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Root cause analysis of epidural spinal cord stimulator implant infections with resolution after implementation of an improved protocol for surgical placement

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Forest W Arnold[1,2], Sarah Bishop[2], David Johnson[3], LaShawn Scott[2], Crystal Heishman[2], Leah Oppy[2], Tyler Ball[4], Mayur Sharma[4], Claudia Angeli[5], Christie Ferreira[6], Yangsheng Chen[6], Susan Harkema[4,5,6] and Maxwell Boakye[4]

Abstract

Background: Placing a spinal stimulator for the purpose of restoring paralysed function is a novel procedure; however, paralysis predisposes people to infection. Preventing surgical site infections is critical to benefit this population.

Objective: The objective of this study was to review the root cause analysis of postoperative wound infections by a hospital epidemiology team following implantation of epidural spinal cord neurostimulators in patients with chronic spinal cord injury.

Methods: A team was assembled to review the case of every individual who had been enrolled to receive a neurostimulator at the facility. A root cause analysis was performed evaluating five categories: the patient; equipment; facility/environment; procedure; and personnel.

Findings: The root cause analysis included 11 patients. Two patients became infected. Three others dehisced their wound without becoming infected. All patients were given preoperative antibiotics on time. A mean of 17 personnel were in the operating room during surgery. Vancomycin powder was used in the patients who either dehisced their wound or became infected.

Conclusions: The root cause analysis provides guidance for other institutions performing the same novel procedure. This analysis did not reveal a direct association, but did generate several areas for improvement including increasing pre-surgical screening, cleaning transient equipment (e.g., computer screens), limiting traffic in the operating room, using new sterile instruments for each stage of the procedure, not reopening the back incision, not applying vancomycin powder, and using an antimicrobial envelope for the stimulator.

Keywords

Neurostimulator, postoperative wound infection, root cause analysis

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[1]Division of Infectious Diseases, Department of Medicine, School of Medicine, University of Louisville, Louisville, KY, USA
[2]Infection Prevention and Control Department, University of Louisville Hospital, Louisville, KY, USA
[3]Quality Management Department, University of Louisville Hospital, Louisville, KY, USA
[4]Department of Neurosurgery, School of Medicine, University of Louisville, Louisville, KY, USA
[5]Frazier Rehab Institute, Louisville, KY, USA
[6]Kentucky Spinal Cord Injury Research Center, University of Louisville, KY, USA

Corresponding author:
Forest W Arnold, Division of Infectious Diseases, Department of Medicine, School of Medicine, University of Louisville, 501 E. Broadway, Suite 140 B, Louisville, KY 40202, USA.
Email: f.arnold@louisville.edu

Background

An epidural spinal stimulation implant is a device that is surgically inserted in the epidural space between the spinal lamina and the dorsal spinal cord in an effort to stimulate the ability to walk again or perform other activities of daily living. It sends electrical impulses to the spinal neuronal networks to modulate nerve impulses and behaviour. Although it has been used as standard of care for treating many types of chronic pain, it is currently a novel means of restoring function in patients with longstanding paralysis after spinal cord injury (Harkema et al., 2011). The team at this university hospital has had the opportunity to participate in early feasibility studies involving epidural spinal cord stimulator implantation (Angeli et al., 2014). Spinal cord stimulator infections (placed for any indication) have been in the range of 2.5–19% (Bendel et al., 2017; Siddiqui et al., 2010).

Despite an increased expectation of infections among this population, three individuals with postoperative dehiscence and another with a wound infection raised concern, so that an internal review was performed. The patient who prompted the investigation had a *Staphylococcus aureus* infection that was treated with cefepime and vancomycin until methicillin-sensitive *S. aureus* (MSSA) was identified, after which time treatment was narrowed to nafcillin and rifampin for six weeks. He responded to treatment without device removal. The data safety monitoring board (DSMB) was contacted who recommended further investigation by an infectious disease specialist and the hospital Department of Infection Prevention and Control to assess issues and institute changes before the next surgery.

The hospital epidemiologist assembled a team from the Infection Prevention and Control and Quality Management Departments. The team observed practice in the operating room (OR) during the next surgery. Three weeks after that surgery, the patient presented with redness and ultimately was diagnosed with a surgical site infection with subsequent removal of the stimulator. Even though the stimulator was apparently working well enabling the previously paralysed patient to move voluntarily and stand unassisted, it was necessary to remove it to clear her infection. Her cultures grew MSSA. She was initially treated with meropenem and vancomycin until the pathogen was identified, at which time she was de-escalated to ceftriaxone for six weeks.

