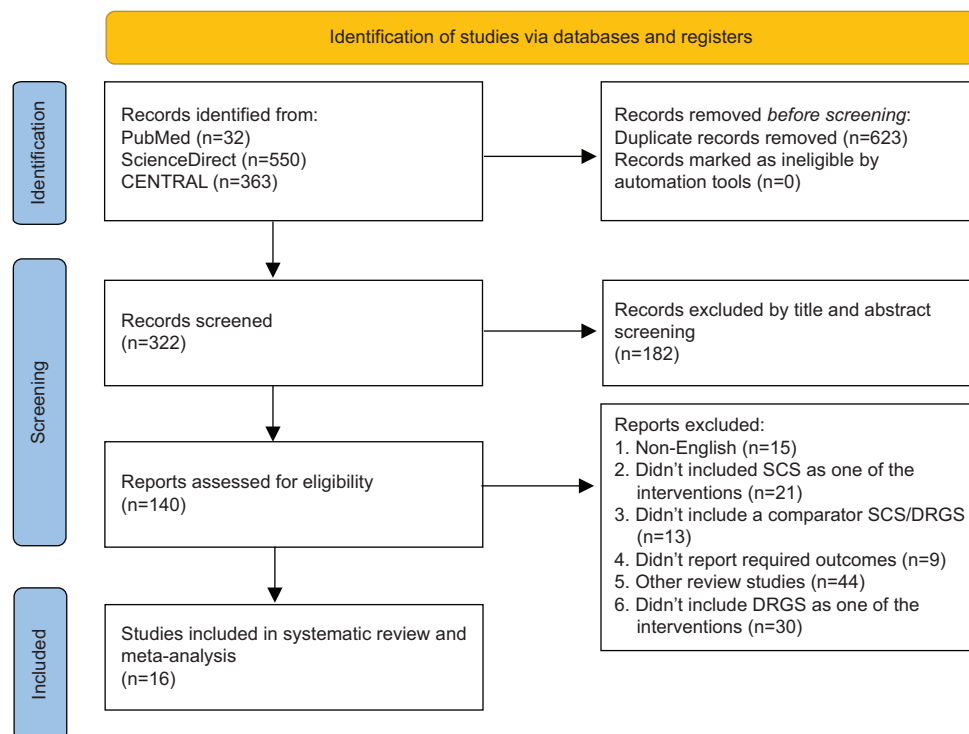


Figure 2: A PRISMA flow diagram summarising the search strategy. **: Records excluded based on title and abstract screening (n = 182). These exclusions were made due to non-relevance, inappropriate study design, or population mismatch with the study inclusion criteria.

