RESEARCH ARTICLE

Surgical Complications of Deep Brain Stimulation in Children Across Targets and Indications

Multicenter Analysis of the CHILD-DBS Registry

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Abstract

Background and Objectives

Deep brain stimulation (DBS) is considered off-label and investigational in pediatric populations with some exceptions. There are limited data on the relative rates of complications after DBS across different indications and targets in children. This study aimed to evaluate the safety of DBS surgery for children with movement disorders (MDs; dystonia, chorea, or tic disorders), drug-resistant epilepsy (DRE), or neurodevelopmental disorders, namely, self-injurious behavior (SIB).

Methods

Data were collected both prospectively and retrospectively from children implanted with DBS through the North American multicenter Child and Youth CompreHensIve Longitudinal Database for Deep Brain Stimulation and included demographic, clinical, operative, and postoperative variables. Complications included infection, noninfectious surgical site findings (dehiscence or seroma), hardware-related issues (disconnection or impedance change), intracranial injury, or other complications. The primary outcome was major complications, defined as any adverse event causing permanent neurologic injury or requiring surgical intervention. The secondary outcome was minor complications, defined as nonmajor complications. Generalized linear models were used to assess for any significant associations with complications.

Results

A total of 130 children and youth (mean age 12.2 ± 4.2; range 3–18) years and weighing 12.5–126.6 kg underwent DBS. The most common indication was MD (77, 59.2%), followed by DRE (47, 36.2%) and SIB (6, 4.6%). Major complications occurred in 11.5%, with a greater likelihood in MD (n = 12, 15.6%) compared with DRE (n = 2, 4.3%; odds ratio [OR] 3.55, 95% CI 2.66–4.73, $p < 0.001$) and significantly associated with lower weight at surgery ($p < 0.001$) and urgent intervention ($p = 0.028$). These included infection (6.2%), hardware malfunction (3.1%), and wound dehiscence (0.8%). Minor complications were also higher with MD compared with DRE (OR 1.83, 95% CI 1.16–2.89, $p = 0.010$) occurring in 22 participants (16.9%; 14 MD, 7 DRE, 1 SIB), including infection (6.2%), high impedance (1.5%), unrelated hydrocephalus (0.8%), perioperative worsening of symptoms (3.8%), incidental tract hemorrhage (2.3%), and noninfectious peri-electrode cystic changes (0.8%).

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Supplementary Material

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Glossary

ANT = anterior nucleus of the thalamus; **BCH** = Boston Children's Hospital; **CHILD-DBS** = Child and Youth CompreHensIve Longitudinal Database for Deep Brain Stimulation Registry; **CM** = centromedian nucleus; **DBS** = deep brain stimulation; **DRE** = drug-resistant epilepsy; **GLM** = generalized linear model; **GPi** = globus pallidus pars interna; **IPG** = implantable pulse generator; **ITB** = intrathecal baclofen pump; **MD** = movement disorder; **MER** = microelectrode recording; **NAcc** = nucleus accumbens; **OR** = odds ratio; **ROC** = receiver operating characteristic; **SIB** = self-injurious behavior; **STN** = subthalamic nucleus; **VNS** = vagus nerve stimulation.

Discussion

DBS-associated complications were low across multiple pediatric indications and targets, with MD associated with higher risk of major complications. Limitations include a focus on surgical postoperative complications and not stimulation-related adverse outcomes. These findings demonstrate the safety profile of DBS in children in a large cohort.

Introduction

Deep brain stimulation (DBS) is increasingly considered for pediatric neurologic indications. A Food and Drug Administration humanitarian device exemption permits treatment of children with dystonia[1-3] who are 7 years and older.[2,4] Beyond this population, DBS is considered off-label and investigational in the pediatric population. Emerging evidence suggests that it may be effective in reducing seizure burden for children with drug-resistant epilepsy (DRE),[5,6] and recently it has been studied in the context of neuropsychiatric and neurodevelopmental disorders, including tic disorders[7,8] and self-injurious behavior (SIB).[9]

The enthusiasm to adopt DBS as a treatment option in children is appropriately tempered by concerns regarding its long-term safety profile. Although there are robust safety data for DBS among adults with movement disorders (MDs) such as essential tremor[10-12] and Parkinson disease,[13-15] DRE,[16-18] and neuropsychiatric conditions,[19] these findings cannot directly translate to children for several reasons. First, it is not known how complications may arise throughout the trajectory of development and with age-related anatomic differences.[20,21] Second, it is generally thought that this procedure is associated with greater risk in children than adults[20,22-25] with additional considerations to pediatric-specific surgical techniques and anesthetic risks.[20,21] Furthermore, DBS is often considered for children with complex medical needs or concomitant developmental delay[6,26,27] and may be offered urgently for severe acute exacerbations including status dystonicus.[3] Last and critically, there remain significant gaps in our understanding of the specific complication profile of pediatric DBS from studies conducted directly in children. Most data are limited to retrospective observational studies or systemic reviews, often derived from procedures conducted at adult centers that may not be experienced in pediatric care.[1,6,23,28]

The knowledge gap in DBS-related complications in children is also indication-specific with greater evidence available for dystonia compared with other conditions. Most evidence for DBS safety is derived from retrospective studies[20,26] focusing on dystonia[2,4] followed by tic disorders.[7,8] It is not known whether the same safety profiles translate to other indications such as DRE. Evidence of safety for DBS for DRE is sparse and consists of case series and systematic reviews[6,28] with a single clinical trial of add-on DBS after nonresponse to vagus nerve stimulation (VNS; the ADVANCE trial[29]). In part due to limited safety data and off-label usage, DBS is not routinely considered for children with DRE,[6] and most high-volume epilepsy centers in North America implant fewer than 5 devices in children annually.[30] The relative rates of complications across different pediatric populations, including those with MD and non-MD alike, have not been studied in general or across multiple centers.[20,26]

Last, there is increased interest in developing DBS for understudied but debilitating and refractory neurodevelopmental disorders, and a recent clinical trial demonstrated the safety and feasibility of DBS for severe SIB.[9] The relative risk of DBS for such novel indications in comparison with more established indications such as MD or emerging indications such as DRE is unknown, and further knowledge to ethically expand the usage of DBS for novel indications in children is needed.

