Care Bundle Approach to Minimizing Infection Rates after Neurosurgical Implants for Neuromodulation: A Single-Surgeon Experience

Elsa V. Arocho-Quinones[1,2], Chiang-Ching Huang[4], Barney D. Ward[3], Peter A. Pahapill[1,2]

■ INTRODUCTION: **Implant-related infections carry a high morbidity. Infectious rates for neuromodulation implants range from 1% to 9% for deep brain stimulation (DBS), 0% to 10% for spinal cord stimulation (SCS) systems, and 3% to 15% for intrathecal (IT) pump systems. Meanwhile, studies of care bundles report infection rate reduction to 1.0% for SCS and 0.3% for cardiac implants. Herein, we evaluate the effectiveness of an infection prevention bundle (IPB) in minimizing infections after surgeries for neuromodulation implants.**

■ METHODS: **An IPB focused on preoperative checklists, screening questionnaires, methicillin-resistant and methicillin-sensitive *Staphylococcus aureus* decolonization, weight-based antibiotic prophylaxis, strict draping and surgical techniques, and wound care education was implemented in our functional neurosurgery division in April 2015. We retrospectively reviewed all surgeries for implantation or replacement of SCS, DBS, and IT pump system components from March 2013 to October 2017. The patients were divided into pre-IPB and post-IPB groups. All procedures were performed by a single surgeon. Each surgical site was considered a unique surgical case. Infection rates were calculated for pre-IPB and post-IPB groups.**

■ RESULTS: **A total of 688 patients underwent 1161 unique surgical procedures (222 DBS electrodes, 419 IPG, 203 SCS, 317 IT pumps) during the study period. There were 546 pre-IPB and 615 post-IPB surgical procedures. The pre-IPB infection rates were 0%, 1.3%, and 8.7% for SCS, DBS, and IT pumps, respectively. The post-IPB infection rates were 0%, 0.3%, and 1.8% for SCS, DBS, and IT pumps, respectively.**

■ CONCLUSIONS: **Implementation of a standardized IPB approach reduced the number of infections for all neuromodulation implants studied. This approach can be adopted within any specialty to potentially decrease the incidence of implant-related infections.**

INTRODUCTION

Implant-related infections carry a high morbidity. Common complications associated with implant-related surgeries include hemorrhage, infection, and hardware failure. Infectious rates for neuromodulation implants range from 1% to 9% for deep brain stimulation (DBS),[1-8] 0 to 10% for spinal cord stimulation (SCS) systems,[9,10] and 3% to 15% for intrathecal (IT) pump systems.[11-13] Meanwhile, studies of care bundles report reduction in infection rates for SCS from 10.4% to 1.0%[9] and rates as low as 0.3% for cardiac implants.[14-16]

Given the implications associated with implant-related infections, such as requirement for further surgical revision, possible hardware removal with exacerbation of the underlying

Key words
- Bundle
- Checklists
- Deep brain stimulation
- Intrathecal pumps
- Spinal cord stimulation
- Surgical implant
- Surgical site infection

Abbreviations and Acronyms
CDC: Centers for Disease Control and Prevention
DBS: Deep brain stimulation
FMLH: Froedtert Memorial Lutheran Hospital
IPB: Infection prevention bundle
IPG: Implantable pulse generator
IT: Intrathecal
MAC: Monitored anesthesia care
SCS: Spinal cord stimulation
SSI: Surgical site infection

From the [1]Department of Neurosurgery, U.S. Department of Veterans Affairs Medical Center, Milwaukee; Departments of [2]Neurosurgery and [3]Biophysics, Medical College of Wisconsin, Milwaukee; and [4]Joseph J. Zilber School of Public Health, University of Wisconsin, Milwaukee, Wisconsin, USA

To whom correspondence should be addressed: Elsa V. Arocho-Quinones, M.D. [E-mail: earocho@mcw.edu]

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disorder, and increased healthcare costs, the standardization of infection prevention strategies should be a top priority of quality improvement initiatives within a functional neurosurgery practice.[1] Furthermore, the implementation of best practices to minimize implant-related infections is necessary to help ensure cost effectiveness and continued access to these therapies. In this study, we sought to evaluate the effectiveness of implementing a custom infection prevention bundle (IPB) in minimizing infections after surgeries for implantation of neuromodulation devices.

METHODS

Study Location

Froedtert Memorial Lutheran Hospital (FMLH) in Milwaukee, Wisconsin, an academic medical center with 804 inpatient beds.

Study Design

To evaluate the effectiveness of an IPB instituted in April 2015, we performed a retrospective chart review of adult patients who underwent surgery for implantation or replacement of SCS, DBS, and IT drug delivery system components at FMLH from March 2013 to October 2017. The patients were divided into 2 groups: the preintervention or pre-IPB group and the postintervention or post-IPB group (Figure 1).

Data collection was focused on demographics (sex, age at time of surgery); length of follow-up; risk factors; surgeries for implantation, revision, and/or removal of hardware; indications for surgery; incidence of infections; and infectious agent(s) identified.

To control for practice-related variabilities, all procedures reviewed were performed by a single surgeon (P.P., senior author). Each surgical site was counted as a unique surgical case. Infection rates were calculated for all initial implantation surgeries and all subsequent revision or replacement surgeries before and after implementation of the IPB. The global incidence of postoperative surgical site infection (SSI) with the use of a 90-day versus a 1-year infection surveillance period was evaluated. Only patients with a minimum follow-up time of 12 months were included in subgroup and risk factor comparisons.

