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How to prevent complications of Interventional Pain Procedures

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Conflicts of Interest

Speaker for:

-Abbott

-Promedica Europe

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AGENDA

- Introduction
- Complications in Interventional Pain Procedures
- Avoiding Complications – Spinal Cord Stimulation
- Conclusion

Open Access Full Text Article

Interventional Pain Procedu
Review Focusing on Safety
Part I Injections for Spinal

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Abstract: In recent years, there has been a considerable increase in the num
the management of acute and chronic pain. Concomitantly, there has also
procedures. The aim of this narrative review is to summarize the primary comp
(fluoroscopic- or ultrasound-guided) interventional procedures. We conclud
dures can be mitigated to a certain degree, they cannot be eliminated altogeth
given considerable attention and physicians should be constantly aware of th

Keywords: chronic pain, pain management, analgesics, opioid, epidural

Introduction

Recent years have witnessed a significant increase in image-guided
and chronic pain.[1–3] However, an increase in the number of com
observed, varying from minor to severe and debilitating.[4–6] The e
low (under 1%) but it is probably underestimated since they are u
injections have been reported as well but the exact mortality rate
procedures).[7] It is estimated that over 9 million epidural injections
joint interventions increased 1.9% annually and 18.8% in total fr
Medicare patients compared with an annual increase of 17% and a
order to avoid adverse events, physicians should be mindful of pat
selection and preparation, are of fundamental importance to ensu
regular education, training, and international certification for heal
disciplinary teams, can also help to minimize the risk of advers
procedures, the number of infiltrative techniques has increased sig
opment of techniques using ultrasound-guidance has allowed their
outpatient settings.[9]

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Neuromodulation: Technology at the Neural Interface

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The Neurostimulation Appropriateness Consensus Committee (NACC)®: Recommendations for the Mitigation of Complications of Neurostimulation

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ABSTRACT

Introduction: The International Neuromodulation Society convened a multispecialty group of physicians based on expertise and international representation to establish evidence-based guidance on the mitigation of neuromodulation complications. This Neurostimulation Appropriateness Consensus Committee (NACC)* project intends to update evidence-based guidance and offer expert opinion that will improve efficacy and safety.

Materials and Methods: Authors were chosen on the basis of their clinical expertise, familiarity with the peer-reviewed literature, research productivity, and contributions to the neuromodulation literature. Section leaders supervised literature searches of MEDLINE, BioMed Central, Current Contents Connect, Embase, International Pharmaceutical Abstracts, Web of Science, Google Scholar, and PubMed from 2017 (when NACC last published guidelines) to October 2023. Identified studies were graded using the United States Preventive Services Task Force criteria for evidence and certainty of net benefit. Recommendations are based on the strength of evidence or consensus when evidence was scant.

Results: The NACC examined the published literature and established evidence- and consensus-based recommendations to guide best practices. Additional guidance will occur as new evidence is developed in future iterations of this process.

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cedures: A Narrative
ıfety and Complications.
Procedures For Back Pain

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com

iled to relieve from chronic pain, interventional procedures may be an een an increase in the use and development of invasive procedures. ations associated with these procedures. Taken this into consideration, it gilant approach, with a focus on patient safety, in order to minimize the e for the patient. This may include careful selection of patients for monitoring and follow-up after the procedure. The aim of this narrative l with commonly performed image-guided (fluoroscopy or ultrasound- reduce the risk of these complications. We conclude that although itigated to a certain degree, they cannot be eliminated altogether. In considerable attention and physicians should be constantly aware of the

plications, spinal cord stimulation, intrathecal drug delivery, low back

for the Study of Pain (IASP) such as "pain that persists or recurs ole or predominant clinical problem in some patients". The most hen conservative treatment fails to relieve pain, interventional nts. Recent years have witnessed a significant increase in image- agement of acute and chronic pain. However, rising numbers of n observed,[1,2] varying from minor to severe and debilitating.[3] ations which may occur following interventional procedures for been reported,[4–11] including infection and spinal cord infarction. ne interventions varies greatly and, although detailed evidence- ated with these procedures,[12] there are considerable variations in

significant **increase** in image-guided **interventional pain procedures**

an **increase in the number of complications related** to these procedures has also been observed, **from minor to severe**.

- **physician expertise**
- **patient selection** and **preparation**,

to ensure the safety of interventional pain procedures.

-**regular education/training**
- **international certification**
- **interdisciplinary teams**

- **balance potential risks and benefits of each procedure**
- carefully consider the individual patient's medical history and risk factors.

