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Acute Surgical Safety of Pediatric Vagus Nerve Stimulation: A 200-Patient Consecutive Series with Literature Benchmarking

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Abstract

Purpose: While vagus nerve stimulation (VNS) remains a foundational neuromodulatory intervention for drug-resistant epilepsy (DRE), reported rates of acute complications, specifically infection and device removal, exhibit significant variability across pediatric cohorts. This investigation seeks to characterize the acute surgical safety profile within a single-surgeon consecutive series of 200 children and provide contextualization through structured literature benchmarking.

Methods A retrospective analysis was performed on 200 consecutive pediatric patients (age <20 years) undergoing primary VNS implantation for DRE between August 2017 and January 2025. Primary endpoints included surgical site infection and device explantation within a 90-day postoperative interval, with minor perioperative events analyzed as secondary outcomes. To establish a comparative framework, a structured review of literature published from 2000 to 2024 was conducted to derive pooled aggregate rates of postoperative infection and explantation.

Results In our institutional cohort of 200 patients (range 1.4–19.8 years), no surgical site infections or device explantations occurred within 90 days (0%; exact 95% CI, 0–1.83% for each outcome). Minor, transient adverse events included temporary hoarseness (2%) and cough (1.5%). The benchmarking review included 50 studies; pediatric-exclusive cohorts had sample-size-weighted infection and explantation rates of 3.15% and 4.41%, respectively.

Conclusion Primary VNS implantation in the pediatric population can be achieved with an excellent acute safety profile. The total absence of infection and explantation in this large series compares favorably to literature benchmarks. These data reinforce the safety of VNS in children and suggest that meticulous surgical technique and standardized perioperative care may minimize hardware-related morbidity.

Introduction

Vagus nerve stimulation (VNS) is an established neuromodulatory therapy for patients with drug-resistant epilepsy (DRE) who are not candidates for curative surgery or in whom surgery has failed.[1–3] Although its precise therapeutic mechanism remains incompletely understood, VNS has demonstrated consistent efficacy as an adjunctive therapy, with approximately half of patients achieving a ≥ 50% seizure frequency reduction across adults and children.[4–6] In pediatric populations, VNS remains the default first-line neuromodulation option due to its established safety profile, regulatory approval, and lower invasiveness.[7,8] Moreover, VNS is used to treat a wide range of structural and genetic etiologies of epilepsy in children with generally favorable responder rates with some variability across conditions.[9,10]

Although the therapeutic profile of VNS for DRE is well established, its safety profile in children warrants closer evaluation. Implantation is often low risk; however, several complications such as infection, hematoma, lead fracture/malfunction, vocal cord palsy, and stimulation-related symptoms have been reported, with infection particularly concerning due to potential device explantation.[11–13] Prior VNS

studies report variable rates of infection and device removal, often combining adult and pediatric cohorts or including different practices across institutions. This heterogeneity makes it difficult to assess institutional performance against established benchmarks and leaves factors contributing to VNS complications in children poorly understood.[14] Therefore, as VNS use continues to expand, there is a need for standardized benchmarks from uniform pediatric cohorts to identify modifiable risk factors and inform strategies to minimize complications.

In this study, we present our institutional experience with VNS implantation in a single surgeon cohort of 200 pediatric patients with drug-resistant epilepsy. We specifically evaluate the acute surgical safety profile of VNS, including surgical site infection and device explantation, and comprehensively characterize all perioperative surgical and stimulation-related complications. To contextualize our findings, we also perform a structured literature review of the pediatric VNS literature to extract reported rates of postoperative infection and device removal for benchmarking. Through this approach, we aim to contribute to the existing literature on VNS safety and provide technical insights that may help minimize complications following VNS implantation.

Methods

Patient cohort. We conducted a retrospective analysis of the electronic medical record, to identify a cohort of 200 consecutive pediatric patients who underwent initial VNS implantation for DRE at Children's Hospital of Philadelphia by the senior author from the beginning of his career in August 2017 through January 2025.

