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Hypoglossal nerve stimulation explantation in patients with obstructive sleep apnea – a systematic review

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Abstract

Objective

Hypoglossal nerve stimulation(HGNS) has emerged as a promising therapeutic approach for Obstuctive sleep apnoea (OSA) patients who are intolerant to continuous positive airway pressure (CPAP) therapy. This paper aimed to explore reasons for HGNS device explantation and associated complications.

Methods

Following PRISMA guidelines, a systematic search across Embase Ovid, PubMed, SCOPUS, and the Cochrane library yielded 14 articles that met the inclusion criteria. Exclusion criteria were (1) systematic reviews and meta-analyses, conference posters, editorials; (2) non-English studies; (3) studies published before 2010.

Results

121 patients were identified as having underwent HGNS device explantation. Of which, 126 reasons were identified for the procedure. The primary reasons included device malfunction (19.8%), infection(19.0%), and device migration(18.3%). Other reasons included discomfort (9.5%), improper placement (6.3%), and ineffective devices (6.3%). Complications were infrequent (2.48%).

Conclusion

Device malfunction, infection, and device migration were prominent reasons for HGNS device explantation. Complications post-explantation were rare but included temporary hypoglossal paresis.

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Keywords

Explantation, hypoglossal nerve stimulation, obstructive sleep apnoea

Introduction

Obstructive sleep apnoea (OSA) is a prevalent sleep disorder and in recent years[1], hypoglossal nerve stimulation (HGNS) has emerged as a promising therapeutic approach for managing moderate to severe OSA in patients who are intolerant to or unsuitable for continuous positive airway pressure (CPAP) therapy[2]. HGNS involves the implantation of a device that delivers electrical stimulation to the hypoglossal nerve, facilitating tongue muscle activation and preventing airway collapse during sleep[3].

While HGNS holds the potential to provide significant relief to individuals suffering from OSA, there is a growing need to understand the factors that lead to the explantation of these devices and the subsequent complications that may arise. Explantation, the removal of the HGNS device, can be attributed to a range of reasons, including technical issues, patient-specific factors, and the presence of adverse events[4]. Furthermore, the period following explantation is critical, as it allows for the observation and analysis of any complications that may occur post-procedure.

This paper aims to systematically review the reasons for explantation of hypoglossal nerve stimulation devices in patients with obstructive sleep apnoea and related conditions. By analyzing the underlying factors contributing to explantation, we intend to shed light on the challenges and considerations associated with this therapeutic modality. Additionally, the

study examines the spectrum of complications that arise after explantation, providing crucial insights into the post-explantation outcomes for patients.

Methods

We followed established guidelines from the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) statement to conduct a systematic search and study selection process. For this report, we focused on the following question: What are the reasons for explantation of hypoglossal nerve stimulation in patients with obstructive sleep apnoea?

Data Sources and Study Selection

We conducted a systematic search across key databases including Embase Ovid, PubMed, the Cochrane Library, and SCOPUS. The search strategy included a combination of relevant keywords and Medical Subject Headings (MeSH) terms related to "hypoglossal nerve stimulation", "explantation", and "obstructive sleep apnoea." The search was limited to studies published from 2010 through 2023 to ensure up-to-date information. The search strategy was adapted to meet the syntax requirements of each individual database, thus ensuring a comprehensive exploration of available literature. We limited our search to primary studies of adults that were published in peer-reviewed journals. Only English articles were selected. For each study, title and abstract were screened independently by 2 reviewers with any conflicts resolved by consensus. Full-text articles of potentially relevant abstracts were retrieved; and were then subsequently rescreened in a similar manner for possible inclusion.

Study Eligibility Criteria

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We included case series, case reports, cohort studies to gather comprehensive data on reasons for HGNS device explantation in patients with OSA, only including full-text studies published between 2010 and 2023. Our study focused exclusively on studies related to HGNS devices, covering both implantation and explantation, specifically pertaining to obstructive sleep apnoea. Data of interest were specifically outlined reasons for explantation as well as specified numbers of patients involved.

We excluded commentaries, meta-analyses, systematic reviews, book chapters, conference abstracts, study protocols, animal studies, non-English papers and letters to editors.

