Received: September 4, 2024 Revised: October 8, 2024 Accepted: October 27, 2024

https://doi.org/10.1016/j.neurom.2024.10.010

Noninfectious Complications of Dorsal Root Ganglion Stimulation: A Systematic Review and Meta-Analysis

Maarten Vanloon, MD[1,2,3]; Tim Van Broeckhoven, MD[1]; Vincent Raymaekers, MD[2,3,4]; Dirk De Ridder, MD, PhD[5]; Bart Billet, MD[6,7]; Sacha Meeuws, MD[8,9]; Tomas Menovsky, MD, PhD[2,4]; Mark Plazier, MD, PhD[3,8,9]

ABSTRACT

Introduction: Dorsal root ganglion stimulation (DRGS) has emerged as a promising treatment for chronic neuropathic pain. However, its safety and complications are not fully understood, with existing literature primarily based on case reports, observational studies, and data base analyses. This systematic review and meta-analysis aims to assess the prevalence of noninfectious complications associated with DRGS, focusing on the trial phase, postimplantation period, and revisions, while identifying risk factors for these outcomes.

Materials and Methods: This systematic review adhered to Preferred Reporting Items for Systematic reviews and Meta-Analyses guidelines and was registered in the International Prospective Register of Systematic Reviews database. A comprehensive search was conducted across multiple data bases in June 2023. Studies included randomized and nonrandomized trials, and cohort studies involving ≥20 patients with DRGS. The exclusion criteria were studies that did not differentiate DRGS-specific complications, focused solely on infections, lacked sufficient data for prevalence estimation, or presented only subanalyses from larger studies. A meta-analysis of proportions was performed to estimate the overall prevalence of complications.

Results: Thirteen studies with 634 participants were included. The pooled prevalence of all complications was 37% (95% CI: 19%–57%), with device-related complications being the most common at 27% (95% CI: 15%–42%). Lead fractures and migrations were the most frequently reported device-related complications with, respectively, 6% (95% CI: 2%–12%) and 6% (95% CI: 2%–10%). Procedure-related complications had a pooled prevalence of 1% (95% CI: 0%–5%), with dural puncture being the most common. The prevalence of DRGS explantations was 12%, primarily due to insufficient pain relief.

Conclusions: DRGS shows a safety profile comparable to that of spinal cord stimulation, with similar rates of lead migrations and fractures. Improvements in surgical techniques, technology, and clinician expertise are expected to reduce complications. Future research should standardize reporting practices and detail implantation techniques to better understand and refine best practices in DRGS implantation.

Keywords: Adverse events, complications, dorsal root ganglion stimulation, meta-analysis, neuromodulation

Address correspondence to: Maarten Vanloon, MD, Universiteitssingel 40, 6229 ER Maastricht, The Netherlands. Email: maarten_vanloon@hotmail.com

[1] Faculty of Health, Medicine and Life Sciences, University Maastricht, Maastricht, The Netherlands;
[2] Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium;
[3] Faculty of Medicine and Life Science, Hasselt University, Hasselt, Belgium;
[4] Department of Neurosurgery, Antwerp University Hospital, Antwerp, Belgium;
[5] Department of Surgical Sciences, Section of Neurosurgery, Dunedin School of Medicine, University of Otago, Dunedin, New Zealand;
[6] Department of Anesthesiology, AZ Delta, Roeselare, Belgium;
[7] STIMULUS research group, Vrije Universiteit Brussel, Brussels, Belgium;
[8] Department of Neurosurgery Jessa Hospital, Hasselt, Belgium; and
[9] Study and Training Centre Neurosurgery Virga Jesse, Hasselt, Belgium

For more information on author guidelines, an explanation of our peer review process, and conflict of interest informed consent policies, please see the journal's Guide for Authors.

Source(s) of financial support: The authors reported no funding sources.

INTRODUCTION

Traditional spinal cord stimulation (SCS) is a well-established and evidence-based treatment for chronic pain syndromes that are unresponsive to conservative measures,[1–5] even though not all meta-analyses to date are uniformly positive.[6] Although SCS has been widely used and supported by literature, its limitations stem from the absence of specific dermatomal or peripheral targets.[7] Dorsal root ganglion stimulation (DRGS) has emerged as a newer form of neuromodulation that allows more localized treatment of neuropathic pain.[8] In a 2018 literature review conducted by the Neuromodulation Appropriateness Consensus Committee, strong evidence was found supporting the use of DRGS for patients with complex regional pain syndrome (CRPS) type I and II, in addition to other chronic pain syndromes affecting the pelvic region and lower extremity.[9]

However, the safety and potential complications of DRGS are not yet fully understood. The existing body of literature on the safety of DRGS relies primarily on case reports and observational studies, in addition to the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) data base. According to a retrospective analysis of the FDA MAUDE data base ($N = 979$) almost half of the complications (47%) were device related, whereas 28% were procedural complications.[10] Most complications involved lead migration (27%) and fracture (10%).[10] In a pooled analysis of the adverse events and complications in 256 implants, a 36% complication rate was noted.[11] Complications include but are not limited to infections, dural puncture, implantable pulse generator (IPG) irritation or pain (10.2%), unwanted stimulation, lead migration (5.9%) and lead fractures (5.9%), in addition to hematoma formation.[8,11] One case report described Twiddler's syndrome, which involves coiling and fracture of the lead after DRGS implantation.[12] A recent systematic review and pooled analysis investigating the infectious complications of DRGS revealed that the risk of infection during the trial phase seems low but significantly increases on implantation.[13] A large consecutive cohort obtained from manufacturer records, which included safety data as a secondary outcome, and a safety analysis reported similar adverse events to those of SCS.[11,14] However, there is no systematic review following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines analyzing the noninfectious complications and adverse events of DRGS and their risk factors.[15] Therefore, the objective of this systematic review and meta-analysis is to assess the overall prevalence of noninfectious complications and adverse events associated with DRGS, specifically focusing on the prevalence during the trial phase, after implantation and/or revision, in addition to identifying the risk factors contributing to these complications and adverse events.

MATERIALS AND METHODS

Study Protocol

The systematic review adhered to the PRISMA guidelines,[15] and a comprehensive protocol was developed before commencing the review process. Furthermore, the review was registered in the International Prospective Register of Systematic Reviews data base with the registration number CRD42023440983.

Search Strategy

We performed an extensive search across multiple data bases, without date restrictions, in June 2023. The data bases searched included Ovid Embase, Ovid Medline, LWW Journals, EBM reviews, Scopus, Web of Science, and PubMed. The full search strategy listing all search terms is available in the Supplementary Data.

Selection Process

The inclusion criteria for this systematic review were 1) randomized and nonrandomized trials, and prospective and retrospective cohort studies; 2) a minimum of 20 participants trialing DRGS to ensure sufficient data quality and mitigate the risk of random complications associated with small sample sizes; 3) adult participants aged ≥18 years; 4) articles published in English; and 5) studies that focused on DRGS and reported complications or adverse events. Studies that specifically reported the absence of complications also were included.

The exclusion criteria were 1) studies presenting complications associated with other implanted technologies in conjunction with DRGS, unless the data specifically distinguished and reported the complications separately for DRGS; 2) articles focusing exclusively on infections; 3) data base studies reporting solely complications without sufficient data to calculate the prevalence; 4) articles presenting subgroups or subanalyses derived from larger studies or data bases, except when new relevant data were provided, with a careful assessment conducted to ensure no duplication or overlap of data; and 5) conference abstracts, poster presentations, and (systematic) reviews without new data.

All titles and abstracts obtained from the search results were manually screened by two independent reviewers (MV and TVB). In case of disagreement, a third author was consulted (VR). Supplementary citations were identified by reviewing the bibliographies of relevant articles. Subsequently, the reviewers evaluated the full-text articles on the basis of the predetermined inclusion and exclusion criteria, documenting the rationale for excluding each full-text article.

Data Collection

Two independent reviewers (MV and TVB) used a structured computer data base to extract data from the full-text articles. In case of any discrepancies, a third independent reviewer (VR) was involved to resolve them and reach a consensus. The data abstraction process adhered to a predefined protocol, including study design, sample size, demographic information of the study population (age, sex, body mass index), DRGS trials, trial duration follow-up duration, (rates of) complications or adverse events, their characteristics, and associated outcomes. Revision surgeries and the specific components being revised (eg, IPG or leads) also were collected. In this systematic review, adverse events or complications were categorized as device related, procedure related, or other.

Furthermore, if available, the reviewers also collected information on possible risk factors for noninfectious complications and adverse events, including patient-related factors such as diabetes mellitus, smoking, connective tissue disorders, and obesity. Almost all studies included in this systematic review did not report these risk factors, so this specific outcome could not be documented.

Other variables collected included the duration of the trial and the specialty of the implanter (eg, anesthesiology, pain management, neurosurgery, among others).

Lastly, funding sources were documented along with any conflicts of interest from the authors. In case of missing data or doubt on overlap of data, efforts were made to contact the study authors to obtain necessary information.

Risk of Bias Assessment

The risk of bias was assessed using a tool designed for non-randomized trials, the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I).[16] Using this tool, we evaluated domains such as confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of reported results. Of note, only two studies reported no conflicts of interest.[17,18]

Evidence Synthesis

Tables summarizing study and patient characteristics, complications, revisions, and explantations were generated. Mean differences were used for continuous outcomes, whereas count data are presented for dichotomous outcomes. Age ranges were converted to estimated standard deviation, if not provided by the study, using the method described by Hozo et al.[19]

A meta-analysis of proportions was performed to estimate the overall summary proportion of complications and adverse events after permanent DRGS implantation. No analysis of complications was performed for the trial period of DRGS owing to the lack of complications reported during this period. A subgroup analysis was performed on device-related, procedure-related, or other complications after permanent implantation. Another subgroup analysis was performed for lead migrations, fractures, and pocket pain of device-related complications. Furthermore, a meta-analysis of proportions was performed on device explantations. No analysis was performed for revisions owing to the lack of reports describing the number of revisions performed. The described analyses involved pooling the count data from the included studies and calculating the summary proportion using statistical models described by Wang.[20] Double arcsine transformations were applied to the data after analysis of raw proportions for variance stabilization.