In this study, we report a cohort study of postoperative complications from the largest reported cohort of pediatric DBS participants across multiple North American centers through the Child and Youth CompreHensIve Longitudinal Database for Deep Brain Stimulation Registry (CHILD-DBS).[31] We compared the relative complication rates across various indications including DRE, MD (i.e., dystonia, chorea or tic disorders), and SIB. We leveraged this unique resource to identify demographic and surgical factors associated with complications. These findings advance our knowledge of DBS in children to inform presurgical counseling and with a view toward development of disease-specific and target-specific guidelines to mitigate risk.

Methods

Standard Protocol Approvals, Registrations, and Patient Consents

The study was approved by the respective ethics boards at each participating site. Written informed consent was obtained from all participants' families.

Participants

Data were collected through CHILD-DBS,[31] a North American multicenter study including 5 tertiary pediatric hospitals, namely The Hospital for Sick Children (Toronto, Canada), Boston Children's Hospital (BCH; Boston, MA), Texas Children's Hospital (Houston, TX), Ann & Robert H. Lurie Children's Hospital of Chicago (Chicago, IL), Le Centre hospitalier universitaire Sainte-Justine (Montréal, Canada), and Le Centre hospitalier universitaire de Sherbrooke (Sherbrooke, Canada). Data were collected prospectively at all sites save for BCH, where data were collected retrospectively.

All participants were referred to a CHILD-DBS center for consideration of DBS surgery. After review by either multidisciplinary epilepsy or MD programs, they were deemed appropriate to undergo DBS. All participants were <19 years at the time of surgery and underwent DBS for DRE, MD, or SIB. All children with SIB were part of a phase 1 clinical trial under separate research ethics oversight and Health Canada monitoring.[9]

Surgery

Participants underwent bilateral DBS targeting the centromedian nucleus (CM), anterior nucleus of the thalamus (ANT), globus pallidus pars interna (GPi), subthalamic nucleus (STN), or nucleus accumbens (NAcc), depending on the indications and expert consensus. At each center, DBS surgeries were performed by experienced pediatric neurosurgeons in a standardized fashion (detailed in eMethods).

Data Extraction

Demographic variables were extracted from the DBS program database and individual electronic medical records, including age at surgery, weight at surgery, history of developmental delay, immunosuppressed status, and any prior non-DBS neurosurgeries. Surgical operative variables included DBS target, use of intraoperative microelectrode recording (MER), laterality of lead placement, single-stage (i.e., bilateral electrode insertion and implantable pulse generator [IPG] insertion under a single setting of general anesthesia) vs dual-stage surgery, IPG location, use of perioperative prophylactic antibiotic, and the urgency of surgery (and reason if urgent). Surgery was classified as urgent when DBS implantation occurred during an unplanned hospital admission because of acute neurologic deterioration and required expedited surgery for medically refractory symptoms. Time to first battery replacement was recorded, when available.

Outcomes

The primary outcome was major postoperative complication after DBS surgery. Major complications were defined as any complication causing permanent neurologic injury, death, or requiring surgical management including hardware revision or device removal. The secondary outcome of interest was minor postoperative complication, defined as any not fitting the criteria of major complication.

The complications themselves were further characterized as either infection (major: requiring surgical intervention, minor: all other infections), intracranial injury (hemorrhage or cyst formation), hardware-related (disconnection or impedance change requiring either surgery or changes in stimulation programming), or postsurgical noninfectious wound-related (dehiscence or seroma formation). Details of any revision or removal surgery performed were summarized, and if infection was identified, the location, presentation, type, and treatment of the infection were described.

Statistical Analyses

All statistical analyses were performed using Python. Demographics across DBS indication groups were compared using the analysis of variance test after confirming normality using the Levene test for homogeneity of variance, and if significant Tukey honestly significant difference test was used to assess individual group differences (Python SciPy). Time to major complications was calculated for participants, when available. All continuous data were reported as mean ± SD.

To assess associations between clinical and surgical factors with the rate of various complications, we employed separate generalized linear models (GLMs) for each complication type of interest (i.e., major complication or minor complication), using a binomial logistic regression framework (Python Statsmodels). To account for potential clustering effects by hospital site, standard errors were clustered at the site. Fixed effects initially included indication (DRE, MD, SIB), prior surgery (yes or no), urgent surgery (yes or no), age at surgery (centered), weight at surgery (centered), and single- vs dual-stage surgery. Models were specified using a logit link function and estimated using maximum likelihood estimation. A backward stepwise selection approach was implemented, iteratively removing nonsignificant predictors based on Akaike Information Criterion. For the final model, odds ratios (ORs) with 95% CIs were computed to quantify the relative risk of complications across groups while controlling for covariates. Convergence diagnostics were evaluated to confirm model stability. The effect modification of weight on age was also assessed. A subgroup analysis was then performed with separate models run for lower vs higher weight groups separated by the median to assess their differential effects on major complications. To determine the weight cutoff associated with the risk of major complications, a receiver operating characteristic (ROC) curve was computed using a logistic regression model with weight as the predictor. The optimal weight threshold was identified using Youden index, and the

corresponding sensitivity and specificity were extracted from the ROC curve.