Data Extraction and Quality Assessment

Two authors (Chu Z, Zhang C) extracted the studies. Data from each study were collected by one researcher and confirmed by another. Discrepancies were discussed and resolved by consensus. We used a customized data extraction form to abstract information on population characteristics, reasons for explantation and presence of complications. We assessed the risk of bias of each study based on the Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group developed by the National Heart, Lung, and Blood Institute for the single-arm controlled trial, a modified version of the Newcastle-Ottawa Scale (NOS) for single-arm cohort studies and the Joanna Briggs Institute Checklist for case series and reports. Results of studies rated as having a low risk of bias are considered valid. Studies rated as having a medium risk of bias are susceptible to some bias but not sufficiently to invalidate the results. The high risk of bias in the remaining studies may invalidate the results. All quality assessments were conducted by 2 reviewers.

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Data Synthesis

The collected data underwent systematic analysis to identify the reasons for HGNS device explantation in patients with obstructive sleep apnoea. Frequencies and proportions of each explantation reason were computed based on the data extracted from the selected studies.

Results

Our search initially retrieved 88 individual studies. After which, 45 duplicate studies were effectively removed. Subsequently, 43 studies underwent evaluation based on their titles and abstracts. Among these, 10 studies were excluded due to incongruence with the predefined inclusion criteria. This led to 33 studies that advanced to the full-text eligibility assessment phase.

19 studies were excluded from the final analysis. This exclusion was attributed to various reasons, including 12 studies with an incompatible study design, 3 studies lacking full-text availability, 3 studies utilizing overlapping databases, and 1 study focusing on an incorrect patient population. The selection process, illustrated in figure 1, resulted in the inclusion of 14 studies that met our specified inclusion criteria.

Quality Assessment

Among the 5 single-arm cohort studies, they were all deemed to be of adequate quality with a score of 5 to 6 (Supplementary Table 1). The risk of bias of the single-arm controlled trial was evaluated to be of some concern (Supplementary Table 2). 2 case series were deemed to be of poor quality with a score of 3 and 4, while the remaining 3 case series were deemed to

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be of high quality with scores of 7 to 8 (Supplementary Table 3). Lastly, all 3 case reports were deemed to be of acceptable quality with a score of 5 and above (Supplementary Table 4).

Explantation Reasons

A total of 126 overlapping reasons of hypoglossal nerve stimulation (HGNS) device explantation were identified from the selected studies, out of 121 patients, with 5 patients having two reasons for explantation rather than one. Table 1 outlines the reasons for explantation described in each study.

The reasons for these explantations were diverse, with various factors contributing to the decision for removal, with more details being found in Table 2. The most common reason for explantation was device malfunction, accounting for 25 cases (19.8%). Technical issues such as malfunctions in device components such as implantable pulse generator (IPG), circuit board, sensing lead and stimulation lead were observed as contributors to this category. Malfunction after cardioversion was also included in this category.

Infection emerged as a notable cause for device explantation, observed in 24 cases (19.0%). This suggests that infections at the site of implantation significantly influenced device removal.

Device migration, defined as the movement of the device from its intended location, was encountered in 23 cases (18.3%), with device expulsion through skin also being noted in 7 out of the 23 cases in this category, suggesting challenges in maintaining device stability.

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Discomfort as the reason for explantation was documented in 12 cases (9.5%), highlighting patient comfort and device integration challenges.

Improper placement of the HGNS device was documented in 8 cases (6.3%), representing instances where the initial positioning of the device did not yield the expected therapeutic outcomes due to improper lead routing causing tethering or the lead being too superficially placed.

8 patients (6.3%) opted for device removal due to unsatisfactory therapeutic outcomes. The ineffectiveness of the devices was not attributable to device failure nor improper implantation.

Post-surgical complications, such as hematoma, allergic reactions and neck swelling, accounted for 5 cases (4%) of devices explantation. These complications encompassed adverse events occurring subsequent to device implantation, contributing to the decision to remove the device.

Other less prominent reasons for explantation include elective removal of unspecified motivation (4 cases, 3.2%), traction-related issues (4 cases, 3.2%), need for MRI (4 cases, 3.2%), nerve palsy (3 cases, 2.4%), poor cosmesis (2 cases, 1.6%), mixed tongue activity (1 case, 0.8%), unrelated systemic septic arthritis (1 case, 0.8%) and need for unrelated surgery (1 case, 0.8%).

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The types of explantations were then subdivided into three categories: 1) explantation alone, 2) revision without component change, 3) explantation with re-implantation, as seen in Table 3.