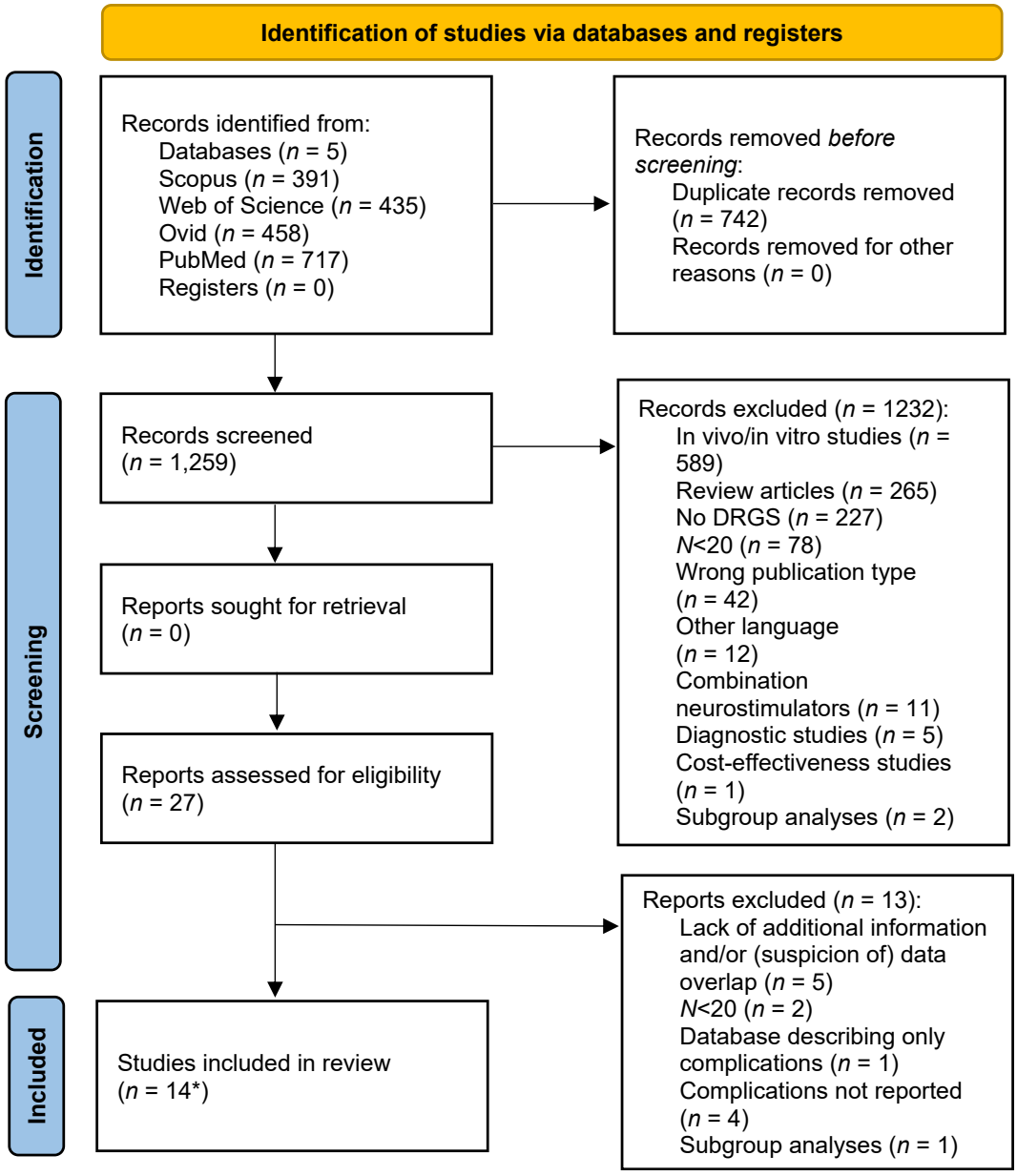

Figure 1. PRISMA flow diagram of the DRGS studies. *One study comprised a subgroup analysis. [Color figure can be viewed at www.neuromodulationjournal.org]

Different statistical methods were used to assess heterogeneity among the included studies. Cochran's Q test, the I^2 statistic, and τ^2 were calculated to evaluate heterogeneity among studies. The restricted maximum-likelihood estimator method was used for calculating τ^2. To identify outliers and influential studies, a Baujat plot, influence diagnostic tests, and leave-one-out analyses were performed for the total complications and device-related complications.[20,21] Outliers and influential studies were not analyzed for procedure-related or other complications owing to the low number of complications in these subgroups. Lastly, a correlation analysis between complications and study publication date was performed.

All statistical analyses were performed using RStudio (version 2024.04.2+764; R Foundation for Statistical Computing, Vienna, Austria) and R (version 4.4.1; R Foundation for Statistical Computing). We used the packages meta (version 7.0-0; R Foundation for Statistical Computing), metafor (version 4.6-0; R Foundation for Statistical Computing), and dmetar (version 0.1-0; R Foundation for Statistical Computing) for the statistical analyses.

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to assess the certainty of evidence.[22]

RESULTS

Study Selection

The full study selection is presented in the PRISMA flow diagram (Fig. 1). After title and abstract screening, 27 studies were assessed for eligibility; 13 studies were excluded after full-text analysis. Corresponding authors were contacted for necessary additional information or clarification. Five studies were excluded owing to no response or (suspicion of) data overlap.[14,23–26] Two studies trialed <20 patients.[27,28] One study was a data base analysis of complications and adverse events exclusively so could not be used to analyze the prevalences.[10] Four studies did not report the presence nor absence of complications.[29–32] One study was a subgroup analysis that did not provide new relevant information.[33]

A total of 14 studies were included. Two studies were grouped together because one included a subgroup analysis that provided additional details regarding complications and adverse events.[34,35] These two studies will henceforth be counted as one study, generating a total of 13 studies for analysis.

Study Characteristics

Five (38%) and eight (62%) studies were retrospective and prospective, respectively (Table 1). Most studies were performed in Germany ($n = 4$), followed by the USA ($n = 3$), and data collection ranged from 2011 to 2021. Safety or complication analyses were the primary outcome measure of five studies (38%) (26–30).

Eleven of the 13 studies reported the medical specialty of the implanters (Table 2). Neurosurgery was the most frequent implanter specialty ($n = 6$, 55%), followed by anesthesiology ($n = 3$, 27%) and pain specialists ($n = 2$, 18%). Eight studies reported the DRGS system used (Table 2). The Axium Neurostimulator system was used by all eight studies.

Eleven studies reported on the implantation method.[17,18,34–38,40–43,46] Only four studies reported on the approach of DRGS implantation, all of which used the contralateral approach.[17,34–36,40] Tension S-loops, also known as strain relief loops, were used in six studies.[17,34–36,40,41,43] The other five studies did not mention the use of strain relief loops.[18,37,38,42,46] Anchors were used in seven studies.[18,34,35,40–43] The study of Chapman et al[34,35] reported mixed usage of anchors

Table 1. Study Demographics and Design.

Study	Design	Country	Data collection, y	Primary outcome measures
Wensing et al[36]	Prospective, single-arm, multicenter cohort	The Netherlands	2013–2016	1. Change in overall pain intensity. 2. Percentage of subjects with >50% pain reduction
Papa et al[37]	Retrospective cohort	Italy	2013–2015	Short- and medium-term safety and efficacy
Piedade et al[38]	Prospective cohort	Germany	2013–2016	Short- and long-term effects for thoracic and upper limb pain
Chapman et al[29,33–35,39]	Retrospective, multicenter cohort	USA	2016–2020	1. Explant rates 2. Lead migration and fracture rate
Hines et al[40]	Retrospective cohort	USA	2016–2020	Incidence of device-related complications
Liem et al[41]	Prospective, multicenter interventional trial	3 European and 4 Australian sites	2011–2013	Long-term efficacy
Morgalla et al[18]	Prospective cohort	Germany	2012–2016	Long-term pain relief for chronic neuropathic groin pain
Morgalla et al[42]	Prospective cohort	Germany	2012–2016	Long-term pain relief for chronic neuropathic pain (excluding groin pain)
Horan et al[43]	Prospective, multicenter cohort	Denmark	2014–2018	Pain intensity
Graca et al[17]	Retrospective cohort	USA	2016–2021	Percentage of subjects with >50% pain reduction
Kretzschmar et al[46]	Retrospective cohort	Germany	2013–2015	Long-term safety and efficacy
Eldabe et al[44]	Prospective, single-arm trial	UK	2013–2020	Pain intensity
Huygen et al[45]	Prospective cohort	The Netherlands	2012–2013	Effectiveness in a typical real-world clinical context

Table 2. DRGS Implanter Specialty and Devices.