The closest protocols available to apply to these patients use data from populations requiring spinal stimulators for pain management (American Society of Anesthesiologists Task Force, 2017; Provenzano et al., 2016; Rudiger and Thomson, 2011), until now. The objective of this study was to report the root cause analysis performed by the hospital epidemiology team of the individuals who received an epidural spinal cord stimulator implantation in order to establish a protocol to prevent and minimise infections.

Methods

Individuals were reviewed who had been a part of one of either spinal stimulator studies at the University of Louisville between December 2009 and September 2015 (IRB nos. 13.0265 and 07.0066). Practice related to infectious diseases from the preoperative period (e.g. screening for infections), the operative period (e.g. surgical antibiotic prophylaxis) and the postoperative period (e.g. dressings and follow-up) were reviewed.

The infection team performed a thorough, systematic root cause analysis seeking details related to five categories: patient; equipment; facility/environment; procedure; and personnel. The research team and the epidemiology team identified 36 variables to query for the 11 study participants (Appendix A).

Antibiotic surgical prophylaxis was administered to the patient before the procedure and was continued for up to 24 h. The procedure included two stages. During stage 1, after routine sterile preparation and draping, the stimulating electrode (Medtronic specify 5-6-5, Minneapolis, MN, USA) was implanted at the T11-L1 epidural space using a dorsal midline incision with the patient in a prone position. The wound was then closed. The exact placement of the stimulator electrode was guided by intraoperative electrophysiological testing using surface-mounted electrodes on lower extremity musculature as previously described (Harkema et al., 2011). Following wound closure, the patient was then rolled onto his or her side in a lateral decubitus position. During stage 2, an incision of 5–6 cm was made in the abdomen and a subcutaneous pocket was created for the stimulator battery. The back wound was reopened and wires from the stimulator were tunnelled from the back to the abdomen through subcutaneous tissue for connection to the battery, which was placed in the subcutaneous pocket. Both wounds were then closed. Electrical impulses to the spinal cord could subsequently be generated using an external remote control device.

Initially, simulators arrived in sterile packaging. Preparation of the OR included moving a multichannel electromyography (EMG) system MA400-28 (Motion Labs Systems, Baton Rouge, LA, USA) with a radiologic C-arm into place. The EMG system includes a customised data-acquisition system, which captures stimulator pulses through a sterilized multi-lead trialling cable (Medtronic 355531, Minneapolis, MN, USA). EMG signals were then synchronized with the stimulator pulse during the intraoperative electrophysiological testing process. Sterile surgical instruments were placed on a table that was pushed to the side between stages and covered with a sterile drape.

Participants were evaluated for infection using the National Health Safety Network (NHSN) surveillance definition (Appendix B). They were also evaluated for a clinical diagnosis of infection based on record review of physician assessments.

Table 1. Epidemiologic information of the 11 participants.

Patient no.	Age (years)	Sex	Weight (kg)	Surgeon	Surgery duration (h:min)	Postoperative dehiscence	Postoperative infection
1	23	M	88	A	2:08	N	N
2	24	M	95	A	3:14	N	N
3	32	M	98	A	3:34	N	N
4	28	M	65	A	2:30	N	N
5	26	M	66	B	3:48	Y	N
6	31	M	65	B	3:28	N	N
7	23	M	83	B	4:06	N	N
8	34	M	55	B	3:10	Y	N
9	23	M	86	B	3:28	Y	N
10	30	M	77	B	3:09	N	Y
11	28	F	82	B	4:16	N	Y

Results

Eleven individuals were reviewed in the root cause analysis. Two participants (10 and 11) were identified with a surgical site infection using NHSN criteria. Identifying infected individuals clinically yielded the same two patients. The incisions of three additional individuals dehisced and required interventions (participants 5, 8 and 9); wound cultures showed no growth. None of them was considered infected using clinical or NHSN criteria. Epidemiologic information of the 11 individuals is summarised in Table 1. No patients had diabetes mellitus. Most participants were male. The single woman was one of the infected individuals (participant 11). The infected patients weighed similarly to the others. The primary surgeon changed after the first four procedures. All preoperative antibiotics were administered within the required time frame before the incision. All participants received cefazolin except one who received vancomycin (participant 2). The duration of surgery was in the range of 2 h 8 min to 4 h 16 min. The two infected individuals had the fifth shortest and the longest durations of surgery, respectively. OR room 5 was used for seven of the 11 patients, including the two infected participants. The mean number of personnel in the OR room was 17. Vancomycin powder was used in seven patients, including both infected individuals (participants 10 and 11) and the three patients who had dehiscence of their surgical wound (participants 5, 8 and 9). The postoperative dressings used were either Tegaderm™ and/or Dermabond®. The dressing used was not documented in four participants, including one of the infected individuals (participant 11). None of the lot numbers or identification numbers of any equipment used for any of the procedures in any patient matched those used for any other patient. No participants received blood product transfusions. All individuals finished 24 h of postoperative antibiotics and were discharged home rather than to another facility (e.g. rehabilitation). Environmental testing is not routine at the hospital, therefore bacterial testing was not performed.