Among the 68 overlapping reasons for explantation alone, out of 63 patients, infection is the leading cause for explantation in 21 cases (30.9%), followed by device malfunction in 10 cases (14.7%) and an ineffective device in 8 cases (11.8%).

Among the 35 patients receiving revision of the device without component change, device migration is the leading cause in 14 cases (40.0%), followed by improper placement in 8 cases (22.9%) and discomfort in 6 cases (17.1%)

Among the 23 patients receiving explantation and reimplantation of the device, device malfunction is the by far the most common reason for the procedure (15 cases, 65.2%).

Explantation Rates

There were a total of 1040 patients that underwent HGNS implantation reported by cohort studies and single-armed controlled trial. Among these patients, 13 patients (1.25%) either had an explantation, revision, or replacement surgery. Among the 5 studies, the percentage of patients who had an explantation, revision, or replacement surgery ranged from 0.1% to 20% (Supplementary Table 5).

Complications

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Among the 121 patients who underwent device explantation, another 5 instances of complications were noted in a total of 3 patients (2.48%), with 2 patients noted to have 2 complications.

Temporary incomplete hypoglossal paresis was encountered in 2 patients, suggesting transient effects on hypoglossal nerve function after device removal. Discontinuation of a new implant, development of seromas and cuff dislocation was observed in one case each. The development of seromas emerged as a complication in one case.

21 cases (17.4%) were explicitly reported to have no complications after explantation, while the majority of cases (97 cases, 80.2%) did not document any complications, suggesting uneventful post-explantation periods.

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Discussion

This study delved into the reasons for the explantation of hypoglossal nerve stimulation (HGNS) devices in patients with obstructive sleep apnoea (OSA). Specific techniques and steps for explantation have been described in detail by Taylor et al.[14]

The results provide valuable insights into the complexities surrounding HGNS therapy and offer directions for refining its implementation and management. It is worth noting that while the majority of HGNS devices documented in the studies in this review were of the INSPIRE brand, Arens 2021 documented those of Apnex Medical Inc (St Paul MN), which subsequently went out of business in 2013 after subpar results from its randomized control trial[18].

Infections at the implantation site played a substantial role in device explantation. The notable proportion of cases attributed to infections emphasizes the significance of aseptic protocols during implantation and perioperative antibiotic prophylaxis. For example, Maurer et el. suggested the intravenous administration of 2 g cephazolin, or other coverage for skin flora should the patient have an allergy to cephalosporin, upon general anaesthesia onset[19]. Thorough assessment for poor wound healing contributors like smoking and diabetes is also advised, alongside preoperative screening and risk factor management.

Another method that could be explored would be the usage of antibacterial envelopes used in cardiac pacemaker implants, which reportedly resulted in a significantly lower incidence of major infections as compared to standard-of-care infection-prevention strategies alone, without a higher incidence of complications[20].

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Device malfunction emerged as a significant reason for HGNS device explantation. Technical issues, such as abnormal impedance values and device component malfunctions, were factors leading to the removal of devices. These findings highlight the need for rigorous quality control during manufacturing and diligent intra-operative monitoring and testing to mitigate technical complications.

Improper placement of the HGNS device reported to be the most common device-related cause of re-operation in the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) databased. Bestourous et al. did not delve into the details of what constituted improper placement, a search of the database revealed a variety of reasons such as superficial placement and/or tunnelling of the stimulation or sense leads, tethering of the stimulation lead in the neck, sense leads touching the intercostal nerve resulting in pain. During stimulation lead placement, attention to tunnelling in a sub-platysmal plane and leaving adequate slack should reduce these issues. During sense lead placement, surgeons need to ensure correct placement between inner and outer intercostal muscles and avoid contact with the rib. With refinements in surgical techniques over the years, we anticipate the rate of improper placement to be reduced in the future.

To address device migration, considering the effectiveness of superior generator placement, particularly in patients with dense breast tissue as demonstrated by Tabatabai 2018[13], could enhance device stability. Selective branch placement could also be exercised, alongside confirmatory testing of HGNS via ultrasonographic technique[21] to confirm base of tongue movement to optimise placement and voltage. Ensuring correct placement of anchoring stitches[3] may decrease inadvertent device migration into an incorrect plane. Twiddler's

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Syndrome is characterised by the spinning of the pulse generator within its subcutaneous pocket, leading to a displacement and malfunction of the leads[22]. Pre-operatively, clinicians should warn patients not to twiddle with the device. Post-operatively surgeons should be aware of patients' habits and monitor for twiddling with history and physical examinations. A chest X-ray should be performed to look for device migration if twiddling is suspected [22].

