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Editorial

Recommendations for Reducing Infection in the Practice of Implanting Spinal Cord Stimulation and Intrathecal Drug Delivery Devices: A Physician's Playbook

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In this edition of Pain Physician, the article "Infectious Complications Related to Intrathecal Drug Delivery System and Spinal Cord Stimulation System Implantations at a Comprehensive Cancer Pain Center" is published. This information, written by Engle et al (1) adds insight and awareness to the problem of infection with implantable devices. In this retrospective review, 131 patients with 142 devices (58% intrathecal drug delivery devices and 42% spinal cord stimulator systems) were examined for surgical site infections (SSIs). Although 80% of study patients had a diagnosis of cancer, the overall infection rate was 2.8% and in line with other studies examining infections in individuals treated with implantable pain therapies for nonmalignant pain. Limited data exist for SSI rates associated with implantable pump therapies; however, the 2.8% infection rate reported here is lower than the infection rate range of 3.4% to 4.6% reported in 2 large systematic reviews on spinal cord stimulator systems for nonmalignant pain conditions (2,3). In addition, Engle et al (1) reported that all device infections occurred at the pulse generator or pump pocket site. Follet et al (4) also reported a higher risk of infection at the pocket site for implantable devices, with 72% of infections for implantable pump therapies and 54% of spinal cord stimulation system infections occurring at the pocket site.

SSIs represent approximately 22% of all health care associated infections, and a majority of these infections are thought to be acquired during surgery (5,6). An infection of an implantable pain therapy results in a poor outcome for all involved. Most importantly, it is a troubling problem for the patient who suffers the infection, but also for the physician, insurer, and society. The need to implant a device is a serious decision and is taken as an important part of the multimodal pain treatment algorithm. In this retrospective review, Engle et al (1) attempt to identify factors that may specifically lead to a higher risk for implantable pain therapy SSIs. As we continue to advance the field of implantable pain therapies, it is important to identify these factors so that modifications in practice can be taken to improve complication rates. Although the sample size was small, one factor was identified as a statistically significant risk factor for SSI: extended surgical time. Others have also identified prolonged operative time in the field of spine surgery as an independent risk factor for postoperative infection (7,8).

Unfortunately, limited research specific to SSIs associated with implantable pain therapies currently exists to help guide the field of interventional pain medicine. Although implantable pain therapy literature is limited on this topic, extrapolation of well-developed practices from other surgical fields can be used at this time to help guide infection control practices. We believe it is now a good time to reflect on these methods. In order to establish a center of clinical excellence in neuromodulation, a careful analysis of the literature suggests some key points that an implant program

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should offer to achieve the best outcomes in infection control. These infection prevention practices can be divided into preoperative, intraoperative, and postoperative measures (Table 1).

In the preoperative stage, known patient risk factors (e.g., tobacco utilization, altered immunity, periodontal disease, diabetes, and obesity) for the development of SSIs should be identified and modified. Perioperative glucose control is imperative. Greater than 80% of health care related Staphylococcus aureus infections are endogenous from the patient (9). Therefore, preoperative screening for methicillin sensitive and methicillin resistant Staphylococcus aureus nasal carriers is recommended (9-14). Decolonization protocols for carriers, including mupirocin nasal ointment and chlorhexidine washings, should be employed. Prophylactic antibiotic therapy under appropriate time parameters with weight-based dosing should be used and has been shown to result in an approximately 50% reduction in the incidence of wound infections independent of surgery type (15,16). In a majority of cases, a single dose of a cephalosporin is recommended. Vancomycin should not be routinely utilized and is indicated for individuals with a beta-lactam allergy, methicillin-resistant Staphylococcus aureus (MSRA) colonization, recent admission to a long-term care facility or nursing home, or if a surgical procedure is being performed in a facility with a recent outbreak of MRSA (17). Although postoperative antibiotics for 7 days were used in the Engle et al (1) study, no advantages have been documented for continued postoperative antibiotic use following routine surgical intervention. Furthermore, literature from other surgical specialties has demonstrated this practice may worsen clinical outcomes (18-21). Further research is warranted to determine if exceptions are needed when implanting high risk individuals such as the studied cancer patients.