Chi-square tests of independence were used to assess differences across indications in the frequencies of prior surgery, urgent surgery, MER use, lead laterality (unilateral vs bilateral), immunosuppression, IPG location (infraclavicular vs abdomen/flank), perioperative antibiotic use, and the number of patients requiring battery changes. Contingency tables were constructed for each and expected counts calculated to compare observed vs expected frequencies. Post hoc pairwise chi-square tests with Bonferroni correction were conducted to determine specific group differences while controlling for multiple comparisons and any significant differences ($p < 0.05$) determined. Accounting for differing follow-up durations, battery replacement rates per year were also compared across indications using a Kruskal-Wallis test with Dunn post hoc analysis (Bonferroni corrected), restricting analysis to patients with follow-up durations above the first interquartile range.

Data Availability

Data used in this article are available on reasonable request to the corresponding author.

Results

Between February 2015 and March 2025, 130 participants with a mean age of 12.2 ± 4.2 years (range 2.5–18.7 years) at the time of surgery underwent a first implant of DBS in the CHILD-DBS registry. All clinical and surgical characteristics are detailed in Table 1 and summarized in Figures 1 and 2.

Participant Demographics

Of the 130 children, 77 (59.2%) were treated for MD, 47 (36.2%) for DRE, and 6 (4.6%) for SIB. MD included 59 children (76.6%) with dystonia, 1 (1.3%) with isolated chorea, 13 (16.9%) with mixed dystonia-chorea, and 4 (5.2%) with tic disorder. Age at surgery varied across indications ($p < 0.001$, $F = 8.247$), and participants with DRE were older (14.2 ± 3.9 years) than those with MD (11.2 ± 4.1 years; $p = 0.001$). Weight at surgery (40.4 ± 20.9 kg; range 12.5–126.5 kg) was greater in DRE (47.8 ± 20.4 kg) than children with MD (36.2 ± 20.8 kg; $p = 0.008$, $F = 4.925$). Participants were followed at their respective CHILD-DBS center for a mean duration of 2.81 ± 2.33 years (range 0.04–10.15 years) post-DBS implantation, similar between DRE, MD, and SIB ($p = 0.06$, $F = 2.811$).

Most children (56%) had a history of developmental delay, whereas a history of previous surgery varied widely among indications (MD: 2, 2.6%, DRE: 33, 70.2%, SIB: none). One participant with MD had a prior intrathecal baclofen pump (ITB) while the other received both ITB and selective dorsal rhizotomy. Among those with DRE, 23 received VNS (48.9%), 4 both VNS and callosotomy (8.5%), 2 hemispherectomy (4.3%), 3 stereo EEG (6.4%), and 1 prior ANT DBS (2.1%).

Surgical Details

Deep brain targets varied across indications. Fifty-six (94.9%) of the children with dystonia underwent GPi DBS, 1 (1.7%) had DBS placed in the STN, and 2 (3.4%) underwent DBS of both the GPi and STN. The one child with isolated chorea and the 13 children with mixed dystonia-chorea all underwent GPi DBS. The 4 children with tic disorders all received GPi DBS. Of the 47 children with DRE, the CM was targeted in 35 (74.5%) and the ANT in 12 (25.5%). The NAcc was targeted in all 6 children with self-injurious behavior.

Urgent DBS surgery was performed in 24 participants (18.5%). This included 21 children with MD (27.3%) implanted for status dystonicus (n = 19) or rapid functional regression because of dystonia (n = 2). Two children with DRE (4.3%) were implanted urgently for status epilepticus (n = 1) and a high severity of seizures (n = 1), while 1 (16.7%) received surgery for severe self-injurious behaviors.

Single-stage surgery (i.e., bilateral electrode insertion and IPG insertion under a single setting of general anesthesia) was conducted in 65 (84.4%) with MD, 29 (61.7%) with DRE, and all 6 (100%) with SIB. Only 13 participants (10.0%) had the IPG placed in the abdomen or flank region, 10 with dystonia, and 3 with DRE; the other 117 participants (90.0%) had IPG placement in the infraclavicular space. Perioperative antibiotics were used in all patients (regimens outlined in eMethods), except for 1 with dystonia who had missing perioperative antibiotic data. Additional surgical operative variables are detailed in the eMethods, including use of intraoperative MER and laterality of lead placement.

Complication Rates

As detailed in Table 2 and summarized in Figure 3, 26 children (33.8%) with MD, 9 (19.1%) with DRE, and 2 (33.3%) with SIB had postoperative complications. The primary outcome of major complications occurred in 15 children (11.5%) in total, including 12 children with (15.6%) MD, 2 with DRE (4.3%), and 1 with SIB (16.7%). Major complications occurred after a median of 188 days (range 11–1,645 days), including 78.5 days (10–370) for infection, 420 days (124–1,645) for hardware malfunction, and 14 days (single case) for dehiscence. Infection requiring removal was the most common major complication (eTable 1) occurring in 8 children (6.2%; n = 2 cranial incision, n = 5 infraclavicular incision, n = 1 infraclavicular incision and intracranial lead), of whom 7 were treated for MD (9.1%) and 1 for SIB (16.7%). Other major complications included wound dehiscence (n = 1 MD) in a participant below the fifth percentile for weight with infraclavicular IPG, as well as hardware malfunction (i.e., disconnection or impedance issue, n = 3 MD and n = 1 DRE) and intracranial injury (n = 1 MD). Major complications resulted in surgical removal in 8 (10.4%) children with MD, 1 (2.1%) with DRE, and 1 (16.7%) with SIB, because of infection (n = 7), device disconnection (n = 1), and intracranial injury (n = 1). Lead revision without removal was required in 4 (5.2%) children with MD (3 with device