Patient-centred considerations also significantly contributed to device removal decisions. Discomfort and concerns about cosmesis prompted some instances of device explantation. Thorough patient assessment and education both before and after device implantation is hence necessary. Addressing discomfort-related explantations, clinicians should ideally explain its possibility before surgery and follow-up post-operatively to gauge patients' threshold for pain.

Explantations due to MRI were mainly due to earlier devices being MRI-incompatible, and this is expected to reduce with the introduction of newer MRI-compatible models[23].

Complications following device explantation were relatively rare, with most cases indicating no complications. Instances of temporary hypoglossal paresis, discontinuation of new implants, and seroma development provide insights into potential post-explantation challenges[5].

Acknowledging limitations, our study's inclusion of case series and case reports may introduce biases. Heterogeneity in reporting practices and variations in terminologies may influence data interpretation. Furthermore, not all cases of explantations were reported, hence it

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reasonable to expect that actual numbers may be higher than those reported in this review. This is compounded by the possibility that not all HGNS trial centres reported explantation numbers. The number of explantations can be expected to increase as the number of implantations increases in coming years.

To enhance the evidence in this domain, future studies should aim for standardized reporting and larger datasets. A comprehensive approach, integrating technical, clinical, and patient-centered perspectives, could provide a holistic understanding of HGNS device explantation.

Conclusion:

In conclusion, device malfunction, infection, device migration, and discomfort stand out as the most prominent factors for HGNS device explantation. Complications of explantation are relatively uncommon but include temporary incomplete hypoglossal paresis, development of seromas and cuff dislocation.

Data availability statement

Due to the nature of the research, supporting data is not available.

Funding Sources

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Conflict of interest statement:

The authors declare no conflict of interest.

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Patient consent statement

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Clinical trial registration (including trial number)

NA

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References

1 Jordan AS, McSharry DG, Malhotra A. Adult obstructive sleep apnoea. *Lancet* 2014;**383:**736-47

2 Yu JL, Thaler ER. Hypoglossal Nerve (Cranial Nerve XII) Stimulation. *Otolaryngol Clin North Am* 2020;**53:**157-69

3 Olson MD, Junna MR. Hypoglossal Nerve Stimulation Therapy for the Treatment of Obstructive Sleep Apnoea. *Neurotherapeutics* 2021;**18:**91-9

4 Patel AU, Yalamanchi P, Peddireddy NS, Hoff PT. Hypoglossal Nerve Stimulator Explantation: A Case Series. *OTO Open* 2022;**6:**2473974x221106778

5 Arens P, Penzel T, Fietze I, Blau A, Weller B, Olze H, et al. Safety and effectiveness in explantation and re-implantation of hypoglossal nerve stimulation devices. *Eur Arch Otorhinolaryngol* 2021;**278:**477-83

6 Bestourous DE, Pasick LJ, Benito DA, Zapanta PE. Adverse events associated with the Inspire implantable hypoglossal nerve stimulator: A MAUDE database review. *Am J Otolaryngol* 2020;**41:**102616

7 Deep NL, Hines JP, Parish JM, Hinni ML, Bansberg SF. Subpectoral implantation of the hypoglossal nerve stimulator: An effective technical modification. *Laryngoscope* 2019;**129:**2420-3

8 Kezirian EJ, Goding GS, Jr., Malhotra A, O'Donoghue FJ, Zammit G, Wheatley JR, et al. Hypoglossal nerve stimulation improves obstructive sleep apnoea: 12-month outcomes. *J Sleep Res* 2014;**23:**77-83

9 Macielak RJ, Olson EJ, Junna MR, Olson MD. Contralateral Rerouting of Hypoglossal Nerve Implant Pulse Generator and Stimulation Lead. *Laryngoscope* 2021;**131:**E2409-e12

10 Pomerantz J, Freedom T, Nickley K, Bhayani M, Gerber M, Freedman N, et al. 0540 Upper Airway Stimulation for Obstructive Sleep Apnoea. *Sleep* 2018;**41:**A202-A