Patients were eligible for inclusion if they: 1) were younger than 20 years at time of implantation, 2) were diagnosed with DRE, 3) underwent first-time placement of VNS. Patients were excluded from study if they: 1) had undergone generator replacement or lead revision, 2) and did not have complete 90-day perioperative documentation.

To characterize the acute surgical safety profile of VNS, we conducted a comprehensive review of all postoperative encounters documented within the electronic medical record, including emergency department presentations and hospital admissions occurring within 90 days of the procedure. Further, to maximally cover all post-operative surgical complaints, we analyzed all phone encounters and ambulatory clinic assessments within the 30-day postoperative window.

The primary outcome was the incidence of surgical site infection, defined by the CDC/NHSN, including superficial, deep, or organ space infections within 90 days of an operative procedure,[15] as well as device explantation for any reason within 90 days of implantation, including removal of the leads or generator. Secondary outcomes included any other perioperative complications or complaints within 90 days, including hematoma, seroma, wound dehiscence, stimulation-related symptoms and device malfunction.

Institutional Care Pathway. Preoperative assessment was performed by the neurosurgery team and multidisciplinary epilepsy conference to decide candidacy for implantation. After implantation, initial

activation was performed at a visit two weeks following surgery, with serial programming adjustments at two-week intervals by the neurology team. Routine postoperative follow-up consisted of coordinated neurology and neurosurgery evaluations.

Surgical Technique. All procedures were performed using a standardized technique. After induction of general endotracheal anesthesia, the patient was positioned supine with neck extension. For patients with a tracheostomy, the tube was turned close to 90 degrees and sutured down, pulling it slightly to the patient's right to allow room for the left-sided incision. An adhesive drape was used between the stoma and the field to prevent secretions from entering the field prior to skin preparation. One dose of cefazolin was administered intravenously before incision. Skin was prepped with an alcohol and betadine scrub followed by two chlorprep sticks. Ioban was used, and care was taken to preserve the Ioban on the skin edge, and to avoid touching the skin with gloves. A transverse cervical incision was used, as well as an incision over the left deltopectoral groove. The subcutaneous pocket was created over the pectoralis fascia with scissors and/or monopolar cautery. The pocket was made slightly oversized to allow the generator and leads to remain far from the chest incision. The tunneler was passed to the medial aspect of the pocket to avoid leads under the chest incision. After tunneling, the tunneling surgeon changed outer gloves. While pulling the leads through the tunneling tube, care was taken to keep the lead and coils off the skin, and these were laid on a vancomycin saline-soaked gauze placed over the skin edge of the chest. One strain-relief loop was fashioned using one anchoring tether and secured with 4 – 0 Nurolon suture. The medial strap muscles were sewn to the sternocleidomastoid to create a muscular barrier between the device and the thin skin of the neck. Platysma was also closed prior to skin layers. Both wounds were irrigated with vancomycin saline. Both wounds were closed with a deep dermal and subcuticular layers as well as skin glue.

Literature Review. To contextualize our institutional findings, we performed a structured literature review. We conducted a SCOPUS, Pubmed, and Web of Science search with the query: "vagus AND nerve AND stimulation" AND "epilepsy" AND ("pediatric OR child"). Articles were filtered from January 1st, 2000 to August 1st, 2024, the time of analysis. Results were further filtered to include only articles with the author keyword "vagus nerve stimulation."

Inclusion criteria were: (1) original research articles, (2) pediatric population (or a clearly defined pediatric subgroup), (3) implantation indication for epilepsy, (4) sample size at least 5 patients, and (5) reporting on post-operative complications. We excluded review articles, case reports, adult-only studies, case series with less than 5 patients, and studies that did not report on the complications of interest.

Data on study design, sample size, and the number of reported infections and/or device explantations from primary VNS implantations were extracted from the final included studies. The pediatric literature benchmark was strictly defined as studies reporting on patients 20 years of age and younger for comparison to our institutional cohort.