Table 1 Cohort Characteristics

	DRE (n = 47)	MD (n = 77)	SIB (n = 6)	*p* Value
Age at surgery, y, mean ± SD	14.2 ± 3.9	11.2 ± 4.1	11.2 ± 2.9	<0.001
Weight at surgery, kg, mean ± SD	47.8 ± 20.4	36.2 ± 20.8	35.8 ± 9.6	0.008
Duration of follow-up since DBS, y, mean ± SD (range)	2.2 ± 1.5 (0.04–6.6)	3.2 ± 2.7 (0.07–10.2)	2.7 ± 0.8 (2.3–4.3)	0.064
Indication for DBS, n (%)				
Epilepsy	47 (100)	—	—	—
Dystonia	—	59 (45)	—	—
Chorea	—	1 (1)	—	—
Mixed dystonia and chorea	—	13 (10)	—	—
Tic disorder	—	4 (3)	—	—
SIB	—	—	6 (100)	—
Target, n (%)				
CM	35 (74)	—	—	—
ANT	12 (26)	—	—	—
GPi	—	74 (96)	—	—
STN	—	1 (1)	—	—
GPi and STN	—	2 (3)	—	—
NAcc	—	—	6 (100)	—
Lead laterality, n (%)				
Unilateral	—	1 (1)	—	0.707
Bilateral	33 (100)	76 (99)	6 (100)	0.707
Prior surgeries, n (%)				
Any	33 (70)	2 (3)	—	<0.001
None	14 (30)	75 (97)	6 (100)	<0.001
ITB	—	1 (1)	—	—
ITB and SDR	—	1 (1)	—	—
VNS	23 (49)	—	—	—
sEEG	3 (6)	—	—	—
Callosotomy and VNS	4 (9)	—	—	—
Hemispherectomy	2 (4)	—	—	—
Prior DBS	1 (2)	—	—	—
Priority of surgery, n (%)				
Elective	45 (96)	56 (73)	5 (83)	0.006
Urgent	2 (4)	21 (27)	1 (17)	0.006
Immunosuppressed state, n (%)	2 (4)	4 (5)	—	0.671
MER used during surgery, n (%)	—	16 (21)[a]	4 (67)	<0.001
IPG location, n (%)				
Infraclavicular	44 (94)	67 (87)	6 (100)	0.348
Abdomen/flank	3 (6)	10 (13)	—	0.348

Continued

Table 1 Cohort Characteristics *(continued)*

	DRE (n = 47)	MD (n = 77)	SIB (n = 6)	*p* Value
Perioperative antibiotics used, n (%)	47 (100)	77 (100)[b]	6 (100)	1.000

Abbreviations: ANT = anterior nucleus of the thalamus; CM = centromedian nucleus; DBS = deep brain stimulation; DRE = drug-resistant epilepsy; GPi = globus pallidus interna; IPG = implantable pulse generator; ITB = intrathecal baclofen pump; MD = movement disorder; MER = microelectrode recording; NAcc = nucleus accumbens; SDR = selective dorsal rhizotomy; sEEG = stereo EEG; SIB = self-injurious behavior; STN = subthalamic nucleus; VNS = vagus nerve stimulator.
[a] Missing MER data for 1 participant in the dystonia group.
[b] Missing perioperative antibiotic data for 1 participant in the dystonia group.

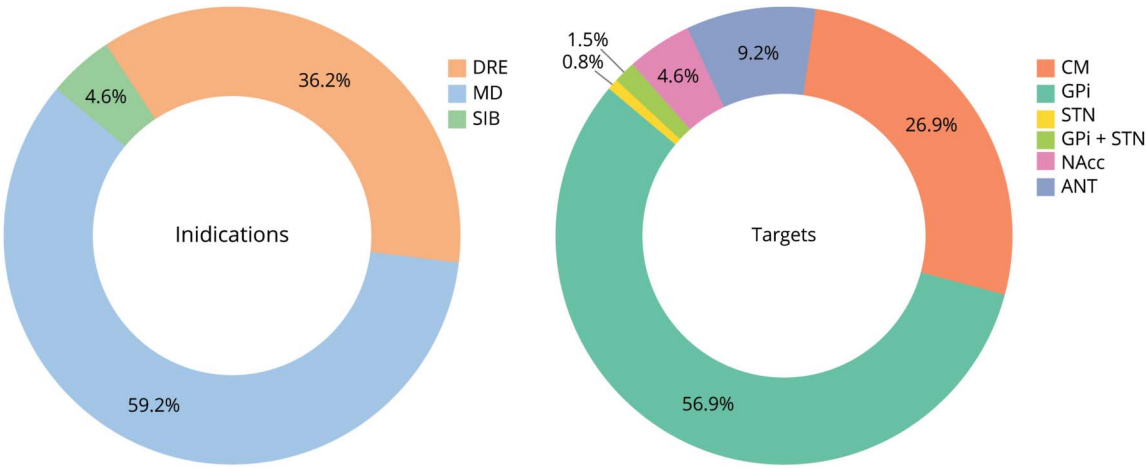
malfunction and 1 with dehiscence) and 1 (2.1%) with DRE (because of malfunction).