Eligibility Criteria

Inclusion Criteria. Men and women older than 18 years of age who underwent elective surgery for implantation or replacement of SCS system components, DBS system components, or IT drug delivery systems at FMLH by a single functional surgeon (P.P., senior author) within the study period of March 2013 to October 2017 and who had a minimum follow-up time of 3 months were included.

Exclusion Criteria. Patients younger than 18 years of age; patients who underwent implant placement or replacement surgeries outside of FMLH, by a surgeon other than P.P., and/or outside of the study period of March 2013 to October 2017; and patients with less than 3 months of follow-up time were not included in the data collection.

Determination of Surgical Site Infection

The diagnosis of deep SSI followed the guidelines by the Centers for Disease Control and Prevention (CDC)[17] and included infections occurring within 30 or 90 days after the operative procedure (of note, our infection surveillance is extended to a minimum of 1 year, given the presence of implantable devices), those involving deep soft tissues of the incision (e.g., fascial and muscle layers), and at least 1 of the following:

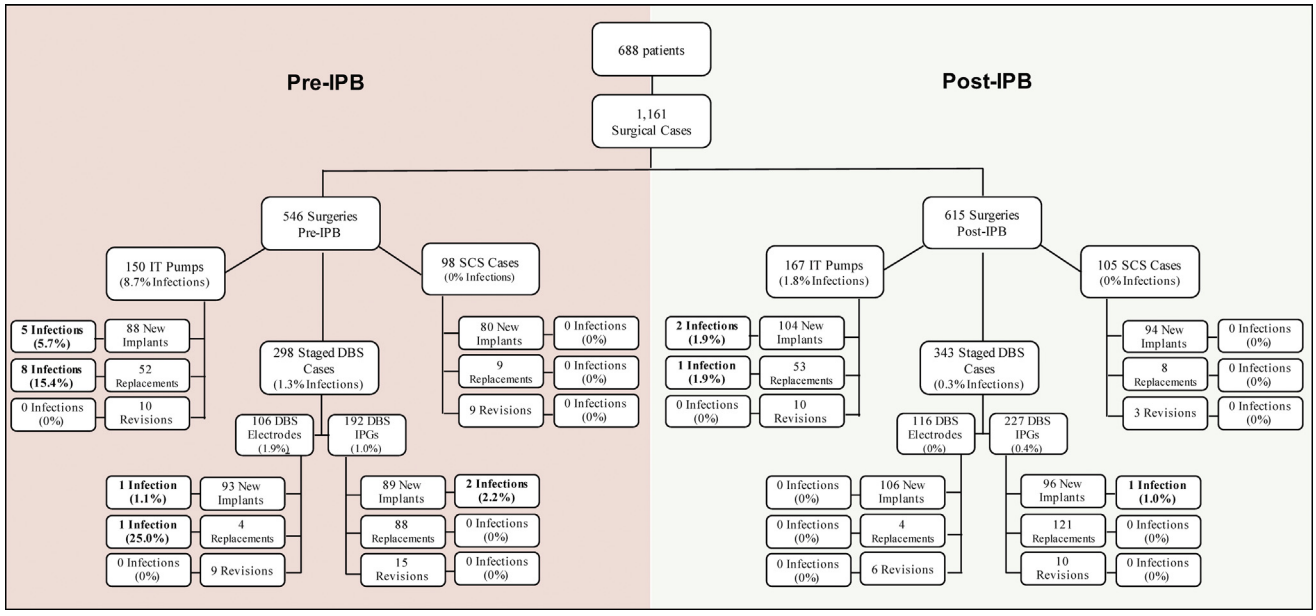

Figure 1. Surgical cases and implant-related infections with 1-year postoperative surveillance. DBS, deep brain stimulation; IPB, infection prevention bundle; IT, intrathecal; SCS, spinal cord stimulation.