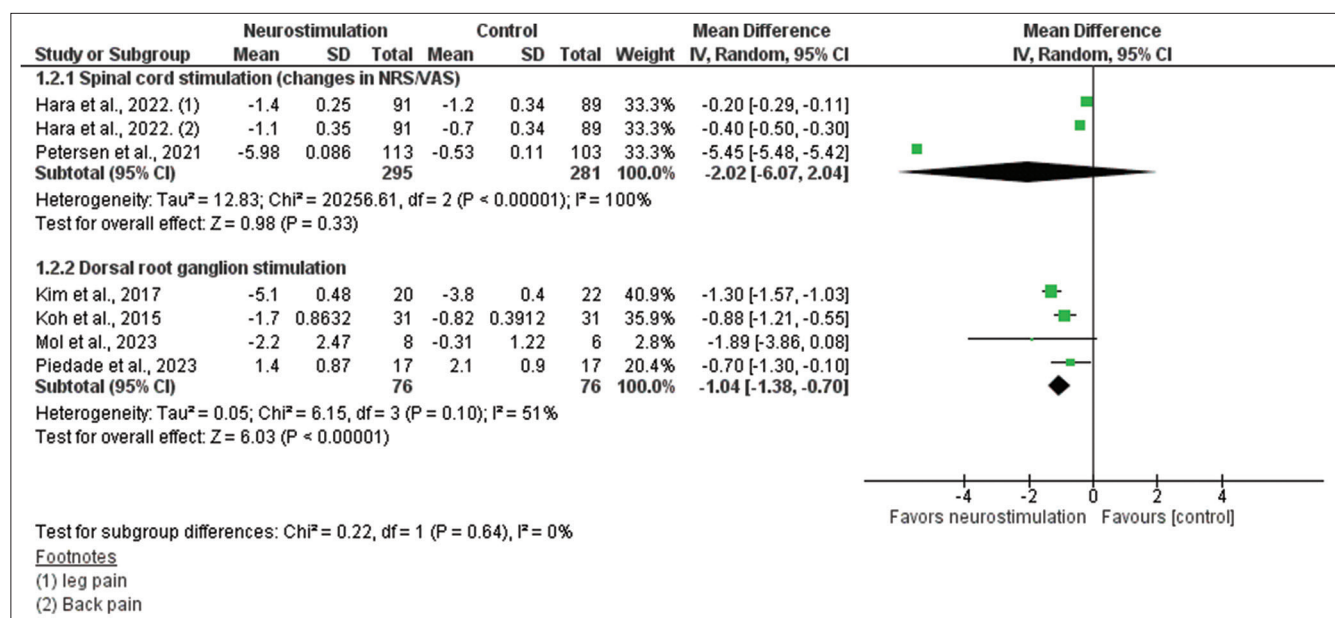


Figure 3: A forest plot showing changes in pain rating scale after neurostimulation compared with conventional medical management.^[11,14,16,19,22,23] SD: Standard deviation, CI: Confidence interval. (1): Refers to leg pain. The forest plot demonstrates the mean difference in pain rating for leg pain after neuromodulation (SCS and DRGS) compared to CMM. It shows that neuromodulation leads to significant pain reduction for leg pain. (2): Refers to back pain. The forest plot illustrates the mean difference in pain rating for back pain after neuromodulation compared to CMM. The results indicate that back pain also improves significantly with neuromodulation, though the effect may vary from leg pain.

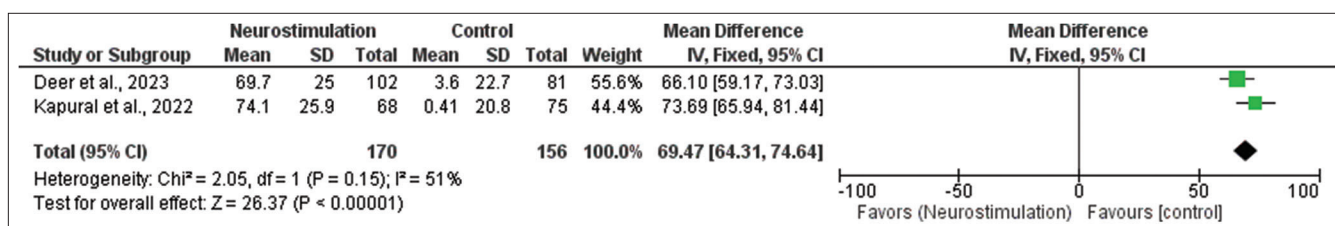


Figure 4: A forest plot showing the percentage change in pain rating after neurostimulation compared with conventional medical management.^[5,13] SD: Standard deviation, CI: Confidence interval.

(PICOS) format in our eligibility criteria, only 8 met our inclusion criteria and were included in the study. The other studies were excluded as follows: 15 were not published in English, 21 did not include SCS as one of the interventions, 30 did not include DRGS as one of the interventions, 44 were review articles, 13 did not include a comparator to SCS or DRGS, and nine did not report the required outcomes. A PRISMA flow diagram summarizing the search strategy is presented in Figure 2.

Characteristics of the included studies

The included studies were either cohort observational studies ($n = 1$) or randomized clinical trials ($n = 7$). These studies were conducted in different settings, including Norway ($n = 1$), the United States of America (USA) ($n = 3$), Germany ($n = 1$), Netherlands ($n = 1$), and Korea ($n = 2$). The type of refractory pain treated also varied across the studies and

included chronic radicular pain, refractory low back pain, chronic neuropathic pain, and nonsurgical refractory pain. Four studies of the included studies analyzed SCS compared to controls, while the remaining four analyzed DRGS. The characteristics of the included studies are presented in Table 1.

Methodological quality

The included cohort observational study had good methodological quality according to NOS.