Study	Specialty implanter(s)	Implantation device(s)*
Wensing et al[36]	Anesthesiology	Axium™ Neurostimulator system
Papa et al[37]	Anesthesiology	Axium™ Neurostimulator system
Piedade et al[38]	Neurosurgery	Axium™ Neurostimulator system; Proclaim™ Neurostimulation System
Chapman et al[29,33–35,39]	Pain specialists, functional neurosurgeon	Axium™ Neurostimulator system; Proclaim™ Neurostimulation System
Hines et al[40]	Neurosurgery	Not reported
Liem et al[41]	Not reported	Not reported
Morgalla et al[18]	Neurosurgery	Axium™ Neurostimulator system
Morgalla et al[42]	Neurosurgery	Not reported
Horan et al[43]	Neurosurgery	Not reported
Graca et al[17]	Pain specialists	Axium™ Neurostimulator system
Kretzschmar et al[46]	Anesthesiology	Not reported
Eldabe et al[44]	Not reported	Axium™ Neurostimulator system
Huygen et al[45]	Not reported	Axium™ Neurostimulator system

*Axium was first owned by Spinal Modulation and later acquired by St Jude Medical in 2015 and subsequently by Abbott in 2017 (later rebranded as Proclaim).

dependent on the implanter. Furthermore, some implanters changed from anchoring to not anchoring or vice versa during the study. One study used anchoring except in two patients.[17] The studies of Morgalla et al[18,42] reported that the authors stopped anchoring owing to lead fractures. One study did not use anchoring.[36] The other studies did not report on the usage of anchoring.[37,38,46] The location of IPG implantation was gluteal,[34,35,41] abdominal,[41] lower back,[38] and flank.[17] The other seven studies did not report on the implantation site of the IPG.[18,36,37,40,42,43,46]

Twelve studies reported a total of 479 patients trialed (Supplementary Data Table S1). The trial duration ranged from three to 29 days with a mean trial duration of 9.5 days (SE = 1.6). One study had on-table trials for some patients.[43] Twelve studies reported the number of failed trials. A total of 92 DRGS trials (19%) failed, of which 88 failures (96%) were due to insufficient pain relief. A total of 634 patients were permanently implanted with DRGS (Table 3). The mean age at implantation was 52 (SE = 1.6) years. Twelve studies including 578 patients with a permanent DRGS implantation reported the indication for DRGS implantation. The most common indications for DRGS were CRPS (n = 210, 36%), followed by neuropathic pain (n = 96, 17%), persistent spinal pain syndrome 2 (n = 95, 16%), postsurgical neuralgia (n = 43, 7%), and postherniorrhaphy pain (n = 30, 5%). Ten studies reported a total of 1247 DRGS leads implanted. Only four studies described the exact number of leads implanted per spinal level.[18,38,42,46] The overall mean follow-up duration was 16.6 months, ranging from one week to seven years. Twelve studies reported a total of 242 patients completed the last follow-up.

Risk of Bias Assessment

The risk of bias for the included studies was evaluated using the ROBINS-I tool (Fig. 2). Three studies were assessed as having a low overall risk of bias.[18,41,42] Eight studies were assessed as having a moderate risk of bias.[17,34–38,40,45,46] Two studies received an overall critical risk of bias assessment.[43,44]

Complications and Adverse Events

A total of 172 complications were reported (Supplementary Data Table S2). The pooled prevalence of all complications or adverse events was 37% (95% CI: 19%–57%), with substantial heterogeneity (I^2 = 95%, τ^2 = 0.118, χ^2 = 233.53, $p < 0.01$) (Fig. 3). The Baujat plot shows two studies that might have a large influence on overall heterogeneity and the pooled prevalence (Supplementary Data Fig. S1). Influence diagnostic tests indicate that no studies significantly affect the pooled prevalence or overall heterogeneity. However, two studies were nearly significant in affecting the pooled prevalence (Supplementary Data Fig. S2).[36,44] A forest plot of the leave-one-out analysis shows that removal of the study by Eldabe et al[44] or Wensing et al[36] reduces the pooled prevalence of all complications from 37% to 31% or 32%, respectively. Removal of either study showed a minor effect on overall heterogeneity (Fig. 4). There was no correlation between all complications and publication date (coefficient: 0.36; 95% CI: −0.24 to 0.75).

When focusing specifically on device-related complications or adverse events, 142 complications were reported. The pooled prevalence of device-related complications was 27% (95% CI: 15%–42%), with significant heterogeneity (I^2 = 91%, τ^2 = 0.064, χ^2 = 132.54, $p < 0.01$) (Fig. 5). The most common device-related complications were lead fractures (n = 48), migrations (n = 44), and pocket pain (n = 12). The Baujat plot and influence diagnostic tests show that the study by Eldabe et al has a significant, large influence on the pooled prevalence and on the overall heterogeneity (Supplementary Data Figs. S3 and S4).[44] A forest plot of the leave-one-out analysis shows that removing the study by Eldabe et al reduces the pooled prevalence of device-related complications from 27% to 22% and overall heterogeneity (I^2) from 91% to 82% (Fig. 6). There was no correlation between device-related complications and publication date (coefficient: 0.42; 95% CI: −0.16 to 0.79).

Lead fractures were identified with a pooled prevalence of 6% (95% CI: 2%–12%), showing moderate heterogeneity (I^2 = 74%, τ^2 = 0.020, χ^2 = 46.89, $p < 0.01$) (Fig. 7a). Similarly, the pooled prevalence of lead migrations was 6% (95% CI: 2%–10%), with moderate heterogeneity (I^2 = 65%, τ^2 = 0.013, χ^2 = 33.95, $p < 0.01$) (Fig. 7b). The pooled prevalence of pocket pain was 1% (95% CI: 0%–4%), also with moderate heterogeneity (I^2 = 65%, τ^2 = 0.010, χ^2 = 34.14, $p < 0.01$) (Fig. 7c). One study only reported 12 cases of temporary motor stimulation.[41] Of note, four studies reported loss of stimulation in a total of 15 patients;[36,43–45] however, most other

Table 3. Demographics of Participants Permanently Implanted, DRGS Indications, Number of Leads, and Patient Follow-Up.

Study	Participants permanently implanted	Sex	Implantation age (mean ± SD)	Diagnoses/indications	Total number of leads	Mean follow-up duration (range)	Participants completed last follow-up
Wensing et al[36]	25	F 12; M 13	52 ± 13	4, CRPS; 4, postamputation pain; 14, postsurgical neuralgia; 1, visceral pain; 2, PSPS2	27	1.5 y (1–2 y)	22
Papa et al[37]	39	F 18; M 26	58 ± 23	12, PSPS2; 8, CRPS; 8, radiculopathy; 3, postherpetic neuralgia; 4, chronic postsurgical pain; 2, postamputation pain; 1, abdominopelvic pain; 1, postsurgical knee pain	72	4 y (15 d–4 y)	39
Piedade et al[38]	18	Not reported	58 ± 23	5, PNI; 5, postsurgical pain; 5, CRPS; 2, postherpetic neuralgia; 1, postamputation pain	33	7.5 mo (3 mo–1 y)	9
Chapman et al[29,33–35,39]	249	F 153; M 96	55 ± 15	106, CRPS; 64, PSPS2; 23, PSPS1; 12, peripheral neuropathy; 11, joint pain; 12, neuropathic pain; 9, radiculopathy; 2, peripheral vascular disease; 10, abdominopelvic pain	756	26 mo (14.7–36.5 mo)[†]	Not reported
Hines et al[40]	31	F 12; M 19	Not reported	30, CRPS; 1, postherpetic neuralgia	Not reported	17 mo (2–45 mo)	13
Liem et al[41]	32	F 17; M 15	52.5 ± 12.4	8, CRPS; 16, PSPS2; 1, PNI; 1, pain after vascular stenting; 6, postsurgical pain	67	6.1 mo (1 wk–12 mo)	22[‡]
Morgalla et al[18]	30	F 13; M 21	50.4 ± 13*	30, postherniorrhaphy pain	59	19.5 mo (3 mo–3 y)	11
Morgalla et al[42]	51	F 27; M 35	56.8 ± 13*	51, chronic neuropathic pain;	93	2 y (1–3 y)	16
Horan et al[43]	33	F 9; M 18	42 ± 10	33, neuropathic pain	Not reported	19.5 mo (3 mo–3 y)	9[‡]
Graca et al[17]	17	F 11; M 9	44 ± 12	17, CRPS	41	4.5 mo (3–6 mo)	17
Kretzschmar et al[46]	21	F 12; M 8	52.5 ± 14.2	4, CRPS upper extremity; 17, CRPS lower extremity;	43	3 y (3 mo–3 y)	21

(Continues)

Table 3. *Continued*

Study	Participants permanently implanted	Sex	Implantation age (mean ± SD)	Diagnoses/indications	Total number of leads	Mean follow-up duration (range)	Participants completed last follow-up
Eldabe et al[44]	32	F 15; M 17	53.03 ± 10.36	13, chronic postsurgical pain; 11, CRPS; 2, postherpetic neuralgia; 2, postamputation pain; 3, peripheral neuropathy; 1, PSPS2;	56	3.5 y (1 mo–7 y)	14
Huygen et al[45]	56	Not reported	Not reported	Not reported	Not reported	6.5 mo (1 mo–1 y)	49

F, female; M, male; PNI, peripheral nerve injury; PSPS1/2, persistent spinal pain syndrome type 1 and 2 respectively.
*Estimated SD.
†Median (interquartile range).
‡The mean was calculated on the basis of different numbers of participants for each questionnaire at the last follow-up.

studies reporting lead fractures or migrations did not mention the number of patients experiencing loss of stimulation.

Procedure-related complications or adverse events were reported with a pooled prevalence of 1% (95% CI: 0%–5%), showing moderate heterogeneity ($I^2 = 75\%$, $\tau^2 = 0.018$, $\chi^2 = 47.61$, $p < 0.01$) (Fig. 8a). The most common procedural complication was dural puncture ($n = 12$, 1.9%). The study of Liem et al reported the highest prevalence of dural puncture ($n = 7/12$, 58%) among the studies.[41] There was no correlation between procedure-related complications and publication date ($p = 0.85$). Other types of complications or adverse events were retrieved, showing a pooled prevalence of 1% (95% CI: 0%–5%) and moderate heterogeneity ($I^2 = 75\%$, $\tau^2 = 0.017$, $\chi^2 = 43.37$, $p < 0.01$) (Fig. 8b). There was no correlation between other complications and publication date ($p = 0.68$).

Seven and 11 studies reported DRGS revisions and explantations, respectively (Supplementary Data Table S3). The prevalence of explantations was calculated at 12% (95% CI: 5%–20%), showing significant heterogeneity ($I^2 = 84\%$, $\tau^2 = 0.027$, $\chi^2 = 60.96$, $p < 0.01$) (Fig. 9). Most explantations were due to insufficient pain relief ($n = 30$, 53%), followed by lead fractures ($n = 9$, 16%), pocket pain ($n = 7$, 12%), and lead migration ($n = 6$, 11%). Of the seven studies reporting revisions, five studies reported the components revised. Owing to the scarcity of data, this was not further analyzed.