Major complications were significantly more likely in MD (OR 3.55, 95% CI 2.66–4.73, $p < 0.001$) and SIB (OR 3.55, 95% CI 1.83–6.88, $p < 0.001$) compared with DRE. Urgent surgery was associated with increased major complications (OR 1.83, 95% CI 1.07–3.14, $p = 0.028$), whereas there was no association with previous surgery (OR 1.41, 95% CI 0.27–7.24, $p = 0.697$) or number of surgical stages (OR 0.87, 95% CI 0.18–4.13, $p = 0.861$). A significant interaction was observed between participant age and weight (interaction term: OR 0.99, 95% CI 0.99–0.998, $p = 0.005$). Subgroup analysis revealed that higher weight was a significant protective factor against major complications among the lower weight (OR 0.94, 95% CI 0.93–0.95, $p < 0.001$), but not higher-weight children ($p = 0.913$). Within the lower-weight subgroup, age was not significantly associated with risk ($p = 0.387$), whereas in higher-weight children, older age was associated with a decreased risk of complications (OR 0.78, 95% CI 0.63–0.97, $p = 0.027$). ROC curve analysis identified an optimal weight cutoff of 27.2 kg for distinguishing higher-risk and lower-risk patients, with a sensitivity of 0.800 and specificity of 0.418.

Minor complications occurred in 22 participants (16.9%), including 14 with MD (18.2%), 7 with DRE (14.9%), and 1 with SIB (16.7%). This consisted of minor infection (n = 8), high impedance (n = 2), wound dehiscence (n = 1), unrelated hydrocephalus (n = 1), perioperative worsening of symptoms (n = 5), incidental tract hemorrhage (n = 3), noninfectious peri-electrode cystic changes (n = 1), and postoperative headache with nausea and vomiting (n = 1). Both MD (OR 1.83, 95% CI 1.16–2.89, $p = 0.010$) and SIB (OR 1.65, 95% CI 1.54–1.78, $p < 0.001$) had significantly higher odds of experiencing a minor complication compared with DRE. By contrast, prior surgery ($p = 0.151$), urgent surgery ($p = 0.800$), age at surgery ($p = 0.825$), weight at surgery ($p = 0.844$), and number of surgical stages ($p = 0.458$) were not associated with minor complications.

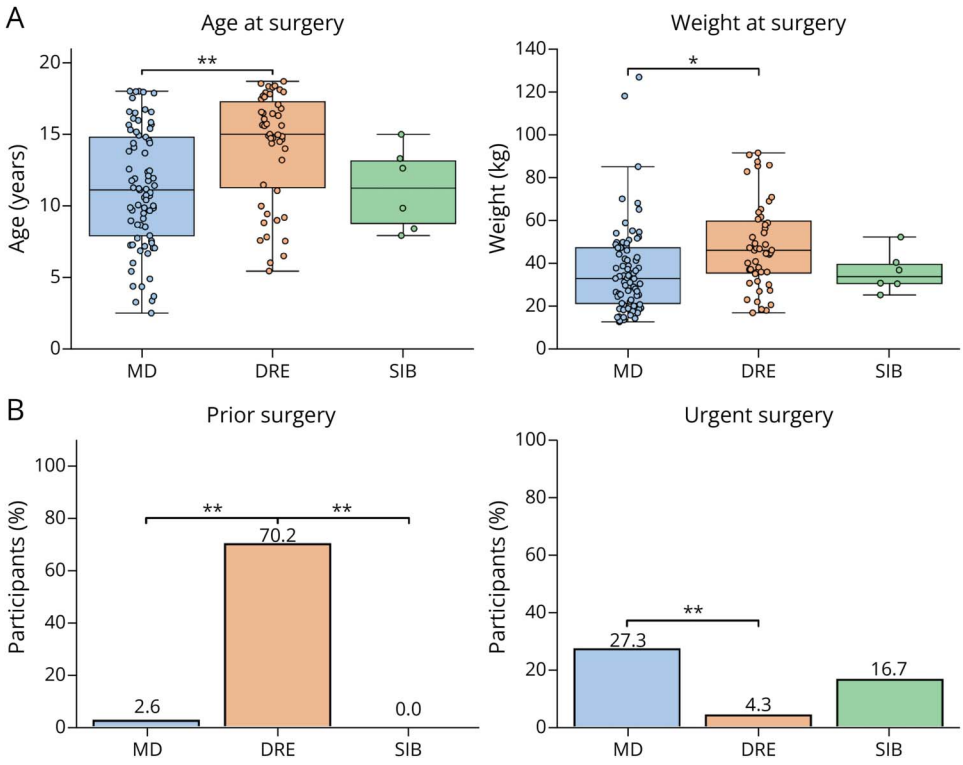
In terms of minor infectious (eTable 1) and noninfectious wound complications, 4 MD and 4 DRE participants had superficial surgical site wound infections successfully treated with antibiotic therapy without surgical intervention. Of them, 1 underwent concurrent VNS insertion at the time of DBS surgery and 1 had an existing VNS, tracheostomy, gastrostomy, and port. Noninfectious wound complications

Figure 1 DBS Surgical Indications and Deep Brain Targets



Indications for DBS as percentages of the total cohort are shown (left), including MDs, DRE, and SIB. The percentage of participants receiving DBS implanted in each target of interest is shown (right). ANT = anterior nucleus of the thalamus; CM = centromedian nucleus of the thalamus; DBS = deep brain stimulation; DRE = drug-resistant epilepsy; GPi = globus pallidus interna; MD = movement disorder; NAcc = nucleus accumbens; SIB = self-injurious behavior; STN = subthalamic nucleus.