Change in pain rating after neuro-stimulation compared to CMM

A subgroup analysis of the effect of SCS showed that patients who received SCS had higher decrease in pain rating compared to CMM mean difference (MD) but with

nonsignificant difference (MD = -2.02; 95% confidence interval [CI] [-6.07, 2.04] $P = 0.33$). When DRGS was considered, a pooled analysis showed that DRG resulted in significantly higher decrease in pain rating compared CMM MD (-1.04; 95% CI [-1.38, -0.70] $P < 0.00001$). The results of the analysis are presented in Figure 3.

Percentage change in the numerical scale rating after SCS compared to CMM

Two studies that analyzed the efficacy of SCS reported a percentage change. The pooled analysis of the two studies showed that SCS resulted in a higher percentage decrease in pain rating compared to CMM MD (69.47; 95% CI [64.31, 74.64] $P < 0.00001$). A forest plot showing the results is presented in Figure 4.

We conducted sensitivity analysis by leave-one-out method for the changes in the pain rating scale to eliminate the heterogeneity and found that Petersen *et al.*^[22] were the main source of heterogeneity as it used high frequency (10 kHz), which was very high compared to the other studies. Hara *et al.*^[11] measured the leg pain and back pain so they were different in their measurements [Figure 5].

The proportion of adverse effects in patients undergoing neurostimulation was 12.5%, with an effect estimate of 0.109 (95% CI: 0.024, 0.195) [Figure 6].

The quality of life was improved after using neurostimulation compared with the control group with MD (0.18; 95% CI [0.15, 0.21] $P < 0.00001$) and $I^2 = 49\%$, $P = 0.12$ [Figure 7].

The funnel plot assessing the publication bias of changes in the pain rating scale showed minimal risk of publication bias [Figure 8].

DISCUSSION

From the results of our analysis, we had the following findings: (1) SCS resulted in a greater decrease in pain rating compared to CMM. (2) DRGS resulted in a greater decrease in pain rating compared to CMM. (3) Even though both methods had a significant decrease in pain rating compared to CMM, the difference observed by SCS was significantly greater compared to DRGS. (4) Neurostimulation was associated with improved quality of life. (5) The proportion of adverse effects associated with neurostimulation was 12.5%. All of them are not life-threatening. They include surgical site infections, replacement of leads, and pulse generator replacement.

Our analysis showed that SCS was superior to CMM in the management of chronic refractory pain. Similarly, previous meta-analyses that have investigated the efficacy of SCS found that it was superior in the management of different types of refractory pain, such as angina, complex regional pain syndrome, and refractory neuropathic pain, among others.^[21,26]