Certainty of Evidence

The GRADE approach was used to assess the certainty of evidence (Table 4). Because most of the included studies are observational, the initial certainty of the evidence was rated as low. The certainty of evidence for device-related complications was downgraded to very low owing to risk of bias, inconsistency, and imprecision. The certainty of evidence for procedure-related and other complications was downgraded to very low owing to risk of bias.

DISCUSSION

We report the first, to our knowledge, systematic literature review and meta-analysis on the noninfectious complications and adverse events of DRGS in trial phase, after permanent implantation, and revisions and their risk factors. An extensive search, selection, and meta-analysis of included studies was performed following the PRISMA guidelines. Thirteen studies with a total of 634 participants were included in this meta-analysis. A low failure rate of DRGS trials was observed, with only 19% of trials failing primarily owing to insufficient pain relief. The pooled prevalence of all complications or adverse events was 37% (95% CI: 19%–57%), and the pooled prevalence of device-related complications was 27% (95% CI: 15%–42%). This finding agrees with previous large studies.[10,11] This led to an average explantation rate of 12%.

Both prospective studies by Eldabe et al[44] and Wensing et al[36] had a large effect, albeit nearly significant, on all complications. When either of these studies was removed from the analysis, the pooled prevalence of all complications decreased from 37% to 31% or 32%, respectively. Moreover, the study by Eldabe et al had a significant influence on device-related complications, and removal led to a decrease in the pooled prevalence from 27% to 22%. Interestingly, lead fractures and migrations were similar in the study by Eldabe et al to those in other studies. The influence of these two studies could be explained by several factors, including

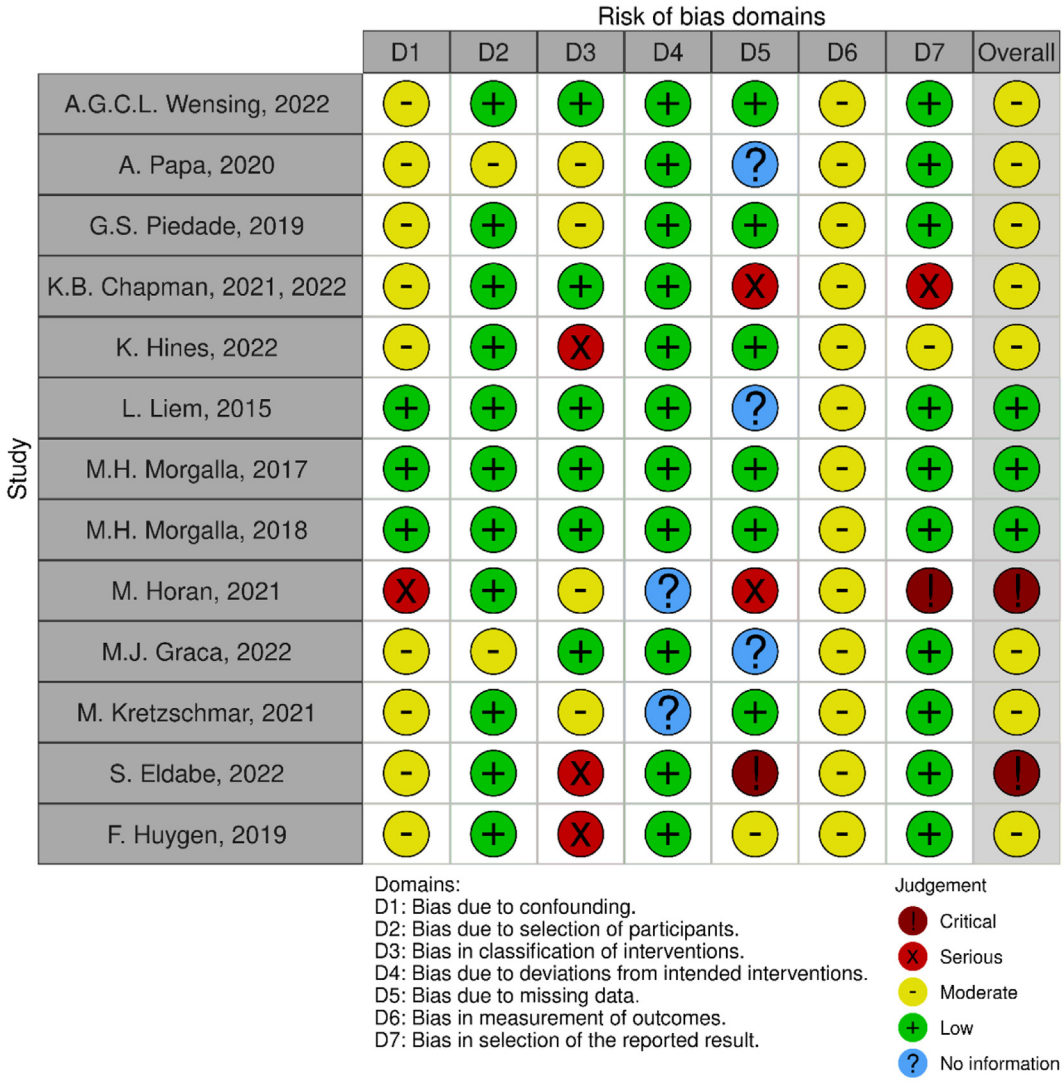

Figure 2. ROBINS-I of the included studies. D, domain. [Color figure can be viewed at www.neuromodulationjournal.org]

loss of stimulation, late failure of therapy, and overreporting. Eldabe et al reported loss of stimulation as a complication in 25% of cases, in addition to early battery depletion, and reported a higher proportion of patients (19%) with pocket pain. Loss of stimulation was reported alongside instances of lead fractures and possibly lead migrations. However, it was not possible to distinguish whether the loss of stimulation was due to lead issues or late therapy failure/habituation. Consequently, there may be some degree of overreporting in these results. Furthermore, Eldabe et al[44] had the longest follow-up duration of seven years. The combination of a higher proportion of pocket pain and possible overreporting of loss of stimulation contributes to an overall higher total effect on all complications and device-related complications, thus influencing the analysis. In contrast, the influence of Wensing et al[36] could be explained by their high proportion of "other" complications.

Most studies did not report data on revisions and risk factors, producing insufficient information to draw concrete conclusions about the frequency and nature of these procedures and associated risk factors for DRGS complications. However, explantation rates were low (12%, 95% CI: 5%–20%), predominantly owing to insufficient pain relief, lead fractures, pocket pain, and lead migration.

As mentioned, device-related complications in DRGS were stated to be in the same range as for SCS.[14] This meta-analysis confirms this statement. The pooled prevalence of lead migrations in this meta-analysis was 6% (95% CI: 2%–10%). This is comparable to the pooled prevalence of lead migration in SCS studies, which is 9.85% (95% CI: 7.41%–12.59%).[47] Furthermore, the pooled prevalence of lead fractures was 6% (95% CI: 2%–12%), which also aligns with the reported prevalence of 6.37% (95% CI: 2.63%–10.10%) in SCS.[48] However, the current prevalence of DRGS device-related complications might be lower owing to several factors. One significant factor is the evolution of the hardware of DRGS systems in addition to the standardization of implantation techniques over the years. Indeed, the studies included in this meta-analysis ranged from 2011 to 2021, during which period the DRGS systems underwent multiple improvements. The DRGS device experienced several updates including the introduction of a new lead tip (approved in 2014), IPG (approved in 2016), external pulse generator (approved in 2017), and programmer (approved in 2016).[49,50] Early

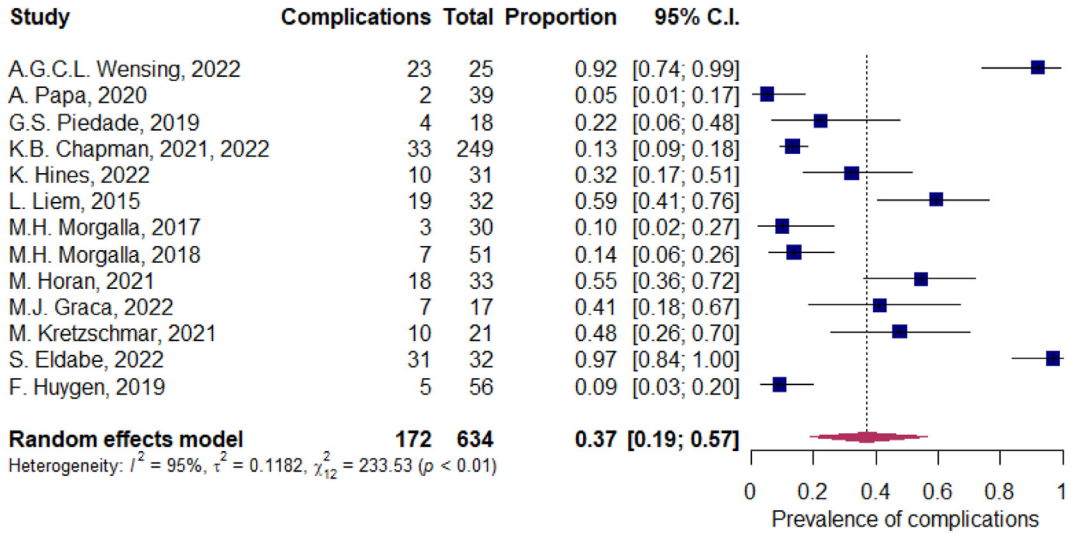

Figure 3. Forest plot displaying the prevalence of all complications or adverse events. [Color figure can be viewed at www.neuromodulationjournal.org]

experiences with first-generation systems showed higher complication rates due to the learning curve associated with new technology. For instance, higher lead-related complications were observed with the older "Ball Tip" leads than with the newer "Slim Tip" leads in the study of Horan et al.[43,49] It is possible that the overlap of data collection years and the hardware improvements during those years caused no correlation between publication date and complications to be found.