11 Steffen A, Sommer JU, Hofauer B, Maurer JT, Hasselbacher K, Heiser C. Outcome after one year of upper airway stimulation for obstructive sleep apnoea in a multicenter German post-market study. *Laryngoscope* 2018;**128:**509-15

12 Suurna MV, Steffen A, Boon M, Chio E, Copper M, Patil RD, et al. Impact of Body Mass Index and Discomfort on Upper Airway Stimulation: ADHERE Registry 2020 Update. *Laryngoscope* 2021;**131:**2616-24

13 Tabatabai GM, Karempelis P, Hsia JC. Hypoglossal nerve stimulator generator migration: INSPIRE device reimplantation with parallels to cardiac implantable electronic devices. *Am J Otolaryngol* 2018;**39:**639-41

14 Taylor Ii J, Yu JL. Hypoglossal Nerve Stimulator Explantation Technique and Outcomes: A Retrospective Case Series. *ORL J Otorhinolaryngol Relat Spec* 2023;**85:**248-52

15 Urban MJ, Calder A, Jhaveri M, LoSavio P. Computed tomography scanning of implanted hypoglossal nerve stimulators and approach to device malfunction: case series. *J Laryngol Otol* 2023;**137:**231-6

16 Vasconcellos AP, Huntley CT, Schell AE, Soose RJ, Boon MS. Dysfunctional hypoglossal nerve stimulator after electrical cardioversion: A case series. *Laryngoscope* 2019;**129:**1949-53

17 Woodson BT, Soose RJ, Gillespie MB, Strohl KP, Maurer JT, de Vries N, et al. Three-Year Outcomes of Cranial Nerve Stimulation for Obstructive Sleep Apnoea: The STAR Trial. *Otolaryngol Head Neck Surg* 2016;**154:**181-8

18 Strohl MM, Yamauchi M, Peng Z, Strohl KP. Insights since FDA Approval of Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnoea. *Curr Sleep Med Rep* 2017;**3:**133-41

19 Maurer JT, Van de Heyning P, Lin H-S, Baskin J, Anders C, Hohenhorst W, et al. Operative technique of upper airway stimulation: an implantable treatment of obstructive sleep apnoea. *Operative Techniques in Otolaryngology-Head and Neck Surgery* 2012;**23:**227-33

20 Tarakji KG, Mittal S, Kennergren C, Corey R, Poole JE, Schloss E, et al. Antibacterial Envelope to Prevent Cardiac Implantable Device Infection. *N Engl J Med* 2019;**380:**1895-905

21 Korotun M, Quintero L, Shikowitz M, Mayo P, Greenberg H. Optimization of Hypoglossal Nerve Stimulation for Obstructive Sleep Apnoea With Ultrasound Assessment of Tongue Movement. *Am J Ther* 2021;**29:**e205-e11

22 Miglani A, Mecham JC, Hines JP, Hinni ML, Miller BW, Bansberg SF. Hypoglossal Nerve Stimulator Twiddler's Syndrome. *Laryngoscope* 2021;**131:**E1019-e21

23 Mashaqi S, Patel SI, Combs D, Estep L, Helmick S, Machamer J, et al. The Hypoglossal Nerve Stimulation as a Novel Therapy for Treating Obstructive Sleep Apnoea-A Literature Review. *Int J Environ Res Public Health* 2021;**18**

Table 1. Study Characteristics and Explantation Reasons

Study	Study type	Total patients	Mean implantation time (months)	Implant Model	Procedure	Patients undergoing procedure	Reason for procedure	Complications
Arens 2021[5]	Case Series	9	61.4 ± 15.4	9 Apnex Medical Hypoglossal Nerve Stimulation System (unspecified model)	Explantation	9	7 Device malfunction 1 Need for MRI 1 Discomfort	1 Discontinuation of new implant 2 Temporary incomplete hypoglossal paresis 1 Cuff dislocation with revision 1 Development of seromas 6 No complications
Bestourous 2020[6]	Retrospective cohort	78	-	78 Inspire implantable pulse generator (unspecified model)	Explantation	31	1 Discomfort 5 Post implantation complications 19 Infection 2 Nerve palsy 3 Device migration 1 Device malfunction	-
			-		Revision	32	5 Discomfort 1 Infection 1 Nerve palsy 4 Traction 13 Device migration 8 Improper placement	-
			-		Replacement	15	1 Infection 1 Overstimulation 3 Device migration 10 Device malfunction	-
Deep 2019[7]	Case report	1	6.8	Inspire II Model 3024 Implantable Pulse Generator	Replacement	1	1 Infection	1 No complications