Statistical Analysis. Literature benchmark rates were calculated as sample-size-weighted averages of the reported study-specific percentages and stratified by cohort composition (pediatric-exclusive versus

mixed or adult cohorts). Two-sided exact 95% confidence intervals for institutional infection and explantation rates were calculated using the Clopper–Pearson method. One-sided, one-sample exact binomial tests evaluated whether institutional rates were lower than the corresponding aggregate pediatric benchmarks, treating each benchmark as a fixed probability. Statistical significance was defined as $p < 0.05$.

Results

Patient Characteristics

A total of 200 consecutive pediatric patients underwent first-time VNS implantation during the study period, with a mean age of 10.8 ± 5 years (range 1.4–19.8). Five (2.5%) patients received planned preoperative transfusions for pre-existing coagulation disorder or thrombocytopenia. Six patients (3%) had had a tracheostomy prior to VNS placement, and 28 (14%) were under five years old.

Table 1
Patient Cohort Characteristics

Age at surgery (years)	**N (%)**
<5	28 (14%)
5 – 12	86 (43%)
12 – 19	86 (43%)
Sex	
Female	88 (44.0%)
Ethnicity	
White	122 (61.0%)
Black	16 (8.0%)
Hispanic	19 (9.5%)
Asian	6 (3.0%)
Multi-racial	6 (3.0%)
Other	28 (14.0%)
Unknown/Refused	3 (1.5%)
Weight at surgery (kg)	
<20	42 (21.0%)
20–50	108 (54.0%)
50–125	50 (25.0%)
Other	
Prior Tracheostomy	6 (3.0%)

Within the 90-day postoperative window, there were no surgical site infections (0%; 95% CI: 0.00–1.83%) and no device explantations (0%; 95% CI: 0.00–1.83%). Minor postoperative complications and stimulation-related symptoms were infrequent. Temporary hoarseness occurred in 4 patients (2%), cough in 3 (1.5%), muscle spasm in 2 (1%), and rash in 2 (1%). Isolated cases (0.5% each) included non-operative pocket hematoma, fluid collection, superficial wound dehiscence, respiratory symptoms, and keloid formation.

There were no cases of lead break, vocal cord paralysis, lethargy, gagging, or swallowing dysfunction within 90 days of implantation.

Table 2
Operative and Postoperative Outcomes

ICU admission postoperatively	***N (%)***
	0 (0%)
Infection	0 (0%)
Explantation	0 (0%)
Other:	
Temporary Hoarseness	4 (2%)
Cough	3 (1.5%)
Muscle Spasm	2 (1%)
Rash	2 (1%)
Pocket Hematoma	1 (0.5%)
Fluid Collection	1 (0.5%)
Wound Dehiscence	1 (0.5%)
Respiratory	1 (0.5%)
Keloid	1 (0.5%)
Lead break	0 (0%)
Vocal Cord Paralysis	0 (0%)
Lethargy	0 (0%)
Gagging	0 (0%)
Swallowing dysfunction	0 (0%)

Literature Review

The structured literature search is summarized in Fig. 1. The initial search yielded 658 articles across the three databases, of which 243 were duplicate records and removed. 415 unique articles remained for screening. 280 articles were excluded through title/abstract review for relevant scope. From these, 135 articles were included in the full text review after exclusion of articles not meeting inclusion criteria (e.g., duplicate cohort, adult-only population, review article, sample size $n < 5$, or not reporting on complications of interest). Among the 135 included studies, 50 studies reported both infection and explantation outcomes, representing an aggregate sample of 3638 patients.