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Guidelines & Publications

Neuromodulation: Technology at the Neural Interface

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The Appropriat

CLINICAL STUDIES

SPINAL CORD STIMULATION IN TREATMENT OF CHRONIC BENIGN PAIN: CHALLENGES IN TREATMENT PLANNING AND PRESENT STATUS, A 22-YEAR EXPERIENCE

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OBJECTIVE: To present an in-depth analysis of clinical predictors of outcome including age, sex, etiology of pain, type of electrodes used, duration of pain, duration of treatment, development of tolerance, employment status, activities of daily living, psychological status, and quality of life. Suggestions for treatment of low back pain with a predominant axial component are addressed. We analyzed the complications and proposed remedial measures to improve the effectiveness of this modality.

METHODS: Study group consists of 410 patients (252 men, 58 women) with a mean age of 54 years and a mean follow-up period of 97.6 months. All patients were gated through a multidisciplinary pain clinic. The study was conducted over 22 years.

RESULTS: The early success rate was 80% (328 patients), whereas the long-term success rate of internalized patients was 74.1% (243 patients) after the mean follow-up period of 97.6 months. Hardware-related complications included displaced or fractured electrodes, infection, and hardware malfunction. Etiologies demonstrating efficacy included failed back syndrome, peripheral vascular disease, angina pain, complex regional pain syndrome I and II, peripheral neuropathy, lower limb pain caused by multiple sclerosis. Age, sex, laterality of pain or number of surgeries before implant did not play a role in predicting outcome. The percentage of pain relief was inversely related to the time interval between pain onset and time of implantation. Radicular pain with axial component responded better to dual Pisces electrode or Specify-Lead implantation.

CONCLUSION: Spinal cord stimulation can provide significant long-term pain relief with improved quality of life and employment. Results of this study will be effective in better defining prognostic factors and reducing complications leading to higher success rates with spinal cord stimulation.

KEY WORDS: Benign pain, Present status, Spinal cord stimulation, Treatment planning

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The Neurostimu
Consensus Com
for Infection Pr

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Research Article

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Pain Management

Long-term safety of spinal cord stimulation systems in a prospective, global registry of patients with chronic pain

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Neuromodulation: Technology at the Neural Interface

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Incidence of Lead Migration With Loss of Efficacy or Paresthesia Coverage After Spinal Cord Stimulator Implantation: Systematic Review and Proportional Meta-Analysis of Prospective Studies and Randomized Clinical Trials

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ABSTRACT

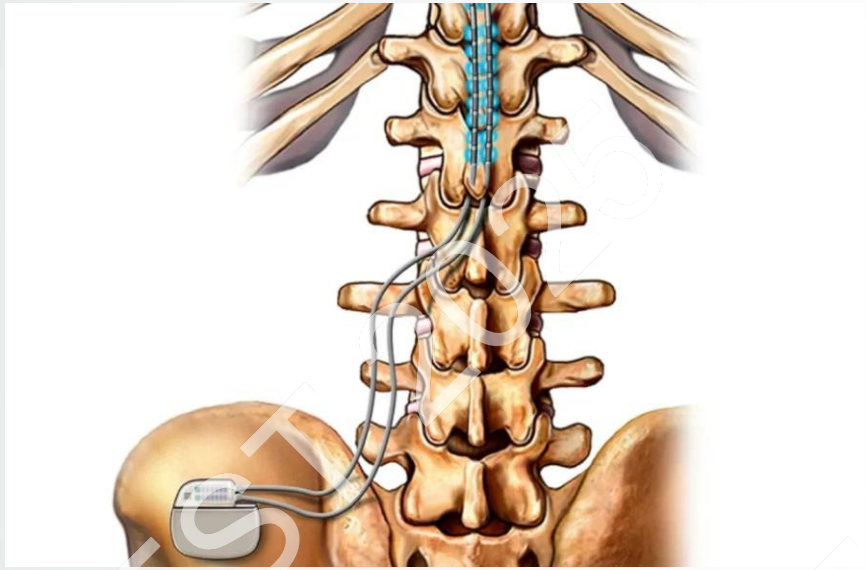
Objective: The objective of this meta-analysis was to approximate the incidence of overall lead migration, clinically significant lead migration, and asymptomatic lead migration in patients who have undergone spinal cord stimulator implantation.