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Kezirian 2014[8]	Single-arm controlled trial	6	-	4 Apnex Medical Hypoglossal Nerve Stimulation System (unspecified model)	Explantation	4	1 Elective removal 2 Ineffective device 1 Infection	-
			0.5 ± 0	2 Apnex Medical Hypoglossal Nerve Stimulation System (unspecified model)	Replacement	2	2 Device migration	-
Macielak 2021[9]	Case report	1	11	-	Revision	1	1 Need for unrelated surgery	1 No complications
Patel 2022[4]	Case series	5	-	5 Inspire implantable pulse generator (unspecified model)	Explantation	5	4 Ineffective device 1 Infection 3 Need for MRI* 1 Poor cosmesis*	-
Pomerantz 2018[10]	Retrospective cohort abstract	2	-	-	Revision	1	1 Discomfort	-
				-	Replacement	1	1 Device malfunction	-
Steffen 2018[11]	Prospective cohort	1	12	Inspire implantable pulse generator (unspecified model)	Explantation	1	1 Poor cosmesis	-
Suurna	Prospective	1	-	Inspire	Explantation	1	1 Elective removal	-

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2021[12]	cohort			implantable pulse generator (unspecified model)				
Tabatabai 2018[13]	Case report	1	4	Inspire implantable pulse generator (unspecified model)	Revision	1	1 Device migration	
Taylorli 2023[14]	Case series	5	39.2 ± 20.5	5 Inspire implantable pulse generator (unspecified model)	Explantation	5	1 Mixed tongue activity 3 Discomfort* 2 Ineffective device	5 No complications
Urban 2023[15]	Case series	4	20 ± 24.7	3 Inspire II Model 3028 Implantable Pulse Generator 1 Inspire implantable pulse generator (unspecified model)†	Explantation	4	1 Device migration 1 Discomfort† 2 Device malfunction	4 No complications
Vasconcellos 2019[16]	Case series	4	10.3 ± 6.2	4 Inspire implantable pulse generator (3024 or 3028, unspecified model)	Replacement	4	4 Device malfunction	4 No complications
Woodson 2016[17]	Prospective cohort	3	-	3 Inspire implantable pulse generator (unspecified model)	Explantation	3	2 Elective removal 1 Unrelated systemic septic arthritis	-

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*Includes 5 patients that had 2 reasons for explantation in total, †The patient with the unspecified implanted pulse generator model correlated with experiencing device discomfort

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Table 2. Synthesised reasons for explantation

	n (% of total reasons [126])
Total Patients	121
Total Reasons*	126 (100)
Device Malfunction	25 (19.8)
Infection	24 (19.0)
Device Migration	23 (18.3)
Discomfort	12 (9.5)
Improper Placement	8 (6.3)
Ineffective device	8 (6.3)
Postimplantation Complications	5 (4.0)
Need for MRI	4 (3.2)
Traction	4 (3.2)
Elective removal	4 (3.2)
Nerve Palsy	3 (2.4)
Poor cosmesis	2 (1.6)
Mixed Tongue Activity	1 (0.8)
Unrelated systemic septic arthritis	1 (0.8)
Overstimulation	1 (0.8)
Need for unrelated surgery	1 (0.8)

*Includes 5 patients that had 2 reasons for explantation

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Table 3. Subdivided reasons for explantation

	Explantation alone	Revision without component change	Explantation with re-implantation
	n (% of total reasons [68])	n (% of total reasons [35])	n (% of total reasons [23])
Total Patients	63	35	23
Total Reasons*	68 (100)	35 (100)	23 (100)
Infection	21 (30.9)	1 (2.9)	2 (8.7)
Device Malfunction	10 (14.7)	-	15 (65.2)
Device Migration	4 (5.9)	14 (40.0)	5 (21.7)
Improper Placement	-	8 (22.9)	-
Discomfort	6 (8.8)	6 (17.1)	-
Ineffective device	8 (11.8)	-	-
Postimplantation Complications	5 (7.4)	-	-
Traction	-	4 (11.4)	-
Need for MRI	4 (5.9)	-	-
Elective removal	4 (5.9)	-	-
Nerve Palsy	2 (2.9)	1 (2.9)	-
Poor cosmesis	2 (2.9)	-	-
Mixed Tongue Activity	1 (1.5)	-	-
Unrelated systemic septic arthritis	1 (1.5)	-	-
Need for unrelated surgery	-	1 (2.9)	-
Overstimulation	-	-	1 (4.3)