Discussion

We identified five areas of potential infectious exposures for patients having spinal stimulator implantation. In chronological order, they addressed preoperative screening, equipment disinfection, the number of personnel and traffic in the OR, operative procedures and wound care. Of the five areas identified, no one cause with a strong association was identified.

The first finding addressed preoperative practice to prevent infection. Baseline laboratory investigations before surgery already included a complete blood count, comprehensive metabolic profile, albumin, transthyretin, vitamin D, a urinalysis and a urine culture. Inflammatory markers at baseline may be relevant if an individual becomes infected later. If participants are carriers of methicillin-resistant *S. aureus* (MRSA) or multidrug-resistant Gram-negative bacteria, they may be predisposed to postoperative infections; therefore, they should be screened. They may then be decolonised or the anticipated prophylactic antibiotic may be altered accordingly. Literature supports decolonisation for MRSA (Bode et al., 2010; Schweizer et al., 2015; Thompson and Houston, 2013). A chlorhexadine bath as part of the preoperative activities may prevent cryptic MRSA from manifesting as a postoperative infection. In

light of these issues, we recommended adding a C-reactive protein, procalcitonin and an erythrocyte sedimentation rate to the screening labs, and to screen for MRSA with a nasal swab as well as multidrug-resistant Gram-negative bacteria with a peri-rectal swab before surgery to direct surgical prophylactic antibiotics.

The second finding addressed equipment disinfection. OR staff confirmed that electromyography equipment (other than the single-use, pre-packaged wires) used in the OR was not cleaned between uses. Any reusable patient care equipment requires appropriate disinfection between uses. Additionally, this equipment is not necessarily stored in the OR and must travel throughout the facility before entering the surgical suite. The electromyography equipment in question is considered non-critical patient care equipment and requires low-level disinfection between patient uses, per Centers for Disease Control and Prevention (CDC) standards (Rutala et al., 2017). This hospital has approved PDI® Sani-cloth AF3 germicidal disposable wipes (Professional Disposables International, Inc., Orangeburg, NY, USA) that are available in the OR and should be utilised for routine disinfection of non-critical patient care items between patient uses. Computer screens may be cleaned with PDI Easy Screen cleaning wipes (PDI, Orangeburg, NY, USA). We verified that these disinfection products are appropriate to use for the equipment and screens, respectively. We recommended that the electromyography equipment undergo an additional cleaning before crossing the clean 'red line' in the OR hallway on the way to the surgical suite since it is not stored in the operating department and travels through the hospital environment.

The third finding addressed OR personnel and OR traffic. It appeared to us that there were too many people in the OR over the course of each procedure. The procedure is unique and interesting, which draws additional people into the OR. Some were just coming in for supplies for a procedure in another OR room. Regardless of the reason for entry, wafting of the air is not desirable. Air is a potential source of microorganisms that can contaminate surgical wounds. Because microbial shedding increases with activity, greater amounts of airborne contamination can be expected with increased movement of surgical team members (Edmiston et al., 1999). Movement, talking and uncovered skin areas can contribute to airborne contamination. Only crucial personnel should be present during the procedure (Association of periOperative Registered Nurses [AORN], 2018). Doors to the OR should remain closed during the procedure (AORN, 2018). Any personnel needing to enter or exit the surgical suite should do so through the sterile core. Furthermore, all required equipment and supplies should be present before the start of the procedure in order to reduce additional movement in and out of the surgical suite. We recommended limiting the number of personnel permitted in the OR and limiting access into the OR during both stages of the procedure. For the purposes of this study, we considered crucial personnel as: neurosurgeons (n = 2); equipment representative (n = 1); study team members (n = 3–4); scrub nurse (n = 1); circulating scrub nurse (n = 1); anaesthesiologists (n = 2); radiologist (n = 1); and an infection preventionist (n = 1).

