

# COMPLICATIONS

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# "An ounce of prevention is worth a pound of cure." Benjamin Franklin



- Device Vs Biologic
  - Device related:
    - Lead migration
    - Lead breakage
    - Disconnection
    - Over/under stimulation
    - Hardware malfunction
    - Battery failure
    - Failure to communicate with IPG

- Biologic:
  - Infection
  - Bleeding (hematoma)
  - Thrombotic events
  - Seroma
  - Nerve damage
  - CSF leakage
  - Pain over IPG
  - Allergic reaction



## **DEVICE RELATED**

- More frequent than biologic
- Lead migration: Most common 13% 22%
  - More with cylindrical leads than paddle leads
  - Loss of therapeutic effect
  - May require revision
- Lead fracture/disconnect: 5.9% 9.1%
- Battery failure: 1.7%
  - Depletion before expected date
  - Unable to charge (loss contact, flipped)



# DEVICE RELATED

Prevention

- Adequate patient selection
- Adequate device selection (knowledge of +/- different dev
- Patient education
- Acquire skills and become proficient:
  - ACGME requirement 5 cases. However 56% of graduated fellows comfortable implanting
  - Training via fellowship, societies, industry
- Preoperative planning
  - IPG location. Consider depth (1.5 2.5 cm) and placing sutures to IPG.
  - Consider referral to paddle lead placement if needed
- Anchoring:
  - Mechanical better?, use non-absorbable suture (Ethibond)



### BIOLOGIC COMPLICATIONS

### OPICS Non-CME Webinar Series designed with the trainee in mind

first Tuesday of the month

## INFECTION

- Incidence 2-10%
- Types:
  - Superficial
  - Deep
  - Epidural Abscess
- Most common location: Pocket
- Most common bacteria: Staph aureus and Strep epidermidis
- Risk factors:
  - Patient: immunosuppression (HIV, steroids), diabetes, tobacco abuse, and obesity
  - Provider: pocket too big, extensive tissue damage, prolonged surgical time, poor hemostasis, poor sterile technique, OR traffic, inadequate antibiotic dose/timing.



NACC 2021 : Recommendations for Surgical Techniques for Neurostimulation

Deer et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation. 2022 Jan;25(1):1-34. doi: 10.1016/j.neurom.2021.10.015. PMID: 35041578.

PAIN

MEDICINE



- Read and follow CDC, WHO, NICE and NACC guidelines for SSI
  - Adequate antibiotic prophylaxis alone reduces 50% of wound infections.
- Blood sugar
  - CDC: <200mg/dl perioperatively
  - American Diabetes Association: A1C target <7%
    - Consider delaying procedure if A1C >8%
  - American College of Surgeons:
    - Immediate postoperative period: 110-150 mg/dl
- Smoking cessation at least 4 weeks before procedure, ideally 8 weeks.
- Smaller incisions with just the adequate exposure
- Avoid excessive electrocautery (reduce tissue trauma)
- Maintain hemostasis (prevent hematoma)



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Table 4. Recommended Infection-Management Practices with Defined Origin of Practice.

Statements	Origin of recommended practice*	Evidence levels <sup>†</sup>	Recommendation strength	Consensus strength
Preoperative practices				
Identify and treat all remote infections for neuromodulation trials and implants	CDC IA	II-2	В	Strong
Optimize glucose control for neuromodulation implants	CDC IA	II-2	В	Strong
Discontinue tobacco use for neuromodulation implants	CDC IB	II-2	В	Strong
Decolonize MSSA and MRSA carriers through the application of mupirocin nasal ointment and chlorhexidine baths	NICE	I	A	Strong
Use preoperative antibiotics for neuromodulation trials and implants	CDC IB and NICE	I	А	Strong
Use preoperative weight-based antibiotic dosing for neuromodulation trials and implants	CDC IB and NICE	I	А	Strong
Use appropriate preoperative timing (within 1 h before surgical incision excluding vancomycin) of prophylactic antimicrobial administration for neuromodulation trials and implants	CDC IB, NICE, and SCIP	I	A	Strong
All patients should bathe or shower and use regular or antimicrobial soap the day before or day of surgery	CDC IB, NICE, and WHO	I	В	Strong
Remove hair (when required) with electric clippers immediately before the surgical procedure	CDC IA and NICE	I	А	Strong
Perform preoperative surgical scrub for a minimum of 2 to 5 min with an appropriate antiseptic before neuromodulation trials and implants	CDC IB and NICE	II-2	В	Strong
Keep nails short and do not wear artificial nails for neuromodulation trials and implants	CDC IB and NICE	II-3	В	Strong
Do not wear hand or arm jewelry for neuromodulation trials or implants	CDC IB and NICE	Ш	В	Strong