Figure 2 Participant Characteristics



(A) Distributions of age (left panel) and weight (right panel) at surgery are shown for each DBS indication. In box plots, central marks indicate the median and edges the 25th and 75th percentiles of the distribution. (B) The percentage of participants in each indication with a history of prior surgical management (left panel) or receiving DBS surgery urgently (right panel) are shown, respectively. DBS = deep brain stimulation; DRE = drug-resistant epilepsy; MD = movement disorder; SIB = self-injurious behavior. $^{**}p < 0.01$; $^{*}p < 0.05$.

occurred in 1 child with dystonia who was below the fifth percentile for weight, experiencing an infraclavicular IPG-associated seroma managed conservatively.

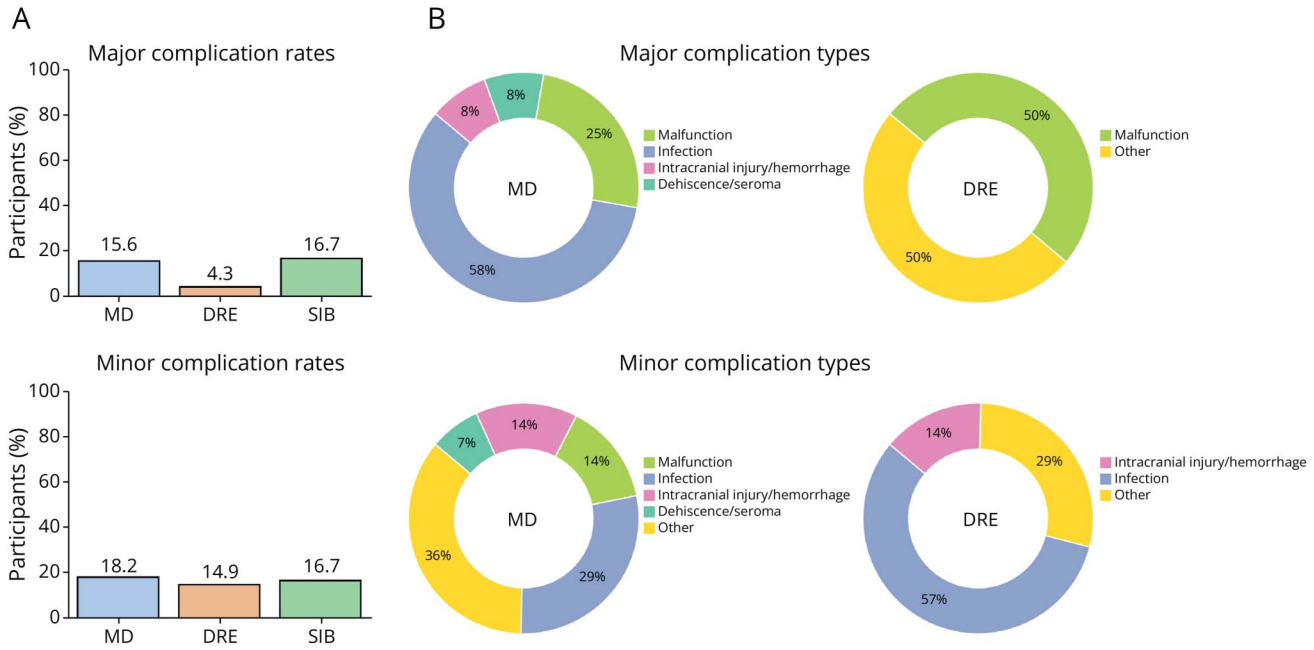
Noninfectious and non–wound-related complications were observed as well. Intracranial injury after DBS insertion resulted in device removal in 1 participant with dystonia because of cyst formation around tip of the right lead. All other intracranial injuries were classified as minor complications because they were largely incidental or resolved without intervention (eMethods). Hardware complications occurred in 6 children (4.6%), including 1 child with DRE (2.1%) requiring removal because of microwire failure and 5 children with MD (6.5%), all with dystonia and loss of stimulation efficacy with associated increased impedances. Programming was modified to rescue therapeutic stimulation for 2

Table 2 Summary of Complications

	DRE (n = 47)	MD (n = 77)	SIB (n = 6)	Total (n = 130)
Complication type, n (%)				
None	38 (81)	51 (66)	4 (67)	93 (72)
Infection	4 (9)	11 (14)	1 (17)	16 (12)
Intracranial injury	1 (2)	3 (4)	1 (17)	5 (3)
Electrode/IPG malfunction	1 (2)	5 (6)	—	6 (5)
Wound dehiscence/seroma	—	2 (3)	—	2 (2)
Other	3 (6)	5 (6)	—	8 (6)
Major complication, n (%)	2 (4)	12 (16)	1 (17)	15 (12)
Removal	1 (2)	8 (10)	1 (17)	10 (8)
Hardware revision	1 (2)	4 (5)	—	5 (4)

Abbreviations: DRE = drug-resistant epilepsy; IPG = implantable pulse generator; MD = movement disorder; SIB = self-injurious behavior.