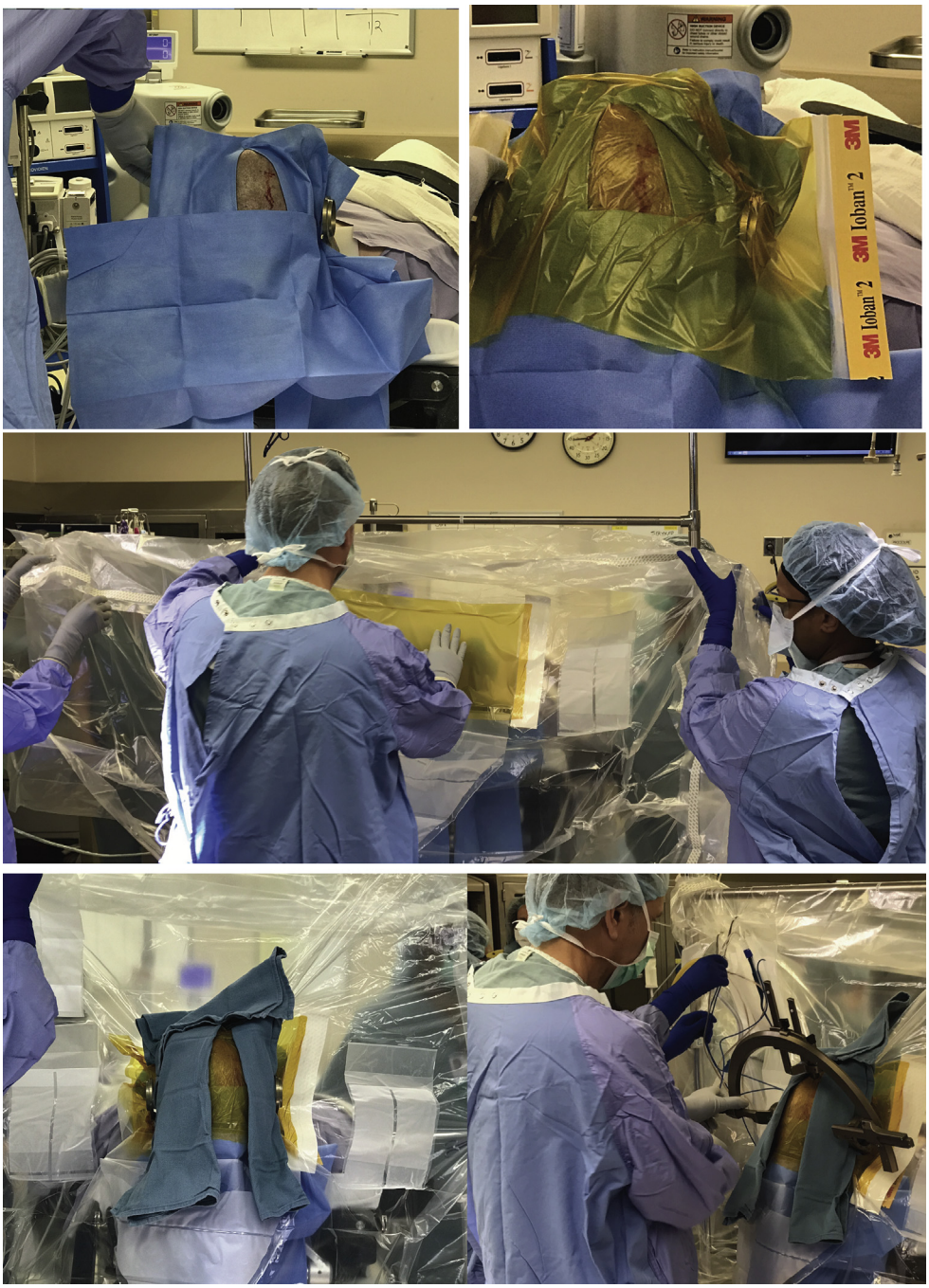

Figure 2. Draping technique for deep brain stimulation stage I surgeries. Top: After a standard skin preparation with chlorhexidine/alcohol–based solution, sterile paper drapes are placed surrounding the incision and are covered by antimicrobial incise drapes. Middle: A second layer of antimicrobial incise drape is first placed over the previously draped incision, and the lateral flanks are then tied around intravenous poles on either side to separate the surgical field from the nonsterile patient field. Bottom: Cuts are made on the incise drape to allow the z-bars through to allow connection to the arc (outer gloves are changed after this step). Exposed nonsterile areas are then covered with sterile towels. Finally, the frame arc is attached and set to predetermined coordinates.