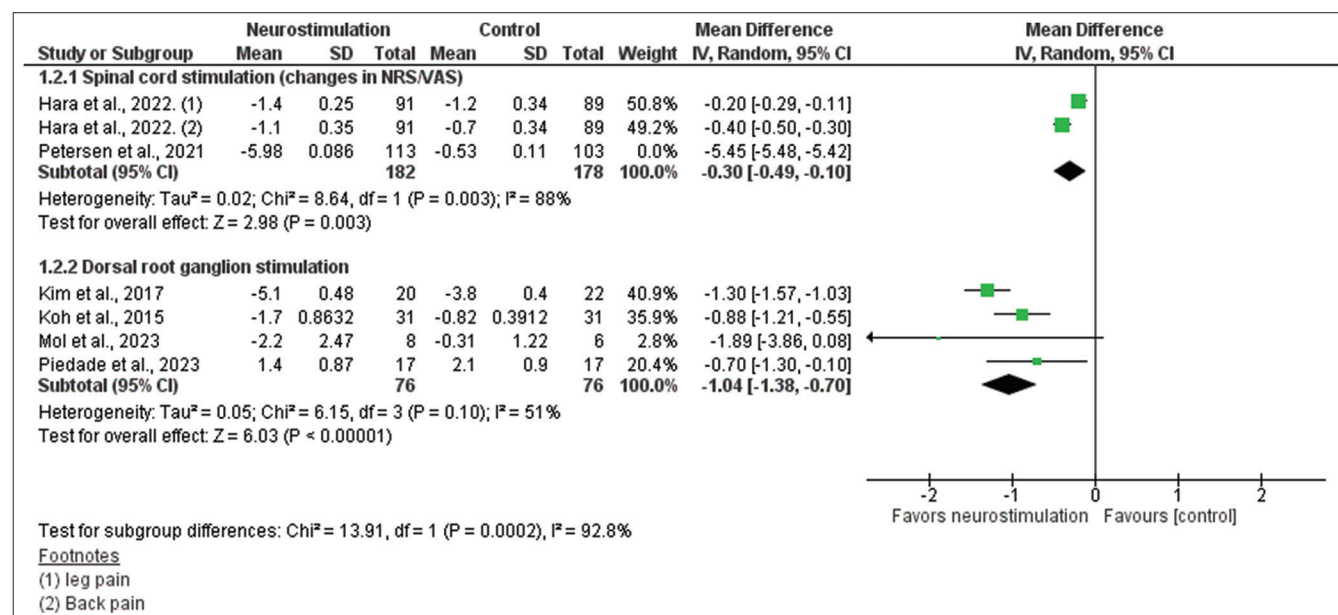


Figure 5: A forest plot showing changes in pain rating scale after neurostimulation compared with conventional medical management by leave-one-out analysis. SD: Standard deviation, CI: Confidence interval. (1): Refers to leg pain in the context of the leave-one-out sensitivity analysis. This analysis examines the robustness of the pooled effect size for leg pain after neuromodulation by sequentially excluding individual studies (e.g., Petersen *et al.*, 2021, which used high-frequency SCS). The results confirm consistent and reliable findings for leg pain. (2): Refers to back pain in the context of the leave-one-out sensitivity analysis. This analysis assesses the reliability of the pooled effect size for back pain after neuromodulation, excluding studies with significant heterogeneity. The analysis validates the stability and consistency of the results for back pain.

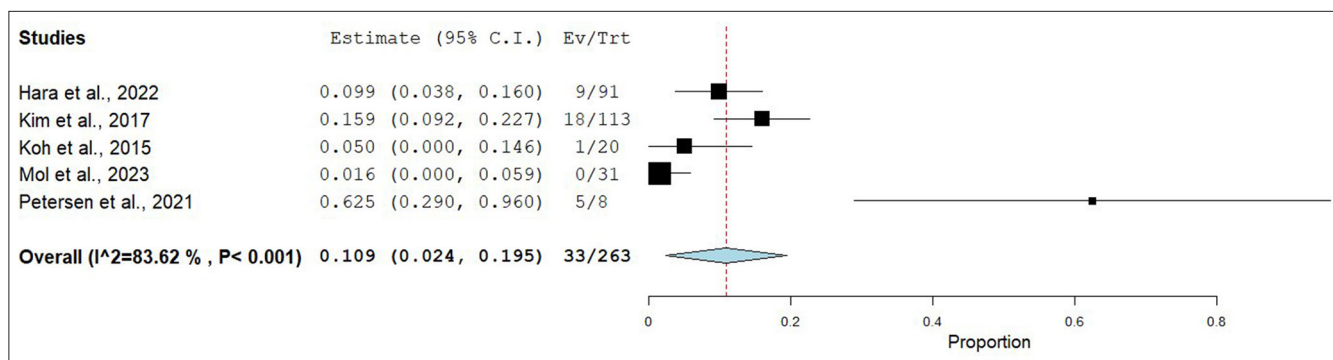


Figure 6: A forest plot showing the proportion of adverse effects in patients undergoing neurostimulation. C.I.: Confidence interval.

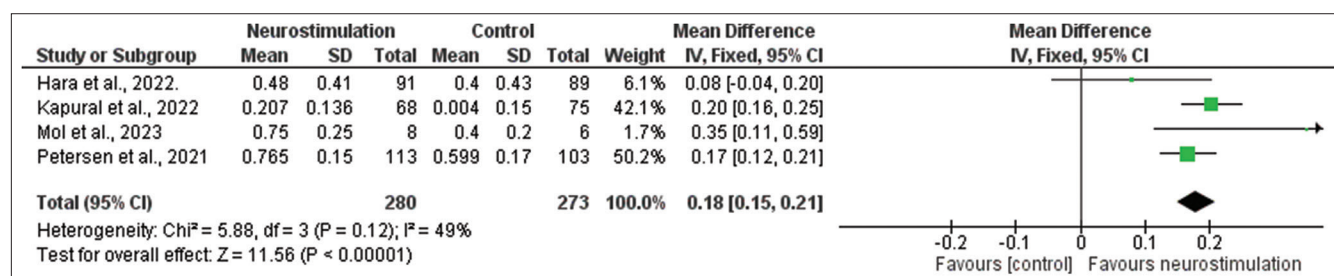


Figure 7: A forest plot showing the quality of life after neuromodulation compared with conventional medical management. SD: Standard deviation, CI: Confidence interval.