Figure 3 Postoperative Complications With DBS



(A) The rates of major (top panel) and minor (bottom panel) postoperative complications are shown for each indication, including MDs, DRE, and SIB. Major complications were defined as those requiring surgical management, including hardware revision or removal. (B) The types of major (top plots) and minor (bottom plots) complications observed for each indication are plotted as percentages of the total number of complications in each indication. DBS = deep brain stimulation; DRE = drug-resistant epilepsy; MD = movement disorder; SIB = self-injurious behavior.

participants. For the other 3, reprogramming was insufficient, with surgical hardware revision required in 2 and removal in 1 at the request of the family in the context of increased beginning impedances 1,645 days after initial implantation. Transient worsening of neurologic symptoms occurred postoperatively in 5 patients without a clear etiology, and no patients experienced permanent neurologic injury (eMethods). Across the cohort, 6 children (4 MD, 2 DRE) died because of their underlying condition and unrelated to postoperative or device complications, as detailed in eTable 2.

Last, 26 participants (20.0%) underwent a total of 33 IPG replacement surgeries for battery depletion, including 15 with MD (19.5%), 6 with DRE (12.8%) and 5 SIB (83.3%). The relative number of patients requiring battery changes occurred at different rates across indications ($\chi^2 = 16.59$, $df = 2$, $p < 0.001$). SIB had significantly higher relative numbers compared with both MD ($\chi^2 = 9.16$, adjusted $p = 0.007$) and DRE ($\chi^2 = 12.10$, adjusted $p = 0.002$), with no difference between MD and DRE ($\chi^2 = 0.519$, adjusted $p = 1.000$). The annualized rate of battery replacement accounting for follow-up duration differed among indications ($H = 16.12$, $p < 0.001$), also significantly higher in SIB (0.396 ± 0.223 replacements/year) compared with MD (0.066 ± 0.131, $p = 0.001$) and DRE (0.053 ± 0.124, $p < 0.001$), with no difference between MD and DRE ($p = 1.000$). Finally, there was no statistically significant difference in time to first battery replacement across indications (662 ± 558 days; $H = 4.16$, $p = 0.125$). IPG replacement was associated with major complications in 2 participants (7.7%). Both were due to IPG wound infections, including in 1 with SIB 10 days after their third IPG replacement and 1 with dystonia 104 days postoperatively (single replacement).

Discussion

In this North American multicenter study of pediatric DBS across multiple surgical indications and brain targets, we describe DBS-related complications from surgery up to 10.2 years of follow-up. We observed a low rate of major complications across indications, particularly in children treated for DRE. Using data from the CHILD-DBS registry, this study provides the largest description of relative rates of postoperative DBS complications across a broad spectrum of indications in children.

Importantly, our finding of an 11.5% rate of major complications challenges the notion that children are at higher risk of complications than adults (ranging from 1.2% to 15%).[32-34] Furthermore, the rate of major infection we report (6.2% overall, 9.1% in MD) was similar to recent studies of pediatric dystonia (10.3%)[26] and less than in older literature (40%–57%).[35,36] Major infection occurred mostly on the order of months postoperatively (median 78.5 days).

We found that different indications conferred unique risk profiles. DRE was associated with significantly lower risk of

major complications (4.3%) compared with MD (15.6%) and SIB (16.7%) and lower than both recent studies (8.3%)[37] and previous reports (~10%)[6] of DRE. This difference may be multifactorial. Although most children were medically complex and had a history of developmental delay,[6,26,27] children with MD were younger and more likely to undergo urgent surgery, both associated with increased risk. All major complications occurred in children with dystonia or chorea, not in those with tic disorders, supporting that baseline morbidity in these specific MD may contribute to risk. In addition, most cases of transient postoperative worsening occurred in MD, highlighting the vulnerability of this group to surgical stress and supporting the use of single-stage surgery and perioperative bridging strategies. Overall, children with MD, especially with dystonia or chorea, require closer monitoring for complications, underscoring the importance of multidisciplinary care.[38,39]

We also report the effects of participant-specific and surgical factors—including age, weight, and urgency of surgery—on the risk of major complications. At present, there is no accepted lower limit of weight or age that would preclude children from DBS. Children within the CHILD-DBS registry were treated as young as 3 years of age, and previous literature has reported children as young as 2 years with DBS.[40] Our results are consistent with previous evidence that smaller size renders DBS a higher risk intervention.[41,42] Lower weight was associated with an increased risk of major complications, particularly among children in the lower-weight subgroup, whereas younger age conferred higher risk primarily in the higher-weight group. This suggests that weight may be the more critical factor in smaller children, whereas in heavier children, developmental immaturity linked to age may play a more prominent role. Our study provides a detailed description of size-dependent noninfectious complications, including wound dehiscence and noninfectious IPG pocket collection, with presumed CSF in 2 participants below the fifth percentile for weight. We hypothesized that smaller children may be at higher risk of such complications because of less developed cranial bones and musculoskeletal tissue,[41,42] whereas lower weight itself may be due to more significant dystonia. Growth-related complications such as wire breakage or tethering were not observed in our study.[26] Both IPGs were placed in the infraclavicular space, supporting the consideration of alternate sites (i.e., flank) depending on patient factors. These findings also highlight the importance of the optimization of nutritional status[43] in children before DBS, which may not be possible in the setting of urgent intervention. Urgent surgery was associated with higher rates of major complications, potentially reflecting the greater clinical severity and medical instability of patients requiring rapid intervention, such as those with status dystonicus. Moreover, urgent surgery may prevent presurgical optimization of therapies for MD, potentially resulting in suboptimal postoperative control of the underlying movements and injury to wounds.

Intracranial injury associated with the DBS leads was uncommon. Nonactionable or incidental findings were observed in 4 participants and only 1 required surgical intervention due to peri-electrode cyst formation. This has been observed in patients with essential tremor after ventralis intermedius nucleus DBS and also required removal.[44] Interestingly another child in our series with drug-induced lupus receiving corticosteroids and who underwent bilateral CM DBS for DRE also developed a delayed cystic lesion around the left electrode, which resolved spontaneously without intervention. Although rare, children may experience postoperative noninfectious cystic lesions causing neurologic deficits, the management of which remains controversial.