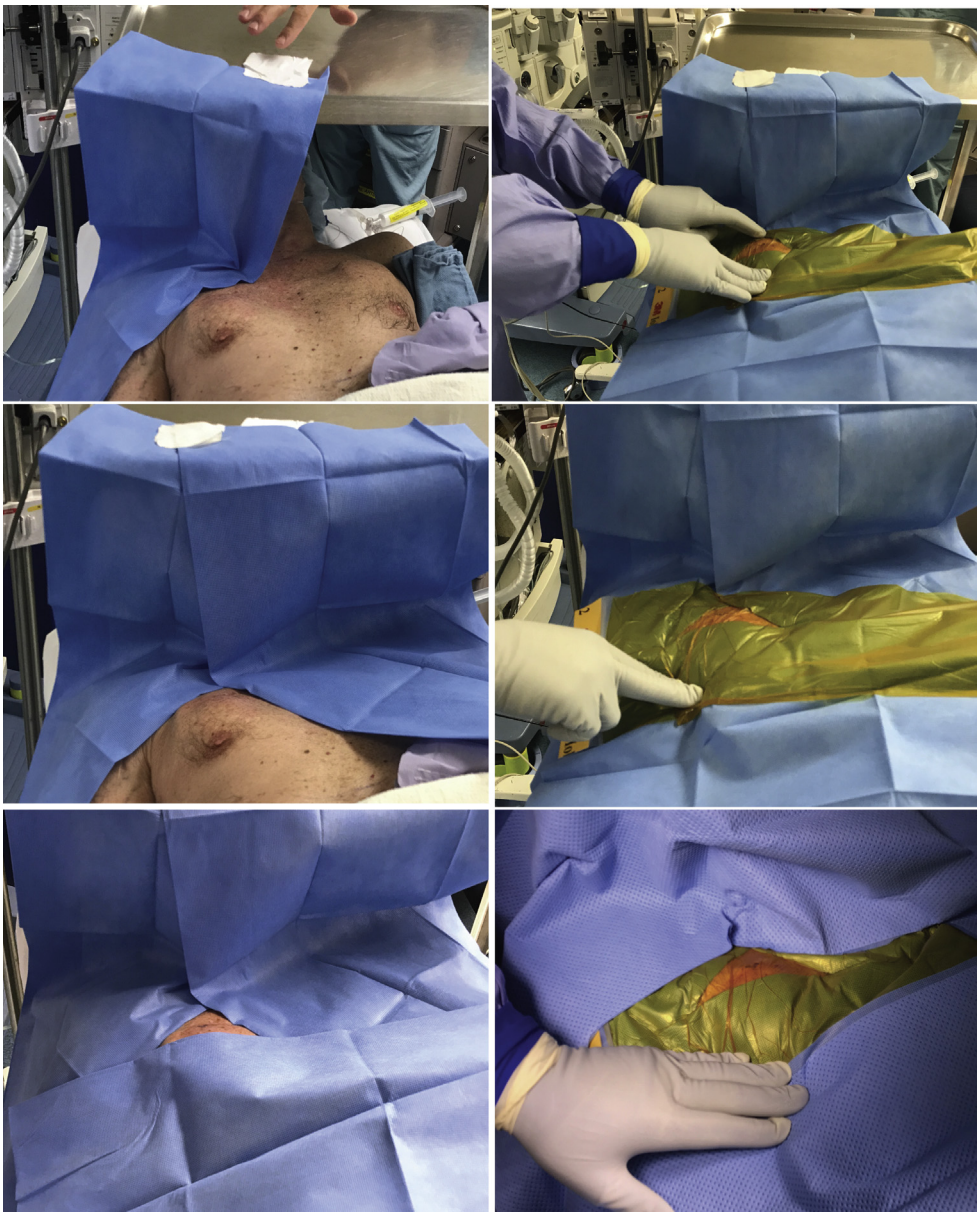

Figure 3. Draping technique for deep brain stimulation implantable pulse generator (IPG) replacement surgeries. Left: A Mayo tray is placed above the patient's head with enough height to ensure patient comfort. After a standard skin preparation with chlorhexidine/alcohol–based solution, sterile paper drapes are attached to the top of the Mayo tray and then around the patient's incision without leaving gaps. Right: Antimicrobial incise drapes are placed over the paper drapes, creating a watertight closure. Surgical field drapes are then placed in standard fashion.

a. Purulent drainage from deep incision.

b. A deep incision that spontaneously dehisces, or a deep incision deliberately opened/aspirated by a surgeon and organism is identified by a culture or non–culture-based microbiologic testing method that is performed for the purpose of clinical diagnosis or treatment; or culture or non–culture-based microbiologic testing method is not performed AND at least 1 of the following signs or symptoms is present: fever (>38°C), localized pain, or tenderness. A culture or non–culture-based test that has a negative finding does not meet this criterion.

c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomic or histopathologic exam, or imaging test.

Table 1. Baseline Patient Characteristics for Pre-IPB and Post-IPB Groups with 1-Year Postoperative Surveillance

		Pre-IPB Group		Post-IPB Group	
Surgery Group	**Characteristic**	**All Patients**	**Infected Patients**	**All Patients**	**Infected Patients**
DBS systems	No. of patients (%)	188 (100%)	3 (1.6%)	198 (100%)	1 (0.5%)
	Average age in years	69 ± 16	75 ± 5	68 ± 15	64
	Sex (M:F)	139:49	3:0	153:45	1:0
SCS systems	Number of patients (%)	51 (100%)	0 (0%)	58 (100%)	0 (0%)
	Average age in years	60 ± 25	N/A	66 ± 12	N/A
	Sex (M:F)	29:22	0:0	32:26	0:0
IT pump systems	Number of patients (%)	93 (100%)	8 (8.6%)	100 (100%)	2 (2.0%)
	Average age in years	46 ± 16	39 ± 15	47 ± 14	44 ± 18
	Sex (M:F)	58:35	4:4	64:36	0:2

IPB, infection prevention bundle; DBS, deep brain stimulation; SCS, spinal cord stimulator; N/A, not applicable; IT, intrathecal.

Only deep SSIs requiring surgery for wound debridement/washout and/or hardware removal were considered in this study. Our infection surveillance extends to a minimum of 1 year, given the presence of implantable devices.

Ethical Review/Approval

The study was performed in the context of quality improvement without experimental practices or the need for patient's identifiable information; therefore, it was granted exempt status by our institutional review board.

Infection Prevention Bundle

The IPB implemented in April 2015 consisted of the following items:

1. Preoperative counseling and questionnaire: patient counseling and preparation instructions, screening questions for signs of infection, and presence of open or nonhealing wounds.
2. Preoperative check list:
   a. Nurse call with reminder of preoperative instructions 2 days before surgery.
   b. Nasal methicillin-resistant and methicillin-sensitive *Staphylococcus aureus* decolonization: twice-daily application of 2% mupirocin ointment to bilateral nares with final application on the morning of surgery.
   c. Body decolonization: Cleansing with 2% chlorhexidine gluconate cloths the evening before surgery and the morning of surgery.
3. Preoperative weight-based antibiotics within 60 minutes of incision
4. Strict draping and surgical techniques (see operating room practice section) (**Figures 2** and **3**)
5. Weight-based postoperative antibiotics for 24 hours for patients staying overnight versus 1 dose for outpatients
6. Postoperative wound care education to patient and family

Operating Room Practice

A single functional neurosurgeon (P.P., senior author) performed every procedure either by himself or with assistance from a single neurosurgical resident. Both surgeon and assistants wore nonpaper gowns and double gloves for every procedure. Exterior gloves were changed after draping for all stage I DBS (electrode placement) procedures. There was no restriction on the number of people allowed in the room at a given time, the frequency of door openings, or the frequency of scrub technician turnover.