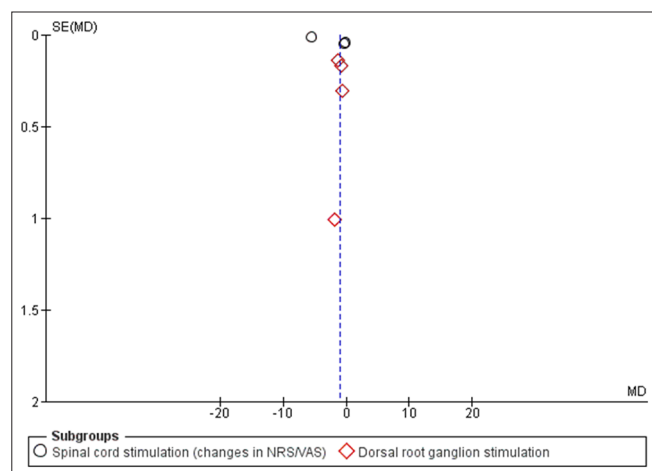


Figure 8: A funnel plot showing publication bias changes in the pain rating scale after neurostimulation compared with conventional medical management. SE: Standard error.

Apart from providing pain relief, it was also noted that SCS had additional benefits such as reducing the angina frequencies in patients with angina and reducing the amount of drugs required to be used in the management of angina, such as nitroglycerine.^[21] Furthermore, SCS has been associated with increased patient satisfaction with the treatment modality and thus enhances their adherence to all the other management

modalities, such as exercise in patients with angina because of the improved analgesia. Similarly, in patients with chronic refractory pain of other types, the achievement of pain relief after a very long time results in a sense of relief and thus increases the chances of the patients adhering to the other treatment modalities. This is also associated with better quality of life as their suffering from annoying feelings of pain is decreased as proven by the present analysis.

Our analysis showed that DRGS was also efficacious and superior to CMM in managing chronic refractory pain. Similar to our analysis, a previous systematic review by Ghorayeb *et al.*, found that DRGS provided pain relief in patients with chronic pelvic pain by $>50\%$.^[9] Furthermore, similar to our study, Ghorayeb *et al.*, 2023 did not that high quality evidence evaluating the impact of DRGS in the management of chronic pain is still lacking.^[9] Furthermore, most clinical trials evaluating the efficacy of DRGS have a small number of participants, thus limiting the extent and the generalizability of the results obtained. Nevertheless, they did observe that pain relief and improvement in quality of life after initiation of DRGS was observed as early as 2 months, and the effects would last as long as 3 years. Therefore, even with the scarce evidence, we can conclude that DRGS is a promising pain management modality that needs to be widely studied to establish its efficacy and thus enable its wide adoption of pain management across the globe.

Limitations

The current review had some limitations; for instance, the review only included 8 clinical trials summarizing data from 838 patients. This limited sample size limits the generalization of the findings of this review to the general target population. Second, the analysis of the review had very high heterogeneity, which was as high as 100%. This may be due to the different conventional management strategies used as the controls included in the study.

Data availability

The data that support the findings of this study are available on request.

CONCLUSION

The findings of our analysis indicate that SCS and DRGS are superior to CMM in the management of chronic refractory pain. However, these findings are based on a limited pooled sample size, and thus, we recommend that future trials recruit more participants. Finally, our findings suggest that better outcomes are achieved with SCS compared to DRGS; however, more trials investigating the efficacy of both these modalities need to be carried out to ascertain the efficacy of these modalities compared to one another.

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Declaration of patient consent: Patient's consent is not required as there are no patients in this study.

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