Upon stratification by cohort composition, pediatric-exclusive cohorts (25 studies; N = 1,446) had sample-size-weighted infection and explantation rates of 3.15% and 4.41%, respectively. Mixed or adult cohorts (25 studies; summed N = 2,192) had corresponding rates of 1.95% and 5.19%

No infections or explantations occurred within 90 days in our institutional cohort of 200 patients (0% for each outcome; exact 95% CI, 0–1.83%). In exploratory comparisons treating the aggregate pediatric rates as fixed benchmarks, one-sided exact binomial tests yielded p = 0.0017 for infection and p = 0.00012 for explantation. These comparisons should be interpreted in the context of differences in follow-up duration and outcome definitions between our cohort and the published studies.

Table 3
Top 10 Largest Pediatric-Exclusive VNS Cohorts Reporting Infection and Explantation

Author, Year	**Sample Size (N)**	**Infection Rate, n (%)**	**Explantation Rate, n (%)**
Orosz et al., 2014	347	9 (2.5%)	13 (3.7%)
Present Study	**200**	**0 (0.0%)**	**0 (0.0%)**
Thompson et al., 2012	146	4 (2.7%)	4 (2.7%)
Elliott et al., 2011	141	3 (2.1%)	1 (0.7%)
Vaiman et al., 2017	74	0 (0.0%)	1 (1.4%)
Smyth et al., 2003	74	6 (8.1%)	7 (9.4%)
Kabir et al., 2009	69	3 (4.3%)	9 (13.0%)
Kuroda et al., 2019	67	5 (7.5%)	3 (4.5%)
Cersósimo et al., 2011	64	2 (3.1%)	1 (1.6%)
Yalnizoglu et al., 2020	58	0 (0%)	8 (13.8%)

Table 4
Top 10 Largest Mixed (Adult & Pediatric) VNS Cohorts Reporting Infection and Explantation

Author, Year	Sample Size (N)	Infection Rate, n (%)	Explantation Rate, n (%)
Elliott et al., 2011	436	11 (2.5%)	7 (1.6%)
Kawai et al., 2017	385	6 (1.6%)	13 (3.4%)
Révész et al., 2016	247	11 (4.5%)	49 (19.8%)
Vonck et al., 2004	118	2 (1.7%)	2 (1.7%)
Durez et al., 2024	110	0 (0.0%)	0 (0.0%)
Meng et al., 2015	95	0 (0.0%)	2 (2.1%)
Kuba et al., 2009	90	0 (0.0%)	3 (3.3%)
Zhu et al., 2020	81	1 (1.2%)	4 (4.9%)
Lagae et al., 2015	70	1 (1.4%)	1 (1.4%)
Elliott et al., 2011	65	0 (0.0%)	3 (4.6%)

These data highlight that our institutional 200-patient cohort maintains no infections or explantations within 90 days, distinguishing our results from the broader literature benchmarks presented in Tables 3 and 4.

Discussion

This study characterized the acute surgical safety of pediatric VNS implantation for DRE within a consecutive, single-surgeon series of 200 patients. While VNS is a low-risk intervention, hardware-related complications and stimulation-associated morbidity remain significant concerns that may necessitate device removal. In our cohort, which included patients aged 1.4–19.8 years, no surgical site infections or device explantations occurred within 90 days. The corresponding sample-size-weighted rates in the pediatric literature were 3.15% and 4.41%, respectively. These findings support the short-term surgical safety of pediatric VNS implantation, although differences in follow-up duration and outcome definitions limit direct comparisons with published cohorts.

We utilized incidence of surgical site infection and device explantation as our primary endpoints, given their status as the most clinically significant acute morbidities following VNS placement. In contrast to minor perioperative events, postoperative infections frequently necessitate surgical re-intervention or hardware removal, as pharmacological salvage strategies often prove insufficient.[16–18] Explantation itself carries additional surgical morbidity, including risk of vocal cord paralysis and vascular injury, and ultimately represents an interruption to neuromodulatory treatment during a period when patients remain susceptible to seizures.[19] The absence of infections and device explantations in our cohort compares favorably to the pediatric VNS literature from our structured review as summarized in Table 3.[20–23] This

finding is significant considering our cohort's inclusion of vulnerable subgroups, specifically children under age 5 or weighing less than 20 kg, as well as those with a tracheostomy, which underscores the robustness of our safety data.[24]