The fourth finding addressed surgical issues. In general, using the same instruments for stage 1 and again for stage 2 may not be ideal. Instruments are routinely reused in the OR for other multi-staged procedures but changing out the instruments between stages of this particular procedure was seen as a potential opportunity to prevent infection. Changing them was verified to be a feasible option in the OR at this hospital. Additionally, because of the movement and increased intraoperative traffic observed during the repositioning of the individual during the procedure, there was a potential risk for contamination of any uncovered sterile equipment. It was determined that instrumentation had been laid out for stage 2 at the start of stage 1. We recommended separating sterile instruments for stages 1 and 2 of the procedure. This could be accomplished by placing stage 2 instruments in the room before stage 1 and allowing them to remain in sterile packaging until the patient was repositioned and it was time to use them.

We did not identify any specific cause for infection related to surgical technique, but we discussed with the surgeons whether there was an option to change their practice of reopening the stage 1 back incision again in stage 2. They developed a method to tunnel wires from the spine to the flank during stage 1. Then, during stage 2, they would retrieve the wires by making a small flank incision and tunnel them to the battery in the abdomen, which was also placed during stage 2.

The fifth finding addressed intraoperative and postoperative wound care. The postoperative dressings were difficult to assess for increased infection risk because there was no group to which to compare since every individual had one. Vancomycin powder, on the other hand, was only used in six of the 11 patients (allowing comparison to the other five). Infections or dehiscence occurred in most participants who received vancomycin powder (five of six individuals). Several meta-analyses have been performed, which concluded that vancomycin powder appears to be safe and effective, but the paucity of data is of poor quality and spans over decades during a time when procedures and surgical antibiotics also changed making it impossible to make a strong recommendation (Chiang et al., 2014; Ghobiral et al., 2015; Hurias et al., 2012). One meta-analysis, which supports the use of vancomycin powder, rated it with primarily level III evidence (Bakhsheshian et al., 2015). Nevertheless, it may be secondarily associated with infections if it causes dehiscence or seromas that predispose to an infection. An alternative to vancomycin powder is to use an antibiotic-impregnated dressing. Medtronic makes an antibacterial envelope (TYRX™ Neuro Absorbable Antibacterial Envelope - Medtronic,

Table 2. Summary of interventions to prevent surgical-associated infections.

• Limit the number of people in the OR
• Limit access (i.e. tape the doors) to the OR during the entire procedure (stage 1 and stage 2) – utilise sterile core access if entrance/exit is required
• Switch to new sterile instruments for stage 2 of the procedure (and have them in the OR and covered before stage 1)
• Clean the electromyography equipment and screens with disposable wipes (such as PDI® Sani-cloth AF3 germicidal wipes; PDI, Orangeburg, NY, USA) before taking equipment into the operating room
• Add pre-screening laboratory tests, including inflammatory markers and swabs for MRSA and multidrug-resistant Gram-negatives
• Decolonise MRSA patients, retest and repeat if necessary (see above)
• Have each patient cleanse skin (neckline to toes) with a 2% chlorhexadine bath wipe one week preoperatively and on the morning of surgery
• Do not use vancomycin powder
• Instead of reopening back incision during stage 2, tunnel wires to flank during stage 1 and retrieve through small flank incision during stage 2
• Use a TYRX™ Neuro Absorbable Antibacterial Envelope in the abdominal pouch site

Minneapolis, MN, USA) for use with implantable stimulators. This product contains minocycline and rifampin which has been shown to reduce medical device implant infections (Kolek et al., 2015). We recommended not utilising vancomycin powder and to use the antibacterial envelope in the abdominal pouch site.

Follow-up and future management

Subsequent management incorporated the interventions (Table 2) that our root cause analysis helped us identify as potential reasons for postoperative wound infections. Some interventions were based on concepts that limit the spread of infections in general when working in a sterile surgical environment, but others were specific to this unique procedure. Three additional individuals have received spinal stimulators as part of the continuation of the same research studies. Compliance with all of the recommendations was carried out and verified. None of the three patients were colonised with multidrug-resistant bacteria. At the time of this writing, the patients are at postoperative days 380, 338 and 30, respectively without evidence of infection.

Conclusion

Due to the significance of the neurostimulator surgery being performed to provide functional and quality-of-life improvements to paralysed people, and due to the consequences of developing an infection in a population who is immunocompromised, the hospital epidemiologist and the Infection Prevention and Control Department were involved at an early stage. In this particular study, three patients had dehiscence followed by two more who had postoperative wound infections. We did not identify a 'smoking gun' in this case, but limiting traffic in the OR, ceasing to use vancomycin powder and changing the incisions during the procedure may have contributed the most to control postoperative infections.

Declaration of conflicting interests

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ORCID iD

Forest W Arnold https://orcid.org/0000-0002-9279-2046

Supplemental material

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