An example of the technical learning curve is presented by the pooled analysis of Chapman et al, which showed that the use of anchoring significantly reduced lead migrations.[34] Fracture rates were similar in unanchored and anchored leads. This might be relevant in regions of the spine that are subject to greater movement and mechanical stress, such as the cervical and lumbar regions. Leads placed in the thoracic and sacral regions, which are generally less mobile, may experience lower rates of migration and fracture. However, in this systematic review, only a few studies reported the exact spinal location of leads, and almost none provided detailed information on complications associated with specific lead locations. Furthermore, there was great heterogeneity of implantation techniques, including variations in anchoring and the use of strain relief loops. Four studies reported using the traditional contralateral approach. Recent advances in implantation techniques have sought to address complications such as lead migration and fracture. Initially, the traditional approach involved placing leads at an oblique angle contralateral to the target foramen, entering the skin two levels below the target foramen.[39,51] This method often involved traversing paraspinal muscles, increasing

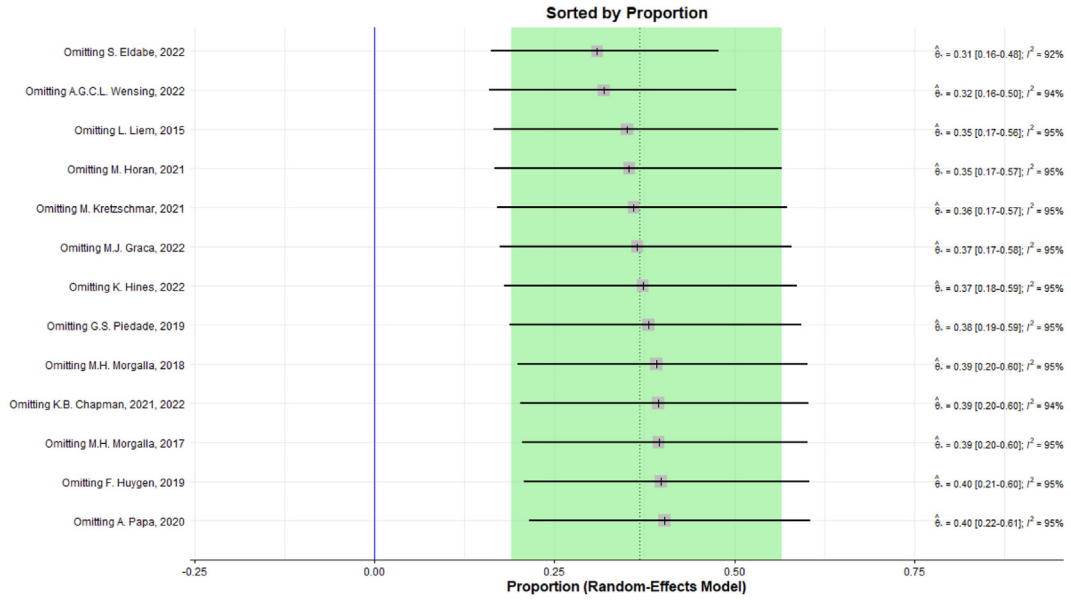

Figure 4. Forest plot displaying the leave-one-out analysis of all complications with recalculated pooled proportions. The vertical dashed line and shaded green area represent the original pooled proportion with its 95% CI, respectively. [Color figure can be viewed at www.neuromodulationjournal.org]

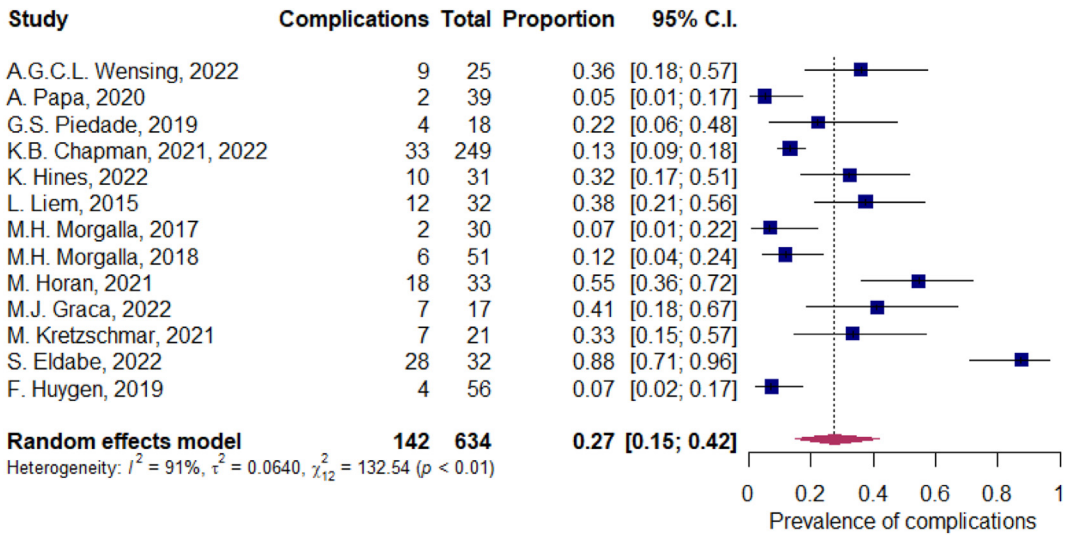

Figure 5. Forest plot displaying the prevalence of device-related complications or adverse events. [Color figure can be viewed at www.neuromodulationjournal.org]

the risk of lead fracture due to entrapment in the superficial plane. To mitigate these risks, a novel ipsilateral, paramedian approach has been introduced, which avoids the paraspinal musculature and focuses on anchoring the leads parallel to the spinous process. This technique not only reduces the incidence of lead fracture and migration but also minimizes postprocedural pain, providing a significant advantage over traditional methods.[39,51] Furthermore, this approach mirrors the trajectory used in traditional SCS, potentially easing the learning curve for practitioners. The lack of data from most studies and the high variability in reporting these techniques limit the ability to draw definitive conclusions about the impact of lead location and implantation techniques on lead migrations and fractures.

The pooled prevalence of pocket pain in this meta-analysis was 1% (95% CI: 0%–4%). The prevalence of pocket pain in SCS varies widely, ranging from 0.9% to 64%.[52] This wide variation is influenced by factors such as differences in reporting methods, implant techniques, and the size and shape of the IPG. The low prevalence observed in this meta-analysis could be attributed to potential underreporting of this complication.

The prevalence of procedure-related complications was low (1%, 95% CI: 0%–5%), with the prevalence of dural puncture being

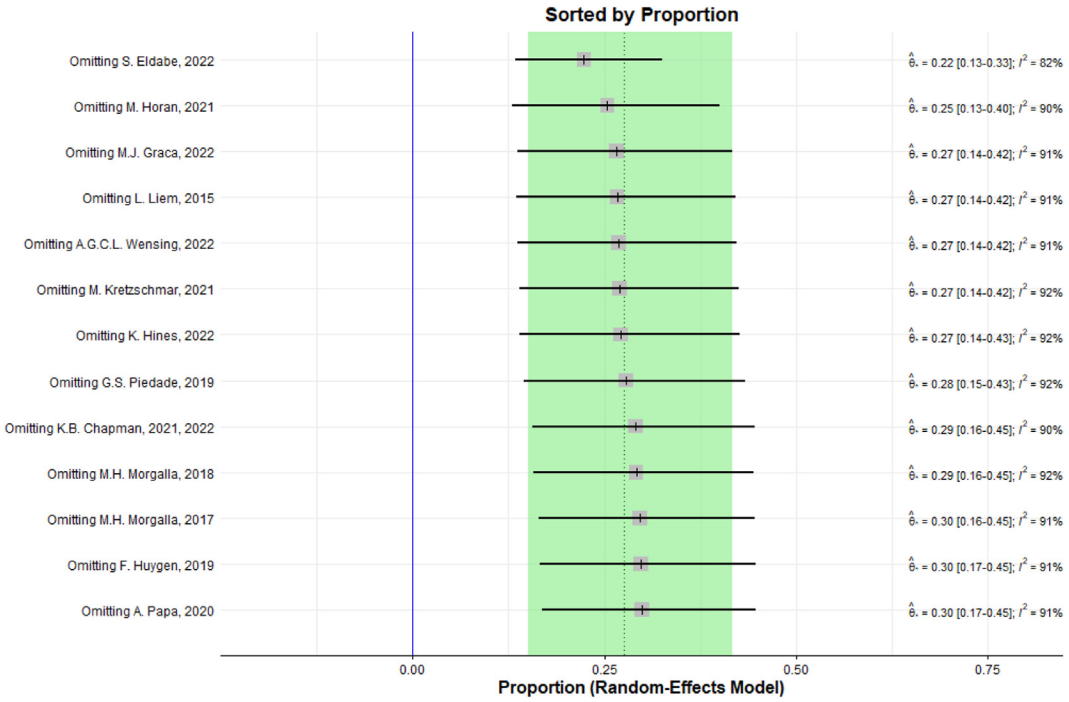

Figure 6. Forest plot displaying the leave-one-out analysis of device-related complications with recalculated pooled proportions. The vertical dashed line and shaded green area represent the original pooled proportion with its 95% CI, respectively. [Color figure can be viewed at www.neuromodulationjournal.org]