Several factors may play a role in the favorable safety profile of our cohort. First, all patients in our cohort underwent VNS implantation by a single pediatric neurosurgeon using standardized operative technique. Surgical consistency ensures uniformity in surgical technique and perioperative management, which has been shown to reduce infection rates and hardware complications across neuromodulation procedures.[25] Second, our cohort was restricted to first-time VNS implantations, in order to control for the fact that replacement and revision surgeries are independent risk factors for VNS infection.[15] Third, the rate of minor perioperative complications in our cohort, including temporary hoarseness (2%), cough (1.5%), muscle spasm (1%), rash (1%), and isolated wound-related issues, were low and consistent with the VNS literature. These symptoms were transient and managed without surgical intervention.

The structured literature review performed in this study provides a useful benchmark for institutional VNS safety assessment. Pediatric-exclusive cohorts had a higher sample-size-weighted infection rate (3.15%) than mixed or adult cohorts (1.95%). This discrepancy may suggest that pediatric patients may possess an elevated risk for complications related to VNS. Anatomically, smaller pediatric patients have less subcutaneous tissue to adequately cover the generator and cervical leads, potentially increasing the risk of wound dehiscence or skin breakdown. Furthermore, the pediatric DRE population often presents with comorbid behavioral or cognitive challenges that can complicate postoperative wound care or increase the likelihood of hardware manipulation. By benchmarking our cohort against pediatric VNS literature, we provide a more standardized approach for interpreting VNS safety outcomes in children.

Some limitations warrant mention in our study. First, the retrospective design may lead to ascertainment bias. We attempt to mitigate this by comprehensive review of the electronic medical record, including emergency department visits from the 90-day period and phone encounters, and ambulatory notes from the 30-day postoperative period. Second, while the 90-day follow-up effectively describes the short-term safety of VNS implantation, it does not account for delayed hardware malfunctions. Furthermore, the literature review conducted to establish our comparative benchmark has limitations. It was designed as a structured scoping review rather than a formal PRISMA-compliant systematic review and meta-analysis. Screening and data extraction were conducted by a single investigator, and a formal quality assessment or risk-of-bias evaluation of the included studies was not performed. Finally, our benchmark utilizes aggregate pooled rates across heterogeneous cohorts, which provides a useful clinical reference but does not account for between-study variance, as a weighted meta-analysis would. The exploratory comparisons treated literature benchmarks as fixed probabilities and did not account for uncertainty in those estimates or between-study heterogeneity. Lastly, these findings reflect a single-surgeon's experience at a high-volume level 4 pediatric epilepsy center, and complication rates may not be broadly generalizable to all institutions. Nonetheless, our large cohort size, inclusion of high-risk subgroups, and comprehensive characterization of surgical complications remain of value.

Conclusion

VNS implantation for pediatric DRE can be performed with an excellent acute postoperative safety profile, which may be attributable to surgical technique and perioperative measures. Compared to the broad pediatric VNS literature, our cohort exhibited no surgical site infections or explantations within 90 days postoperatively while maintaining similarly low rates of minor perioperative complications. These findings support the safety and feasibility of VNS implantation in children, including the very young and those with tracheostomies. Moreover, our study provides a framework for benchmarking institutional VNS outcomes against specific literature standards that may help other institutions improve their safety experience with VNS.

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Declarations

Author Contribution

R.M. collected the data and drafted the main manuscript. K.U. contributed to manuscript writing. S.B.T., S.E.M., and K.G. provided guidance on the study and manuscript development. B.C.K. supervised the study and critically revised the manuscript.