Prevention

PAIN

THE ASSOCIATION OF

MEDICINE

Deer et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation. 2022 Jan;25(1):1-34. doi: 10.1016/j.neurom.2021.10.015. PMID: 35041578.

A REAL	HOT Non-CME Well TOPICS designed with t	<b>pinar Ser</b> he trainee	ies in mir	nd	ASR	
	first Tuesday of the	month		-	PAIN PRO	GRAM DIRECTORS
	<ul> <li>Intraoperative practices</li> <li>Wear a surgical mask for neuromodulation trials and implants</li> </ul>	CDC IB	II-3	В	Strong	notion
	Wear a cap or hood to fully cover hair for	CDC IB	II-3	В	Strong	Prevention
	neuromodulation trials and implants Use sterile gown and gloves for neuromodulation trials and implants	CDC IB	II-3	В	Strong	
	Double glove	CDC II and NICE	II-1	В	Strong	
	Use alcohol-based CHG for preoperative skin antiseptic agent. If chlorhexidine is contraindicated, use alcohol- based solution of povidone-iodine	CDC IA and NICE	I	A	Strong	
	If an incise drape is used, then an iodophor-impregnated drape for neuromodulation implants is recommended	NICE	I	А	Strong	
	Use laminar flow and HEPA filters in OR for neuromodulation implants	CDC IB	I.	А	Strong	
	Limit procedure room traffic for neuromodulation trials and implants	CDC II and NICE	I.	А	Strong	
	Keep procedure room doors closed during neuromodulation trials and implants	CDC IB	II-3	В	Strong	
	Limit tissue trauma, maintain hemostasis, eradicate dead space, and avoid electrocautery at tissue surface	CDC IB and NICE	Ш	В	Strong	
	Irrigate with saline through a bulb syringe before closure of surgical wound	NICE	T	В	Moderate	Deer et al. The Neurostimulation
	Use implant strategies to limit operative time		II-2	В	Strong	Appropriateness Consensus
	Postoperative practices				2	Committee (NACC):
	Apply an occlusive dressing following neuromodulation trials and implants for 24 to 48 h	CDC IB and NICE	II-2	В	Strong	Recommendations for Surgical Technique for Spinal Cord
	Do not routinely use topical antimicrobial agents for surgical wounds that are healing by primary intention	NICE	1	В	Strong	Stimulation. Neuromodulation. 2022 Jan;25(1):1-34. doi:
	Understand maximum time criterion for defining a deep SSI of an implantable device (1 y post implant)	CDC	Ш	В	Strong	10.1016/j.neurom.2021.10.015. PMID: 35041578.

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#### Table 4. Continued

Statements	Origin of recommended practice*	Evidence levels <sup>†</sup>	Recommendation strength	Consensus strength	Prevention
Do not continue antibiotics into the postoperative period for neuromodulation trials and implants beyond 24 h	SCIP	I	А	Strong	
Educate patient and family on proper incision care, symptoms of SSI, and importance of reporting symptoms	CDC II and NICE	Ш	В	Strong	
Wash hands before and after dressing changes	CDC IB	III	В	Strong	
Use sterile technique for dressing changes	CDC II and NICE	III	В	Moderate	
When SSI is suspected, prescribe an antibiotic that covers the likely causative organisms. Consider local resistance patterns and culture results in choosing an antibiotic	NICE	Ш	В	Strong	
HEPA, high efficiency particulate air; MSSA, methicillin-sensitive S aure	<i>eus</i> ; NICE, National Institute	for Health and Care	Excellence; OR, operating	g room; SCIP,	

Surgical Care Improvement Project.