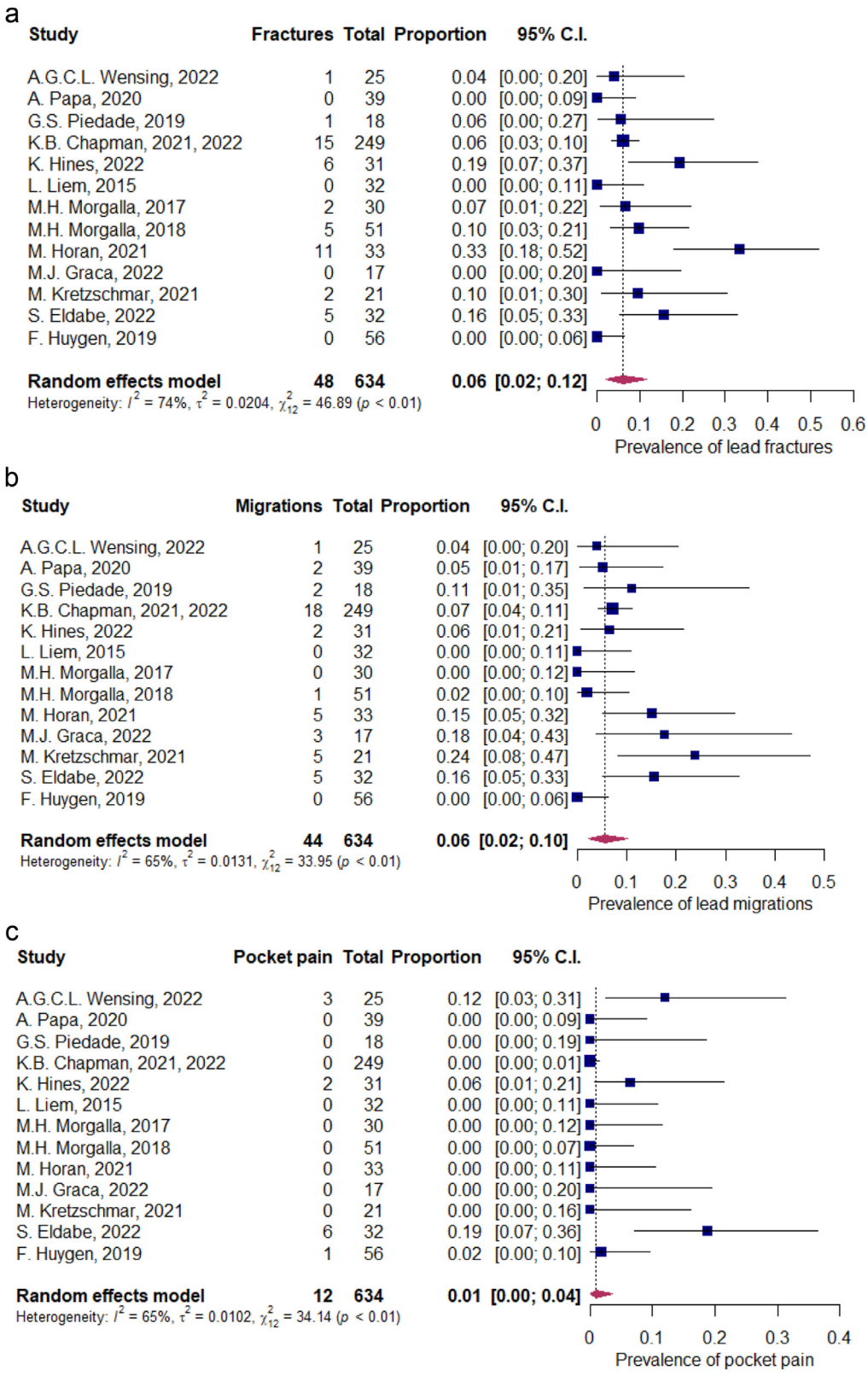

Figure 7. a. Forest plot displaying the prevalence of lead fractures. b. Forest plot displaying the prevalence of lead migrations. c. Forest plot displaying the prevalence of pocket pain. [Color figure can be viewed at www.neuromodulationjournal.org]

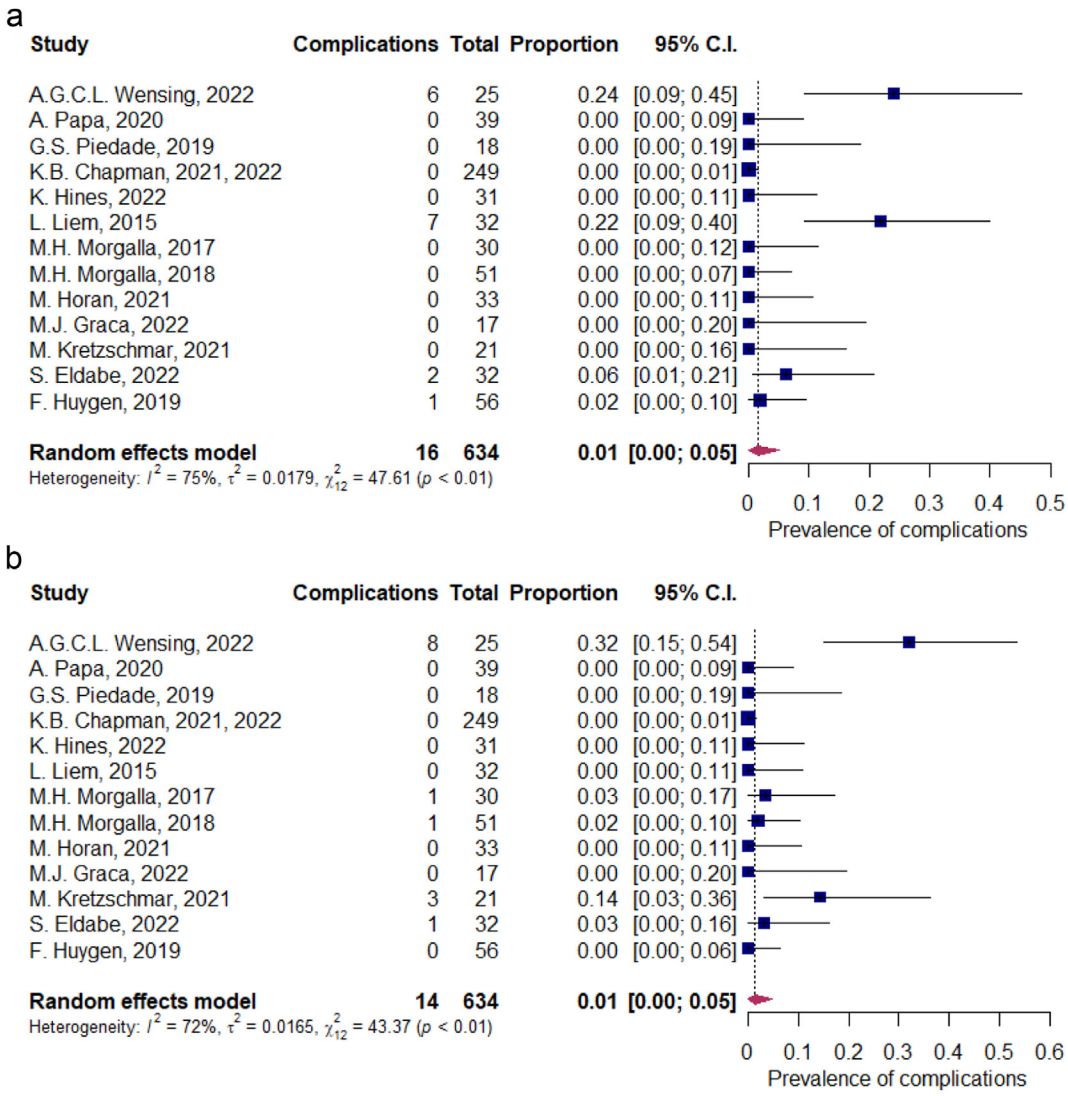

Figure 8. a. Forest plot displaying the prevalence of procedure-related complications or adverse events. b. Forest plot displaying the prevalence of other complications or adverse events. [Color figure can be viewed at www.neuromodulationjournal.org]

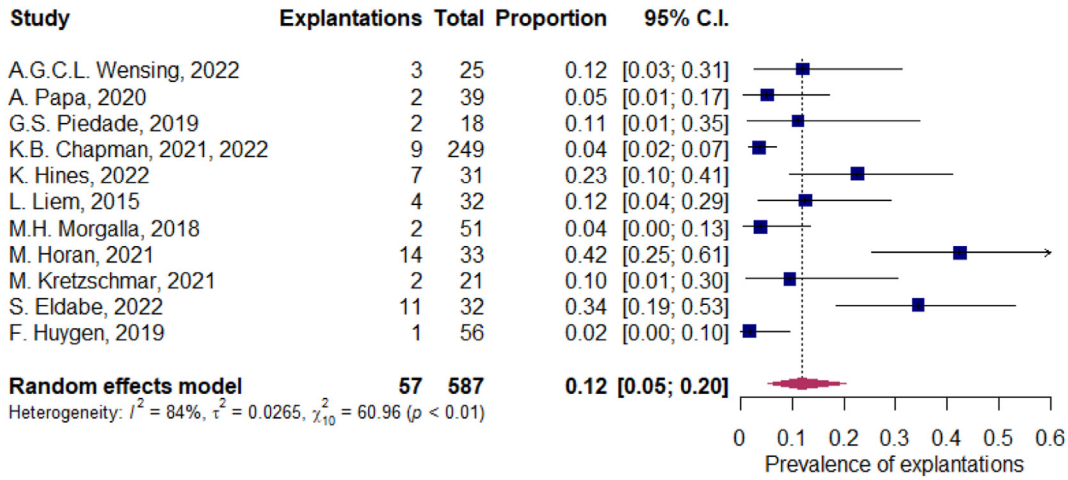

Figure 9. Forest plot displaying the prevalence of explantations. [Color figure can be viewed at www.neuromodulationjournal.org]

Table 4. GRADE Evidence Profile: Noninfectious Device-Related, Procedure-Related, and Other Complications of Permanent Implantation.

Outcome	Number of studies	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of participants	Proportion (95% CI)	Certainty in evidence	Importance
Device-related complications	13	Serious	Serious	Not serious	Serious	634	0.27 (0.15–0.42)	Very low	Critical
Procedure-related complications	13	Serious	Serious	Not serious	Not Serious	634	0.03 (0.00–0.07)	Very low	Important
Other complications	13	Serious	Serious	Not serious	Not serious	634	0.03 (0.00–0.09)	Very low	Important

consistent with previous studies estimating the risk of unintentional dural puncture during SCS trial or implant procedures at 0.2% to 2%.[14,52] It is noteworthy that the study by Liem et al reported a higher prevalence of dural puncture, potentially attributed to the novelty of DRGS at the time of their study in 2011.[41] This suggests that the true prevalence of dural puncture in DRGS might be lower given DRGS systems, procedural techniques, and practitioner experience have evolved.