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Figures

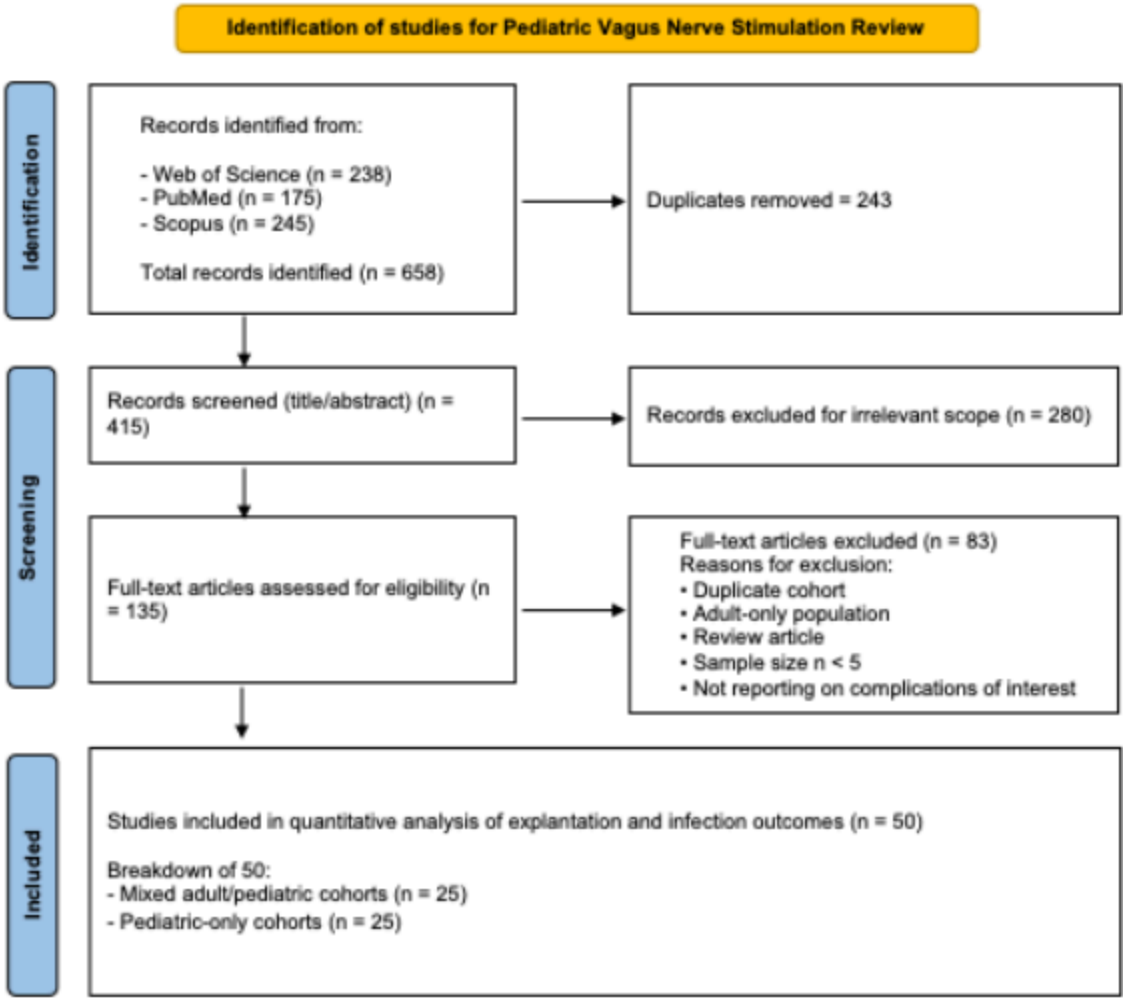


Figure 1

Flow diagram of the structured literature search. Flowchart detailing the identification, screening, and inclusion phases for articles reporting acute postoperative complications (infection and explantation) following vagus nerve stimulation for drug-resistant epilepsy. The search encompassed SCOPUS, PubMed, and Web of Science databases from January 2000 to August 2024, ultimately yielding 50 studies for aggregate benchmarking.