DBS surgeries were performed in a staged fashion. Stage I DBS surgeries (electrode implantation) were performed with the patient under monitored anesthesia care (MAC) and local anesthesia. Microelectrode recording was used in all stage I DBS surgeries. Stage II DBS (IPG insertion and connection) was performed with the patient under general anesthesia. DBS IPG replacements were performed with the patient under MAC and local anesthesia. SCS paddle and battery implantations were performed with the patient under MAC and local anesthesia. Initial IT pump system implantations and revisions were performed with the patient under general anesthesia. Routine IT pump replacements were performed with the patient under MAC and local anesthesia.

Local hair was removed with electric clippers immediately before surgery. Standard surgical site skin preparation was performed by an operating room nurse using a chlorhexidine/alcohol–based solution. Additional skin cleansing with povidone-iodine was performed for all stage I DBS procedures before placement of stereotactic headframe pins and before local anesthetic infiltration to the proposed scalp incision. This was followed by a final skin preparation with a chlorhexidine/alcohol–based solution before draping.

Table 2. Implant-Related Infections with 90-Day versus 1-Year Postoperative Surveillance Protocol

	Pre-IPB		Post-IPB		Pre-IPB		Post-IPB	
Surgical Cases	**Number of Patients**	**Infections (%)**	**Number of Patients**	**Infections (%)**	**Unique Surgical Cases**	**Infections (%)**	**Unique Surgical Cases**	**Infections (%)**
All case types								
90-day surveillance	332	11 (3.3%)	356	1 (0.3%)	546	16 (2.9%)	615	1 (0.2%)
1-year surveillance		15 (4.5%)		3 (0.8%)		17 (3.1%)		4 (0.7%)
All DBS cases								
90-day surveillance	188	2 (1.1%)	198	0 (0%)	298	3 (1.0%)	343	0 (0%)
1-year surveillance		3 (1.6%)		1 (0.5%)		4 (1.3%)		1 (0.3%)
Electrode cases								
90-day surveillance	76	2 (2.6%)	72	0 (0%)	106	2 (1.9%)	116	0 (0%)
1-year surveillance		2 (2.6%)		0 (0%)		2 (1.9%)		0 (0%)
DBS IPG cases								
90-day surveillance	112	1 (0.9%)	126	0 (0%)	192	1 (0.5%)	227	0 (0%)
1-year surveillance		2 (1.8%)		1 (0.8%)		2 (1.0%)		1 (0.4%)
All SCS cases								
90-day surveillance	51	0 (0%)	58	0 (0%)	98	0 (0%)	105	0 (0%)
1-year surveillance		0 (0%)		0 (0%)		0 (0%)		0 (0%)
All IT pump cases								
90-day surveillance	93	8 (8.6%)	100	1 (1.0%)	150	13 (8.7%)	167	**1 (0.6%)**
1-year surveillance		8 (8.6%)		2 (2.0%)		13 (8.7%)		3 (1.8%)

All case types = SCS + DBS + IT pumps.
Bold value indicate statistically significant decrease in % infections (Refer to **Supplementary Figure 1** and **Supplementary Table 1**).
IPB, infection prevention bundle; DBS, deep brain stimulation; IPG, implantable pulse generator; SCS, spinal cord stimulator; IT, intrathecal.

Sterile draping was performed by the attending neurosurgeon with or without assistance from a resident or a scrub technician. Two layers of iodophore-impregnated incise drapes were used in all stage I DBS procedures (**Figure 2**). Paper drapes and iodophore-impregnated incise drapes were used to achieve watertight closures in all DBS IPG, SCS, and IT pump placement and replacement procedures (**Figure 3**). Sterile draping of the C-arm fluoroscopy machine was performed by the scrub technician.

All implants remained closed in their package until immediately needed and were soaked in vancomycin solution (1 mg/mL) before implantation. All pump implants were anchored with 2–0 silk sutures, and the rest of the implants were anchored with 2–0 Vicryl sutures. Wound irrigation with saline was carried out with a bulb syringe before wound closure. Wound closures were performed following the anatomic layers with 0 Vicryl for fascial layers, 2–0 Vicryl for the intermediate subcutaneous layers, an inverted layer of 3–0 Vicryl for the more superficial subcutaneous layers, and a running 4–0 Vicryl subcuticular suture with Dermabond for the final skin closure. All wounds were dressed with Telfa nonadherent dressing (Covidien, Northfield, Illinois, USA) and Tegaderm transparent film dressing (3M, St. Paul, Minnesota, USA) for 24 to 48 hours.

Statistical Analysis

Data analysis focused on calculation of infection rates with mean ± standard deviation, and group comparisons were made by the Student t test and the rate ratio test.[18] The Wilson score interval was used for calculating the binomial proportion confidence limits. Data analysis was performed with statistical software R3.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Population

A total of 688 patients (460 men, 224 women; 50 ± 17 years old) underwent a total of 1161 unique site surgeries during the study period. This included 222 DBS electrode surgeries (199 initial, 8 replacements, 15 revisions), 419 IPG surgeries (185 initial, 209 replacements, 25 revisions), 203 SCS surgeries (174 initial, 17 replacements, 12 revisions), and 317 IT pump system surgeries (192 initial, 105 replacements, 20 revisions). Of those procedures, 546 were performed before the implementation of the IPB (pre-IPB), and 615 were performed after the implementation of the IPB (post-IPB) (**Tables 1–3**, **Figure 1**).