Intraoperative practices that should be employed include appropriate skin preparation agent selection. The surgical prep should be wide and well outside the surgical area. Chlorhexidine alcohol preparations have been shown to be superior to povidone-iodine based agents and are associated with lower SSI rates (22). Chlorhexidine and povidone-iodine based products are often combined with isopropyl alcohol. Operating room traffic should be limited. The use of fluoroscopy is mandatory for implantable pain therapy surgical operations. The intraoperative fluoroscopy device (i.e., C-arm) should be draped in a sterile cover. Even though the fluoroscopy machine is draped it should not be considered sterile. Biswas et al (23) demonstrated that the C-arm drape becomes contaminated at multiple locations during spine surgery. Surgical technique should be optimized to achieve hemostasis, minimize devitalized

Table 1. *Methods to decrease the rate of implantable pain therapy surgical site infections*

Preoperative	Intraoperative	Postoperative
- Identifying patient risk factors	- Appropriate agent selection for skin antisepsis	- Occlusive dressing for a minimum of 24 to 48 hours
- Optimization of immune and nutritional status	- Wide prep and drape	- Attention to tape allergies and skin irritants
- Optimizing comorbidities such as diabetes, immunosuppression, and dental disease	- Operating rooms with laminar flow and HEPA filters	- Continued comorbidity optimization
- Preoperative screening and decolonization for SA carriers	- Limit OR traffic	- Education regarding fever and warning signs of early infection
- Appropriate selection of intravenous antibiotic prophylaxis based on hospital pathogens	- Adequate hemostasis	- Close postoperative wound surveillance
- Weight-based dosing antibiotics	- Limit tissue trauma and avoid the electrocautery at tissue surface	- Consult with an infectious disease specialist if any sign or warning signals of infection are present
- Appropriate hair removal	- Vigorous wound irrigation	
- Evaluation for skin lesions or areas of local infection	- Careful attention to wound closure and careful tissue approximation	
	- Limit surgical time	

SA = Staphylococcus Aureus; HEPA = High-Efficiency Particulate Air; OR = Operating Room

tissue, and eliminate dead space at the surgical site (24). Also the surgeon should strive to minimize the surgical time. Prior to closure and insertion of the spinal cord stimulator generator or pump, wound irrigation should be used to remove foreign material, debris, and blood clots. Irrigation containing antibiotics has not been shown to positively influence infection rates when compared to normal saline solution only, but many physicians prefer adding antibiotic agents such as bacitracin to the irrigation (25-27). Vigorous irrigation appears to be the critical component to improving outcomes regardless of the solution preference. A multilayer surgical incision closure is recommended. Tissue tension should be avoided, especially at the generator and implantable pump sites, to avoid wound breakdown and necrosis. Once closure is completed an occlusive sterile dressing should be used for a minimum of 24 to 48 hours (28,29).

Postoperatively, the patient should be evaluated for wound healing within the first 10 days of the implant, when possible. If a dressing change is required during the postoperative period, sterile technique is recommended. If there is any evidence of skin irritation, erythema, or swelling more careful follow-up is required. If there is any concern of a superficial infection, incision and drainage should be considered and augmented with appropriate antibiotic treatment. In some cases, an elliptical skin excision of tissue may salvage a system. If the infection appears to be deeper in the tissue and close to the implantable device, the old surgical adage should be followed that "when in doubt, take it out." Once the infection is successfully treated, the device can then be replaced at a period of 12 weeks if all factors that increased the risk for infection are controlled. Consultation with an infectious disease specialist should be considered prior to re-implant if possible.

In conclusion, it is of paramount importance that pain physicians who manage implantable pain therapies have a strong understanding of SSI prevention and control. The study by Engle et al (1) serves as a starting point for further research specific to implantable pain therapies that identifies risk factors for SSIs in high risk populations. Hopefully this study will encourage others to further explore methods to improve SSIs rates associated with implantable pain therapies. The use of logical medical practice and attention to detail can markedly improve the outcomes with implantable devices. The recommendations in this communication are based on general principles for controlling SSIs. The failure to follow evidence-based recommendations for preventing infection may lead to adverse outcomes, device explants, and failure of implant programs to remain viable. It should be noted, that in the best of hands and the ideal circumstances, infections will still occur. The purpose of this editorial communication is to provide comment on the actions that physicians can take to minimize this devastating complication and to help protect patients in the United States and in the world wide community.

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