The prevalence of other types of complications or adverse events also was low (1%, 95% CI: 0%–5%). These types of complications were usually not related to the device or procedure, such as accidentally switching off the device or pocket hematoma due to a fall.

Limitations and Future Research

This study has several limitations that should be acknowledged. First, the significant heterogeneity among the included studies suggests variability in study populations, methods, and reporting standards, which may affect the generalizability of the results. Second, there was considerable heterogeneity in the reporting of implantation techniques. The methods used for lead anchoring and the application of strain relief loops varied widely among the studies, with some reporting the use of specific techniques whereas others did not provide such details. This inconsistency complicates the ability to draw firm conclusions about the influence of these techniques on complications. Third, there was a lack of detailed data on the spinal levels at which leads were implanted. Most studies did not specify the exact locations of lead placements and corresponding complications, such as whether they were in the cervical, thoracic, lumbar, or sacral regions. This lack of specificity limits the understanding of ways the anatomical site of lead implantation may affect the rates of lead migration and fracture. Fourth, there was an absence of data on patient-bound risk factors such as obesity, connective tissue disorders, smoking, and other comorbidities that could influence complication rates. Fifth, there also was a notable lack of details on revisions and revision procedures. Information on the frequency of revisions and the types of revisions conducted was frequently missing, which hinders the ability to fully assess the long-term safety of DRGS implants. Sixth, underreporting of complications is another concern because some studies did not clearly state whether complications were absent or simply not recorded, such as pocket pain, potentially leading to an underestimation of some specific adverse events. Seventh, although we calculated the average follow-up duration, the proportional meta-analysis did not account for varying follow-up times across studies. This limits the ability to assess whether complication rates, such as lead migration and fracture, increase with longer follow-up durations. Lastly, the predominantly observational nature of the study designs, with a mix of retrospective and prospective approaches, introduces inherent biases and limits the strength of the evidence.

For future research, we strongly recommend the standardized reporting of the number of leads per spinal level and the associated complications per lead per spinal level. Detailed documentation of the exact anatomical locations of lead placements and any corresponding complications will significantly enhance the understanding of ways different spinal regions affect the rates of lead migration and fracture. In addition, improving the reporting of implantation techniques is crucial. Consistent and thorough descriptions of methods used for lead anchoring, the application of strain relief loops, and other procedural details will enable more accurate assessments of their effects on device-related complications. Including information on revisions and patient-specific risk factors such as obesity, connective tissue disorders, and smoking status in future studies also will be beneficial. This will help identify patient populations at higher risk and refine implantation strategies to reduce complications. Standardizing these reporting practices will facilitate more robust comparisons across studies and contribute to the development of best practices in DRGS implantation and management. Moreover, future systematic reviews and meta-analyses should explore the relationship between operator experience and complication rates, particularly by examining whether studies with larger cohorts indicate lower complication rates, potentially reflecting the implanter's expertise. Furthermore, future analyses should investigate the impact of follow-up duration on complication rates to determine whether longer follow-up periods reveal increasing rates of lead migration and fracture.

CONCLUSIONS

The findings of this meta-analysis show that DRGS is as safe as SCS, with a comparable prevalence of lead migrations and fractures. Increased experience among implanters and the continuous improvement of surgical techniques, in addition to improved technology, are likely to reduce the incidence of complications over time. Future research should focus on standardizing reporting practices, particularly the number of leads per spinal level and associated complications, and detailed descriptions of implantation techniques. This will enhance the understanding of influencing factors in the complication rate and help refine best practices in DRGS implantation and management.

Acknowledgements

The authors thank Prof Sam Eldabe for his valuable feedback and insights regarding his study included in this meta-analysis and systematic review.

Authorship Statements

Maarten Vanloon, Tim Van Broeckhoven, and Vincent Raymaekers designed and conducted the study. Maarten Vanloon

conducted the statistical analyses. All authors contributed to the interpretation of the data and revisions of the manuscript. All authors reviewed and approved the final submitted version.

Conflict of Interest

Bart Billet is a consultant for Saluda Medical, Salvia BioElectronics, Medtronic, Nevro, and Abbott. Sacha Meeuws is a consultant for Abbott, Medtronic, and Salvia BioElectronics. Mark Plazier is a consultant for Abbott, Medtronic, and Salvia BioElectronics. Mark Plazier is an editorial board member of the journal *Neuromodulation: Technology at the Neural Interface*. The remaining authors reported no conflict of interest.

How to Cite This Article

Vanloon M., Van Broeckhoven T., Raymaekers V., De Ridder D., Billet B., Meeuws S., Menovsky T., Plazier M. 2025. Noninfectious Complications of Dorsal Root Ganglion Stimulation: A Systematic Review and Meta-Analysis.
Neuromodulation 2025; 28: 234–248.

SUPPLEMENTARY DATA

To access the supplementary material accompanying this article, visit the online version of *Neuromodulation: Technology at the Neural Interface* at www.neuromodulationjournal.org and at https://doi.org/10.1016/j.neurom.2024.10.010.

REFERENCES

1. Duarte RV, Nevitt S, McNicol E, et al. Systematic review and meta-analysis of placebo/sham controlled randomised trials of spinal cord stimulation for neuropathic pain. *Pain*. 2020;161:24–35. https://doi.org/10.1097/j.pain.0000000000001689.
2. Fatima K, Javed SO, Saleem A, et al. Long-term efficacy of spinal cord stimulation for chronic primary neuropathic pain in the contemporary era: a systematic review and meta-analysis. *J Neurosurg Sci*. 2024;68:128–139. https://doi.org/10.23736/S0390-5616.23.05930-1.
3. Karri J, Orhurhu V, Wahezi S, Tang T, Deer T, Abd-Elsayed A. Comparison of spinal cord stimulation waveforms for treating chronic low back pain: systematic review and meta-analysis. *Pain Phys*. 2020;23:451–460.
4. Taylor RS. Spinal cord stimulation in complex regional pain syndrome and refractory neuropathic back and leg pain/failed back surgery syndrome: results of a systematic review and meta-analysis. *J Pain Symptom Manage*. 2006;31(suppl 4):S13–S19.
5. Zhou M, Zhong H, Xing C, et al. Comparison of clinical outcomes associated with spinal cord stimulation (SCS) or conventional medical management (CMM) for chronic pain: a systematic review and meta-analysis. *Eur Spine J*. 2023;32:2029–2041. https://doi.org/10.1007/s00586-023-07716-2.
6. O'Connell NE, Ferraro MC, Gibson W, et al. Implanted spinal neuromodulation interventions for chronic pain in adults. *Cochrane Database Syst Rev*. 2021;12:CD013756. https://doi.org/10.1002/14651858.CD013756.pub2.
7. Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: a systematic review. *Pain Phys*. 2016;19:E33–E54.
8. Potter ST, Welch S, Tata F, Probert S, Nagpal A. Dorsal root ganglion stimulation. *Phys Med Rehabil Clin N Am*. 2022;33:359–378. https://doi.org/10.1016/j.pmr.2022.02.005.
9. Deer TR, Pope JE, Lamer TJ, et al. The neuromodulation appropriateness consensus committee on best practices for dorsal root ganglion stimulation. *Neuromodulation*. 2019;22:1–35. https://doi.org/10.1111/ner.12845.
10. Sivanesan E, Bicket MC, Cohen SP. Retrospective analysis of complications associated with dorsal root ganglion stimulation for pain relief in the FDA MAUDE database. *Reg Anesth Pain Med*. 2019;44:100–106. https://doi.org/10.1136/rapm-2018-000007.
11. Huygen FJPM, Kallewaard JW, Nijhuis H, et al. Effectiveness and safety of dorsal root ganglion stimulation for the treatment of chronic pain: a pooled analysis. *Neuromodulation*. 2020;23:213–221. https://doi.org/10.1111/ner.13074.
12. Vanloon M, Raymaekers V, Meeuws S, Plazier M. Twiddler's syndrome after dorsal root ganglion stimulation: a case report. *Heliyon*. 2023;9:e18365. https://doi.org/10.1016/j.heliyon.2023.e18365.
13. Moman RN, Peterson AA, Maher DP, et al. Infectious complications of dorsal root ganglion stimulation: a systematic review and pooled analysis of incidence. *Neuromodulation*. 2022;25:956–964. https://doi.org/10.1111/ner.13473.
14. Deer T, Pope J, Hunter C, et al. Safety analysis of dorsal root ganglion stimulation in the treatment of chronic pain. *Neuromodulation*. 2020;23:239–244. https://doi.org/10.1111/ner.12941.
15. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71. https://doi.org/10.1136/bmj.n71.
16. Sterne JA, Hernán MA, Reeves BC, et al. Robins-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. 2016;355:i4919. https://doi.org/10.1136/bmj.i4919.
17. Graca MJ, Lubenow TR, Landphair WR, McCarthy RJ. Efficacy and safety of cervical and high-thoracic dorsal root ganglion stimulation therapy for complex regional pain syndrome of the upper extremities. *Neuromodulation*. 2022;26:1781–1787. https://doi.org/10.1016/j.neurom.2022.09.007.
18. Morgalla MH, Bolat A, Fortunato M, Lepski G, Chander BS. Dorsal root ganglion stimulation used for the treatment of chronic neuropathic pain in the groin: a single-center study with long-term prospective results in 34 cases. *Neuromodulation*. 2017;20:753–760. https://doi.org/10.1111/ner.12713.
19. Hozo SP, Djulbegovic B, Hozo I. Estimating the mean and variance from the median, range, and the size of a sample. *BMC Med Res Methodol*. 2005;5:13. https://doi.org/10.1186/1471-2288-5-13.
20. Wang N. Conducting meta-analyses of proportions in R. *J Behav Data Sci*. 2023;3:64–126. https://doi.org/10.35566/jbds/v3n2/wang.
21. Harrer M, Cuijpers P, Furukawa TA, Ebert DD. *Doing Meta-Analysis with R: A Hands-On Guide*. 1st ed. Chapman & Hall/CRC Press; 2021.
22. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336:924–926. https://doi.org/10.1136/bmj.39489.470347.AD.
23. Al-Kaisy A, Royds J, Al-Kaisy O, et al. Explant rates of electrical neuromodulation devices in 1177 patients in a single center over an 11-year period. *Reg Anesth Pain Med*. 2020;45:883–890. https://doi.org/10.1136/rapm-2020-101681.
24. Al-Kaisy A, Royds J, Costanzi M, et al. Effectiveness of "transgrade" epidural technique for dorsal root ganglion stimulation. A retrospective, single-center, case series for chronic focal neuropathic pain. *Pain Phys*. 2019;22:601–611.
25. Falowski SM, Deer T, Tubic G, Mehta P. Multicenter retrospective analysis of dorsal root ganglion stimulator placement using intraoperative neuromonitoring in asleep patients during early periods of adoption. *Neuromodulation*. 2021;24:753–757. https://doi.org/10.1111/ner.13286.
26. Hagedorn JM, Deer TR, Falowski SM, et al. An observational study of intraoperative neuromonitoring as a safety mechanism in placement of percutaneous dorsal root ganglion stimulation and spinal cord stimulation systems. *J Pain Res*. 2020;13:3349–3353. https://doi.org/10.2147/JPR.S289416.
27. Lu L, Lau M, Akers L, et al. Intraoperative neurophysiological monitoring during lead placement for dorsal root ganglion stimulation: a literature review and case series. *Neuromodulation*. 2024;27:160–171. https://doi.org/10.1016/j.neurom.2023.04.468.
28. Mol F, Scheltinga M, Roumen R, et al. Comparing the efficacy of dorsal root ganglion stimulation with conventional medical management in patients with chronic post-surgical inguinal pain: post hoc analyzed results of the SMASHING study. *Neuromodulation*. 2023;26:1788–1794. https://doi.org/10.1016/j.neurom.2022.09.014.
29. Chapman KB, Tupper C, Yang A, van Helmond N, Yousef T. Intermittent dorsal root ganglion stimulation is as efficacious as standard continuous dosing in treating chronic pain: results from a randomized controlled feasibility trial. *Neuromodulation*. 2022;25:989–997. https://doi.org/10.1016/j.neurom.2021.10.008.
30. Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017;158:669–681. https://doi.org/10.1097/j.pain.0000000000000814.
31. Hunter CW, Sayed D, Lubenow T, et al. DRG FOCUS: a multicenter study evaluating dorsal root ganglion stimulation and predictors for trial success. *Neuromodulation*. 2019;22:61–79. https://doi.org/10.1111/ner.12796.
32. Verrills P, Mitchell B, Vivian D, Cusack W, Kramer J. Dorsal root ganglion stimulation is paresthesia-independent: a retrospective study. *Neuromodulation*. 2019;22:937–942. https://doi.org/10.1111/ner.12921.
33. Chapman KB, Spiegel MA, van Helmond N, et al. Dorsal root ganglion stimulation as a salvage therapy following failed spinal cord stimulation. *Neuromodulation*. 2022;25:1024–1032. https://doi.org/10.1016/j.neurom.2022.04.050.
34. Chapman KB, Mogilner AY, Yang AH, et al. Lead migration and fracture rate in dorsal root ganglion stimulation using anchoring and non-anchoring techniques: a multicenter pooled data analysis. *Pain Pract*. 2021;21:859–870. https://doi.org/10.1111/papr.13052.
35. Chapman KB, Yang A, Mogilner AY, et al. Dorsal root ganglion stimulation device explantation: a multicenter pooled data analysis. *Pain Pract*. 2022;22:522–531. https://doi.org/10.1111/papr.13113.