Table 3. Incidence of Implant-Related Infections per Surgical Case Type with 1-Year Postoperative Surveillance

	Pre-IPB		Post-IPB		Pre-IPB		Post-IPB	
Surgical Cases	Number of Patients	Infections (%)	Number of Patients	Infections (%)	Unique Surgical Cases	Infections (%)	Unique Surgical Cases	Infections (%)
All DBS cases	188	3 (1.6%)	198	**1 (0.5%)**	298	4 (1.3%)	343	**1 (0.3%)**
Electrode cases	76	2 (2.6%)	72	**0 (0%)**	106	2 (1.9%)	116	**0 (0%)**
New implants	67	1 (1.5%)	70	0 (0%)	93	1 (1.1%)	106	0 (0%)
Replacements	4	1 (25%)	4	0 (0%)	4	1 (25%)	4	0 (0%)
Revisions	8	0 (0%)	5	0 (0%)	9	0 (0%)	6	0 (0%)
DBS IPG cases	112	2 (1.8%)	126	**1 (0.8%)**	192	2 (1.0%)	227	**1 (0.4%)**
New implants	54	2 (3.7%)	63	**1 (1.6%)**	89	2 (2.2%)	96	**1 (1.0%)**
Replacements	53	0 (0%)	68	0 (0%)	88	0 (0%)	121	0 (0%)
Revisions	12	0 (0%)	7	0 (0%)	15	0 (0%)	10	0 (0%)
All SCS cases	51	0 (0%)	58	**0 (0%)**	98	0 (0%)	105	**0 (0%)**
New implants	40	0 (0%)	47	0 (0%)	80	0 (0%)	94	0 (0%)
Replacements	9	0 (0%)	8	0 (0%)	9	0 (0%)	8	0 (0%)
Revisions	9	0 (0%)	3	0 (0%)	9	0 (0%)	3	0 (0%)
All IT pump cases	93	8 (8.6%)	100	**2 (2.0%)**	150	13 (8.7%)	167	**3 (1.8%)**
New implants	44	3 (6.8%)	52	**1 (1.9%)**	88	5 (5.7%)	104	**2 (1.9%)**
Replacements	52	5 (9.6%)	53	**1 (1.9%)**	52	8 (15.4%)	53	**1 (1.9%)**
Revisions	10	0 (0%)	10	0 (0%)	10	0 (0%)	10	0 (0%)

Bold values indicate marked reductions in % infections in the post-IPB period.
IPB, infection prevention bundle; DBS, deep brain stimulation; IPG, implantable pulse generator; SCS, spinal cord stimulator; IT, intrathecal.

Postoperative Follow-Up

The mean follow-up time was 32 months (range, 24–53months) in the pre-IPB group and 20 months (range, 12–31months) in the post-IPB group. In patients with IT pump delivery systems for intractable cancer-related pain, follow-up time was limited because of cancer-related deaths (9 of 12 in the pre-IPB group and 1 of 2 in the post-IPB group). As such, the follow-up times in this subgroup ranged from 4 to 36 months in the pre-IPB group and 3 to 15 months in the post-IPB group.

Incidence of Infection and Infection Surveillance Periods

The overall infection rate for all surgical case types (i.e., SCS + DBS + IT pumps) was 2.9% in the pre-IPB group and 0.2% in the post-IPB group when infections occurring within 90 days from surgery were considered and 3.1% in the pre-IPB group and 0.7% in the post-IPB group when infections occurring within 1 year from surgery were considered (Table 2). The average time from surgery to SSI was 1.3 months in the pre-IPB group and 4.2 months in the post-IPB group (Table 4).

When a 90-day infection surveillance period was used, the incidence of infection in the pre-IPB group was 0%, 1%, and 8.7% for SCS, DBS (stages I + II), and IT pump cases, respectively. By contrast, the post-IPB infection rates were 0%, 0%, and 0.6% for SCS, DBS (stages I + II), and IT pump cases, respectively. When a 1-year infection surveillance period was used, the incidence of infection in the pre-IPB group was 0%, 1.3%, and 8.7% for SCS, DBS (stages I + II), and IT pump cases, respectively. By contrast, the post-IPB infection rates were 0%, 0.3%, and 1.8% for SCS, DBS (stages I + II), and IT pump cases, respectively (Table 2, Supplementary Table 1 and Supplementary Figure 1).

Surgical Site Infection-Causative Organisms

Under the 1-year infection surveillance period, the infectious agents identified included *Staphylococcus aureus* (3), *Staphylococcus epidermidis* (4), *Escherichia coli* (2), *Enterobacter aerogenes* (1), *Corynebacterium jeikeium* (1), *Morganella morganii* (1), *and Pseudomonas aeruginosa* (3), *Propionibacterium granulosum* (1) (Table 4).