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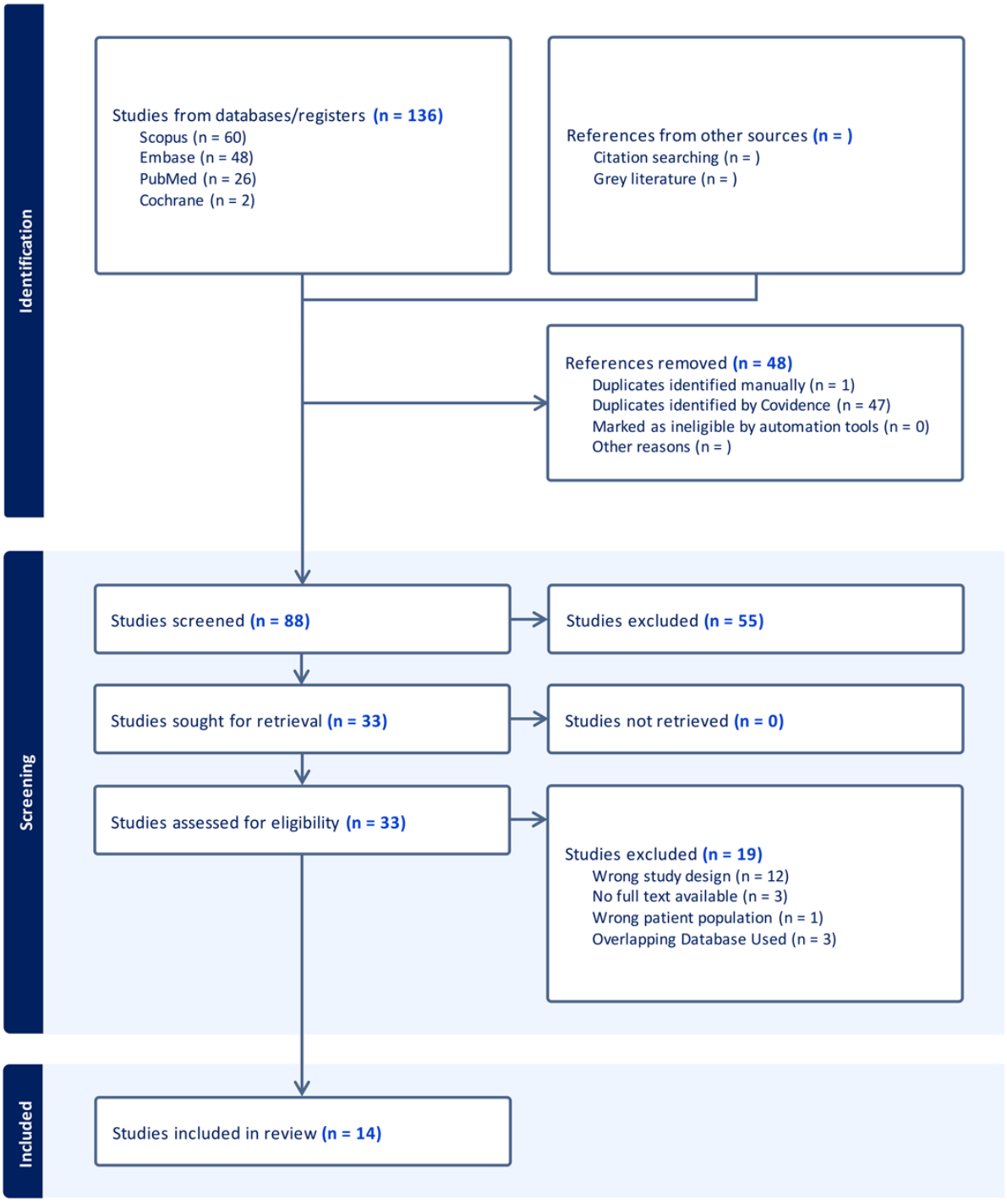
Figure 1. Flow diagram of search and study process



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