36. Wensing AGCL, Breel JS, Hollmann MW, Wille F. Prospective observational cohort study on dorsal root ganglion stimulation in chronic postsurgical pain: results of patient-reported outcomes at two years. *Neuromodulation*. 2022;25:998–1005. https://doi.org/10.1016/j.neurom.2021.11.005.
37. Papa A, Saracco E, Di Dato MT, et al. Dorsal root ganglion stimulation for the management of chronic neuropathic pain: a retrospective case series during four years follow-up in a single center. *TOPAINJ*. 2020;13:35–41. https://doi.org/10.2174/1876386302013010035.
38. Piedade GS, Vesper J, Chatzikalfas A, Slotty PJ. Cervical and high-thoracic dorsal root ganglion stimulation in chronic neuropathic pain. *Neuromodulation*. 2019;22:951–955. https://doi.org/10.1111/ner.12916.
39. Chapman KB, Spiegel MA, Dickerson DM, et al. A paramedian approach for dorsal root ganglion stimulation placement developed to limit lead migration and fracture. *Pain Pract*. 2021;21:991–1000. https://doi.org/10.1111/papr.13063.
40. Hines K, Swaminathan V, Thalheimer S, Kogan M, Wu C, Sharan A. Single-center retrospective analysis of device-related complications related to dorsal root ganglion stimulation for pain relief in 31 patients. *Neuromodulation*. 2022;25:1040–1044. https://doi.org/10.1111/ner.13498.
41. Liem L, Russo M, Huygen FJPM, et al. One-year outcomes of spinal cord stimulation of the dorsal root ganglion in the treatment of chronic neuropathic pain. *Neuromodulation*. 2015;18:41–48 [discussion: 48–49]. https://doi.org/10.1111/ner.12228.
42. Morgalla MH, Fortunato M, Lepski G, Chander BS. Dorsal root ganglion stimulation (DRGS) for the treatment of chronic neuropathic pain: a single-center study with long-term prospective results in 62 cases. *Pain Phys*. 2018;21:E377–E387. https://doi.org/10.36076/ppj.2018.4.e377.
43. Horan M, Jacobsen AH, Scherer C, et al. Complications and effects of dorsal root ganglion stimulation in the treatment of chronic neuropathic pain: a nationwide cohort study in Denmark. *Neuromodulation*. 2021;24:729–737. https://doi.org/10.1111/ner.13171.
44. Eldabe S, Copley S, Gulve A, et al. A prospective long-term follow-up of dorsal root ganglion stimulation for the management of chronic intractable pain. *Pain*. 2022;163:702–710. https://doi.org/10.1097/j.pain.0000000000002405.
45. Huygen FJPM, Liem L, Nijhuis H, Cusack W, Kramer J. Evaluating dorsal root ganglion stimulation in a prospective Dutch cohort. *Neuromodulation*. 2019;22:80–86. https://doi.org/10.1111/ner.12798.
46. Kretzschmar M, Reining M, Schwarz MA. Three-year outcomes after dorsal root ganglion stimulation in the treatment of neuropathic pain after peripheral nerve injury of upper and lower extremities. *Neuromodulation*. 2021;24:700–707. https://doi.org/10.1111/ner.13222.
47. West T, ElSaban M, Hussain N, et al. Incidence of lead migration with loss of efficacy or paresthesia coverage after spinal cord stimulator implantation: systematic review and proportional meta-analysis of prospective studies and randomized clinical trials. *Neuromodulation*. 2023;26:917–927. https://doi.org/10.1016/j.neurom.2023.03.016.
48. Eldabe S, Buchser E, Duarte RV. Complications of spinal cord stimulation and peripheral nerve stimulation techniques: a review of the literature. *Pain Med*. 2016;17:325–336. https://doi.org/10.1093/pm/pnv025.
49. Horan M, Blichfeldt-Eckhardt MR. Response to letter to the editor regarding "complications and effects of dorsal root ganglion stimulation in the treatment of chronic neuropathic pain: a nationwide cohort study in Denmark". *Neuromodulation*. 2020;23:1047. https://doi.org/10.1111/ner.13269.
50. Lubenow T, Nijhuis H. Response to "complications and effects of dorsal root ganglion stimulation in the treatment of chronic neuropathic pain: a nationwide cohort study in Denmark". *Neuromodulation*. 2020;23:1046. https://doi.org/10.1111/ner.13268.
51. Chapman KB, Sayed D, Lamer T, et al. Best practices for dorsal root ganglion stimulation for chronic pain: guidelines from the American society of pain and neuroscience. *J Pain Res*. 2023;16:839–879. https://doi.org/10.2147/JPR.S364370.
52. Deer TR, Russo MA, Sayed D, et al. The neurostimulation appropriateness consensus committee (NACC)®: recommendations for the mitigation of complications of neurostimulation. *Neuromodulation*. 2024;27:977–1007. https://doi.org/10.1016/j.neurom.2024.04.004.

COMMENTS

This meta-analysis, which excludes infectious complications, provides a good overview of average lead migration and fracture rates relating to DRGS. Recent developments in DRGS to try and reduce these complications include the placing of S-loops (or M-loops) to prevent migration and investigations scrutinizing anchoring techniques that may reduce either migration or fracture (eg, Chapman et al). However, these two issues remain a problem, and further technologic advances to reduce these are likely to encourage a greater uptake of this therapy. It still stands, however, that DRGS stimulation is highly effective for specific types of neuropathic pain, especially focal pain such as groin, knee, foot, and hand. It therefore remains an important part of the armamentarium of neuromodulation therapies.

Alexander Green, MD, BSc, MBBS
Oxford, UK

***

DRGS is now in its second decade of use and has been shown to be efficacious in a variety of neuropathic pain syndromes. However, although my personal experience with the technique is quite favorable, there is most definitely a learning curve qualitatively different from that of traditional SCS owing to the differences in the leads themselves (much thinner) and in the locations (epidural space vs dorsal root ganglion/nerve root). In this analysis, the authors review the published data of noninfectious complications of DRGS, reporting rates of lead migration and fracture similar to that of traditional SCS. As the authors note, future studies such as these that further specify the location of the leads would be a great addition to the literature, given my experience (and that of others) suggests that lead fractures are significantly more common in the lumbar region than in the thoracic and sacral region. Longer-term follow-up, considering that the leads are quite thin and may be prone to fracture more than are traditional thicker SCS leads, would be quite beneficial.

Alon Mogilner, MD, PhD
New York, NY, USA