Initial Implantations versus Replacement Surgeries

The infection rates for initial implantations were 0% for SCS systems (n = 80), 1.1% for DBS for electrodes (n = 93), 2.2% for IPGs (n = 89), and 5.7% for IT pump systems (n = 88) in the

Table 4. Characteristics of Infected Patients in Pre-IPB and Post-IPB Groups

Study Period	Patient	Sex	Age	Implant Type	Infected Surgical Site(s)	Time to SSI (months)	Organism(s)
Pre-IPB	P1	F	48	ITP	Lumbar wound	1.0	*Pseudomonas aeruginosa*
Pre-IPB	P2	M	42	ITP	IT catheter, pump	0.5	*Pseudomonas aeruginosa, Staphylococcus epidermidis*
Pre-IPB	P3	F	30	ITP	Lumbar wound	0.5	No growth at explant
Pre-IPB	P3	F	30	ITP	IT catheter, pump	1.1	No growth at explant
Pre-IPB	P4	F	60	ITP	IT catheter, pump	1.3	*Enterobacter aerogenes*
Pre-IPB	P5	M	66	ITP	IT catheter, pump	0.3	*Escherichia coli*
Pre-IPB	P6	F	25	ITP	IT catheter, pump	0.4	*Escherichia coli*
Pre-IPB	P7	M	37	ITP	IT pump	2.1	*Staphylococcus epidermidis*
Pre-IPB	P8	M	24	ITP	IT pump	1.5	No growth at explant
Pre-IPB	D1A	M	73	DBS	Electrode, IPG	0.9	MRSA
Pre-IPB	D2A	M	81	DBS	Electrode	0.2	*Morganella morganii*
Pre-IPB	D3B	M	72	DBS	IPG	**5.7**	*Staphylococcus aureus Corynebacterium jeikeium*
Post-IPB	P9	F	57	ITP	IT catheter, pump	**4.9**	*Pseudomonas aeruginosa*
Post-IPB	P10	F	31	ITP	IT pump	2.9	No growth at explant
Post-IPB	D4B	M	64	DBS	IPG	**4.7**	*Staphylococcus epidermidis Propionibacterium granulosum Klebsiella oxytoca*

Time in bold type = time greater than 90 days or 3 months.
IPB, infection prevention bundle; SSI, surgical site infection; IT, intrathecal; DBS, deep brain stimulation; MRSA, methicillin-resistant *Staphylococcus aureus*; IPG, implantable pulse generator.

pre-IPB group and 0% for SCS systems (n = 94), 0% for DBS electrodes (n = 106), 1% for IPGs (n = 96), and 1.9% for IT pump systems (n = 104) in the post-IPB group (Table 3, Figure 1).

The infection rates for replacement surgeries were 0% for SCS systems (n = 9), 25% DBS electrodes (n = 4), 0% IPGs (n = 88), and 15.4% for IT pump system components (n = 52) in the pre-IPB group and 0% for SCS systems (n = 8), 0% for DBS electrodes (n = 4), 0% for IPGs (n = 121), and 1.9% IT pump system components (n = 53) in the post-IPB group (Table 3, Figure 1).

Risk Factors

There was no significant difference in sex distribution or age between the groups. The diagnoses or indications for surgery included movement disorders (e.g., Parkinson disease, essential tremor, dystonia), spasticity (secondary to cerebral palsy, spinal cord injury, stroke, and multiple sclerosis), and intractable cancer-related pain.

Three patients in the pre-IPB DBS group (3 of 188) required wound debridement and hardware removal from 4 distinct surgical sites. One of these patients experienced an infection after having undergone multiple surgeries for revision, removal, and replacement of a malfunctioning thalamic electrode within a period of 1 month. Given the low incidence of infection in the DBS group, it was not possible to assess the contribution of risk factors (e.g., diagnosis, comorbidities). Similarly, there were no infections in the SCS group; therefore, contribution of risk factors to incidence of infection was not necessary.

The incidence of infection was highest for the IT pump system groups, with a total of 13 SSIs (8 of 93 patients) in the pre-IPB group and 3 SSIs (2 of 100 patients) in the post-IPB group. This difference was significant when pre-IPB and post-IPB IT pump system cases were compared by unique surgical site ($P = 0.012$) but not when they were compared by number of patients ($P = 0.086$). Obesity (body mass index >30 kg/m^2) and a history of previous hardware-related SSI were associated with a higher incidence of infection in both the pre-IPB and post-IPB groups, but this did not reach statistical significance ($P = 0.65$ and 0.72, respectively). Other risk factors associated with a higher incidence of infections included neurogenic bowel/bladder, cerebral palsy, and history of quadriparesis/quadriplegia, although similarly these did not reach statistical significance (Table 5).

DISCUSSION

The infection rates were lower for both pre-IPB and post-IPB groups when the new 90-day infection surveillance period recommended by the CDC National Healthcare Safety Network[17] was used, compared with the previous recommendation of a 1-year surveillance for procedures involving implants.[19] Consistent with the 2018 report by Abode-Iyamah et al.,[20] our findings suggest that use of the shorter infection surveillance period of 90 days may underestimate the incidence of implant-related infections and ultimately lead to loss of opportunities in the identification of risk factors and interventions to prevent or mitigate these infections.