\*The origin of recommended practice defines the supporting surgical guideline.

<sup>+</sup>I: at least one controlled and randomized clinical trial; II-1: well-designed, controlled, nonrandomized clinical trials; II-2: cohort or case studies and well-designed controls, preferably multicenter; II-3: multiple series compared over time, with or without interventions, and surprising results in noncontrolled experiences; III: clinical experience-based opinions, descriptive studies, clinical observations, or reports of expert committees. Adapted from Deer et al.43

> Deer et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation. 2022 Jan;25(1):1-34. doi: 10.1016/j.neurom.2021.10.015. PMID: 35041578.

PAIN

EDICINE



# Epidural hematoma

- Anesth incidence 1 in 150,000
  - Neuromod 0.01% 0.3% (bigger needle, paddle lead?)
- Anticoagulants Did not hold or not enough time
- 37% of patients without antithrombotic therapy.
- Spinal stenosis: most common spinal disease related wit epidural hematoma (check your images before neuraxial Px)
- Extensive thin-walled valve-less venous plexus.
  - Fragility increases with age
  - Plexus distention close to segments of central canal stenosis
- Other risk factors: Thrombocytopenia, CKD, liver disease, INR>1.5, surgical scarring at the area of insertion.
- If not identified/treated promptly, can lead to severe neurological symptoms with paresis or paralysis. 0.03%



# Epidural hematoma

- Early identification
  - Focal back pain
  - Lumbar radiculitis
  - Weakness
  - Incontinence (bowel or bladder)
- Coordinate with Emergency medicine, Radiology, Neurosurgery.
- MRI or CT scan
- Ideally, surgical evacuation < 12 hours





## THROMBOTIC EVENTS

- Chronic pain is a hypercoagulable state
  - Increase fibrinogen and factor VII
  - Reduce fibrinolytic activity and prostacyclin
  - Increased platelet activity
- Holding anticoagulants
  - Trial and permanent
- Discontinuation of ASA -> Rebound effect on TXA2 production
  - Increased risk of MI day 8<sup>th</sup> when used for secondary prophylaxis.
- Warfarin initial protein C inhibition.



## THROMBOTIC EVENTS

- Always discuss with prescribing physician
- Avoid stopping anticoagulation
  - DVT 3 months
  - MI 3 months (if DES placement, 6-12 months)
  - Stroke 9 months
- Consider bridging: Mechanical heart valve, Hx of VTE while on anticoagulation and CHADSVASc score >6
- Consider a shorter trial (72 hours)





### DURAL PUNCTURE

- Incidence 0.2 3%
- Risk factors: Spinal stenosis at entry, obesity and spinal deformities
- PDPH:
  - Positional headache, diplopia, tinnitus, neck pain, photophobia,
  - Females 11.1% > Males 3.6%
  - Young 11% > older than 50 years old 4.2%



### DURAL PUNCTURE

prevention,

- Review imaging before procedure
  - Avoid entering on level with stenosis
- Use fluoroscopy to advance needle
- Avoid turning needle beyond 90 degrees inside the epidural space
- Treat conservatively first
  - Fluid, supine position, caffeine
  - Prophylactic blood patch not recommended
  - Consider SPG block.
- Blood patch could be attempted, discussion of risk/benefit should be held with patient



### NERVE INJURY

- Up to 2.35%
- Risk factors: previous surgery at the site of needle placement, spinal canal stenosis, and spinal deformity
- Direct injury:
  - Needle puncture
  - Lead placement (percutaneous/paddle)
- Delayed:
  - Epidural hematoma
  - Abscess
- Can leave sequalae with sensorimotor deficits, paralysis, and/or neuropathic pain



### **NERVE INJURY**

- Review advanced imaging (MRI) avoid stenosis level
- Use fluoroscopy to advance needle.
- Avoid deep sedation or general anesthesia (decreases feedback from patient)
  - Consider neuromonitoring if they are needed.



Thank you!