A small subset of children (4.6%), mostly with MD, also presented with hardware malfunction diagnosed because of high impedances that prohibited programming and required revision, including in 1 participant 1,645 days after initial implantation. The incidence of these complications is far less than previously reported (18%–19%).[26] We did not observe any fractures of electrodes of extension wires, which has been previously described with a prevalence of 8.4%.[26] The discordance may be related to the use of newer models of DBS hardware, which potentially have lower rates of fracture.[45] Nonetheless, the presence of high impedances, even in the absence of worsening neurologic status or years after implantation, should prompt interrogation and operative intervention if reprogramming is unsuccessful.[45]

Last, we found that 20.0% of participants underwent IPG replacement surgery for battery depletion, with 2 experiencing major infections directly related to replacement. This is of importance given the risk of IPG site infection[46] that further increases with recurrent revisions,[47] often required in children given the higher stimulation settings.[48] Children with SIB had a significantly higher rate of IPG replacement (83.3%) despite similar postoperative follow-up duration to MD and DRE, which included the patient experiencing major infection after their third IPG replacement. A potential reason may be the higher stimulation amplitudes required with NAcc DBS, ranging from 3.5 to 5.3 mA in a subset of participants from the phase 1 clinical trial.[9] This contrasts with approximately 1.0–3.0 mA in status dystonicus, the most severe form of dystonia.[3] Although rechargeable IPGs decrease the number of operations for replacement,[49] they may not be reasonable for very young children or those with behavioral dysregulation. Hence, demonstration of the safety of IPG replacement is valuable in children with DBS.

This study presented a large pediatric cohort describing surgical complications after DBS from the multicenter CHILD-DBS registry. Several limitations warrant attention. First, the registry is an ongoing initiative, and additional data may expand on these findings. We chose the current date to present this analysis because of the maturity of the data and follow-up more than 10 years. Although this is the longest reported follow-up in children, it is also limited by the relative scarcity

of pediatric DBS. The ability to comment on longer-term complications associated with DBS such as those related to participant growth is limited and will be addressed in subsequent follow-up studies of our cohort. Second, certain populations are importantly less represented in the CHILD-DBS registry than others. In particular, those with SIB were treated through a phase 1 clinical trial because of the investigational nature of NAcc DBS for this indication.[9] Third, our study focused only on surgical postoperative complications and not on DBS programming-related complications or adverse outcomes related to stimulation itself.[50] Future studies of children in the CHILD-DBS registry will warrant exploration of this understudied facet of DBS implementation. Last, although we accounted for potential clustering effects by hospital site using clustered standard errors in the GLMs, we did not compare outcomes between the centers themselves. As the cohort in the CHILD-DBS registry expands in the future across all sites, this will be an important area of investigation to help further standardize surgical procedures in the future.

The findings of this study underscore the need for standardized guidelines and best practices for pediatric DBS. Although DBS was overall safe across indications, the presence of indication-specific risks, demographics-associated differences in complications, and variations in hardware-related issues highlight the necessity of developing structured perioperative management strategies to optimize outcomes. Establishing guidelines for preoperative evaluation, surgical techniques, postoperative monitoring, and infection prevention protocols, addressing indication and participant-specific factors, may help minimize complications and improve long-term device durability.[32,33,45] As pediatric DBS continues to evolve, further multicenter studies will be critical in refining current understanding of participant selection criteria and evaluating long-term outcomes. Finally, future research into whether technical advances such as rechargeable IPGs[49] and improved electrode and other hardware designs[45] may further reduce the need for surgical revisions and further enhance the safety and efficacy of DBS in children.

In conclusion, we present the first multicenter description of DBS-associated complications in children across a wide range of indications and targets. These findings illustrate that pediatric DBS is safe but with notable risks that must be monitored for to ensure optimal outcomes, supporting its continued and growing application to children and the development of disease-specific and target-specific guidelines to further mitigate risk.

Author Contributions

A. Balachandar: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; analysis or interpretation of data. L.H. Verhey: drafting/revision of the manuscript for content, including medical writing for content; analysis or interpretation of data. K. Mithani: drafting/revision of the manuscript for content, including medical writing for content; analysis or interpretation of data. H. Suresh: drafting/revision of the manuscript for content, including medical writing for content; analysis or interpretation of data. E.N. Kerr: drafting/revision of the manuscript for content, including medical writing for content; analysis or interpretation of data. S.C. Breitbart: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. F. Kisteroff: major role in the acquisition of data. M.L. Huynh: major role in the acquisition of data. A. Fasano: drafting/revision of the manuscript for content, including medical writing for content; study concept or design; analysis or interpretation of data. D. Ebrahimi-Fakhari: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; analysis or interpretation of data. K. Yang: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. M. Ruppert-Gomez: major role in the acquisition of data. S.S.D. Stone: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design. W. Northam: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design. N. Gadgil: major role in the acquisition of data; study concept or design. J.S. Raskin: drafting/revision of the manuscript for content, including medical writing for content; study concept or design. A. Weil: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design. A. Hadjinicolaou: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. I.A. Meijer: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. C. Iorio-Morin: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data. C. Gorodetsky: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design; analysis or interpretation of data. G.M. Ibrahim: drafting/revision of the manuscript for content, including medical writing for content; major role in the acquisition of data; study concept or design; analysis or interpretation of data.

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