Table 5. Baseline Demographics, Risk Factors, and Incidence of SSI with 1-Year Surveillance Protocol for Patients with IT Pump Systems

	Pre-IPB Group		Post-IPB Group	
Characteristic	**All Patients**	**Infected Patients**	**All Patients**	**Infected Patients**
No. of patients (%)	93 (100%)	8 (8.6%)	100 (100%)	2 (2.0%)
Average age (years)	46 ± 16	39 ± 15	47 ± 14	44 ± 18
Sex (M:F)	58:35	4:4	64:36	0:2
Characteristic	**Total Patients**	**Infected Patients (%)**	**Total Patients**	**Infected Patients (%)**
Previous implant revision (noninfectious)	2	0 (0%)	8	0 (0%)
Previous implant-related SSI	1	**1 (100%)**	4	**1 (25%)**
Obesity (BMI >30 kg/m^2)	22	**4 (18.2%)**	15	**1 (6.7%)**
Diabetes	4	0 (0%)	9	0 (0%)
Paraplegia	29	**2 (6.9%)**	31	1 (3.2%)
Quadriplegia/quadriparesis	51	**5 (9.8%)**	67	1 (1.5%)
Neurogenic bowel/bladder	66	**8 (12.1%)**	66	2 (3.0%)
Spinal cord injury	32	**2 (6.3%)**	44	0 (0%)
Cerebral palsy	24	**4 (16.7%)**	24	1 (4.2%)
Demyelinating disorder	19	1 (5.3%)	26	1 (3.8%)
History of stroke, ICH	13	**1 (7.7%)**	14	0 (0%)
Cancer	16	**1 (6.3%)**	5	0 (0%)
Statin use	12	0 (0%)	19	0 (0%)

Bold values indicate the risk factors associated with >6% infections in both pre-IPB and post-IPB periods.
IPB, infection prevention bundle; SSI, surgical site infection; BMI, body mass index; ICH, intracerebral hemorrhage.

There were no infections in the SCS group in either the pre-IPB or the post-IPB periods. This may be related to the fact that several of the items included in the IPB were already being used in this group before April 2015. For the staged DBS cases, only 1 infection occurred after implementation of the IPB such that the overall infection rate decreased from 1.3% (4/298) to 0.3% (1/343) after its application ($P = 0.293$). The infection rate for the IT pump system group decreased from 8.7% to 1.8% after implementation of the IPB ($P = 0.012$).

There was a higher incidence of infections in the IT pump system replacement group (15.4%, n = 52) compared with initial placements (5.7%, n = 88) in the pre-IPB study period. This higher incidence of infection for implant replacements is consistent with various reports.[2,5,6] There was also a higher incidence of infections for electrode replacement surgeries (25%, n = 4) compared with initial placements (1.1%, n = 93) in the pre-IPB study period, although this large difference is likely related to the small number of electrode replacement surgeries (Figure 1, Table 3). It is also important to note that the 1 patient in whom an infection occurred after electrode replacement surgery had undergone multiple surgeries for revision, removal, and replacement of a malfunctioning thalamic electrode within a period of 1 month. All IPG SSIs occurred after initial IPG implantation surgeries (2 in the pre-IPB and 1 in the post-IPB study periods), and none occurred after IPG replacement surgeries, in contrast to previous reports.[2,5,6]

Overall, the infection rates for IT pumps were higher than for other implant groups. It is possible that the higher incidence of infections observed in the IT pump system groups was related to the patients' comorbidities, inasmuch as there was a trend toward a higher incidence of infections in patients with obesity (body mass index >30 kg/m^2), neurogenic bowel and bladder, history of cerebral palsy, and limited mobility from quadriparesis/quadriplegia, although this did not reach statistical significance (Table 4).[21-24] We also speculate that the higher incidence of infections in the IT pump system groups could be related to the use of silk sutures for anchoring the device, because all pump implants were anchored with 2–0 silk sutures, whereas the rest of the implants were anchored with 2–0 Vicryl sutures. Surgical silk is a braided and black dyed suture derived from the silkworm larva that has been shown to induce a strong host inflammatory response[25,26] and has been associated with late abscess formation.[27]

Study Limitations

Although based on a high volume of surgical procedures from a single center and by a single surgeon, thus limiting practice-related variables, this study is limited by its retrospective nature. It is possible that some patients may have moved away or sought care by other providers, which could lead to underestimation of infection rates in either group. In patients with IT pump delivery systems for intractable cancer-related pain, follow-up times were limited because of cancer-related deaths (9 of 12 in the pre-IPB group and 1 of 2 in the post-IPB group). However, after adjustment for the number of deaths in each group, the infection rate in the pre-IPB IT pump group increased to 9.2%, whereas the infection rate in the post-IPB group remained unchanged at 1.8%.

The protocols listed in our study were developed before the publishing of the updated Neurostimulation Appropriateness Consensus Committee consensus guidelines; as such, some items deviate from the published recommendations. For instance, several of our practice habits, including some components of our IPB, such as the use of vancomycin/gentamicin for preoperative prophylaxis and the use of vancomycin irrigation, were acquired over the years and were originally based on our experience with specific high-risk patient populations. Although in our cohort we did not identify any antibiotic-related complications, we realize that this practice raises concerns for the possible development of antibiotic resistance. We have since modified our protocols to more closely follow the Neurostimulation Appropriateness Consensus Committee published guidelines.

Finally, the low incidence of infection during both pre-IPB and post-IPB periods precluded the proper evaluation of risk factors in the current study, which emphasizes the need for future prospective large volume studies.

CONCLUSIONS

This study represents the most comprehensive report to date on the use of an IPB approach for implantable neuromodulation devices. Implementation of a standardized IPB reduced the number of infections after implantation and replacement of DBS system components, SCS system components, and IT drug delivery systems. This is a simple approach that can be easily customized and adopted within any branch of neurosurgery and across specialties to potentially decrease the incidence of implant-related infections and improve patient outcomes. This work will add to the growing literature on risk factors for infectious complications and infection prevention strategies as applied to neuromodulation therapies with implanted neurologic devices. This is of special relevance because the implementation of best practices to minimize implant-related infections is necessary to help ensure cost effectiveness and continued access to these therapies.

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