Materials and Methods: A comprehensive literature search was performed for studies published before May 31, 2022. Only randomized controlled trials and prospective observational studies with more than ten patients were included. Two reviewers analyzed the articles from the literature search for final inclusion, after which, study characteristics and outcome data were extracted. The primary dichotomous categorical outcome variables were the incidence of overall lead migration, clinically significant lead migration (defined as lead migration resulting in loss of efficacy), and asymptomatic lead migration (defined as lead migration discovered incidentally on follow-up imaging) in patients with spinal cord stimulator implant. Freeman-Tukey arcsine square root transformation for meta-analysis of proportions using random effects (DerSimonian and Laird method) was used to calculate incidence rates for the outcome variables. Pooled incidence rates and 95% CIs were calculated for the outcome variables.

Results: Fifty-three studies met the inclusion criteria, with a total of 2932 patients having received spinal cord stimulator implants. The pooled incidence of overall lead migration was 9.97% (95% CI of 7.62%–12.59%). Only 24 of the included studies commented on the clinical significance of reported lead migrations, of which every lead migration was clinically significant. In these 24 studies, 96% of the reported lead migrations required a revision procedure or explant. Unfortunately, no studies that reported lead migration commented on asymptomatic lead migrations; therefore, the incidence of asymptomatic lead migrations could not be defined.

Conclusions: This meta-analysis found that the rate of lead migration in patients who have received spinal cord stimulator implants is approximately one in ten patients. This likely closely approximates the incidence of clinically significant lead migration owing to the included studies not routinely performing follow-up imaging. Therefore, lead migrations were primarily discovered owing to loss of efficacy, and no included studies clearly reported asymptomatic lead migration. The results of this meta-analysis can be used to inform patients more accurately on the risks and benefits of spinal cord stimulator implantation.

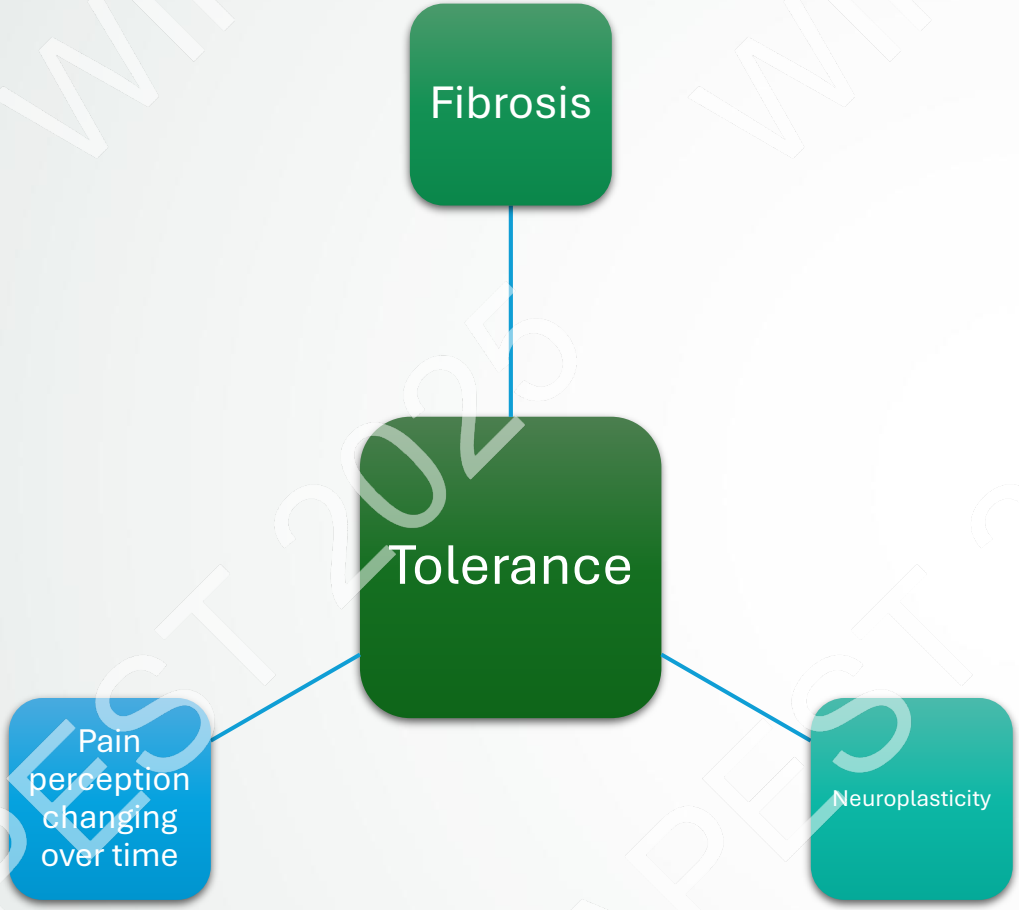
Biological Complications

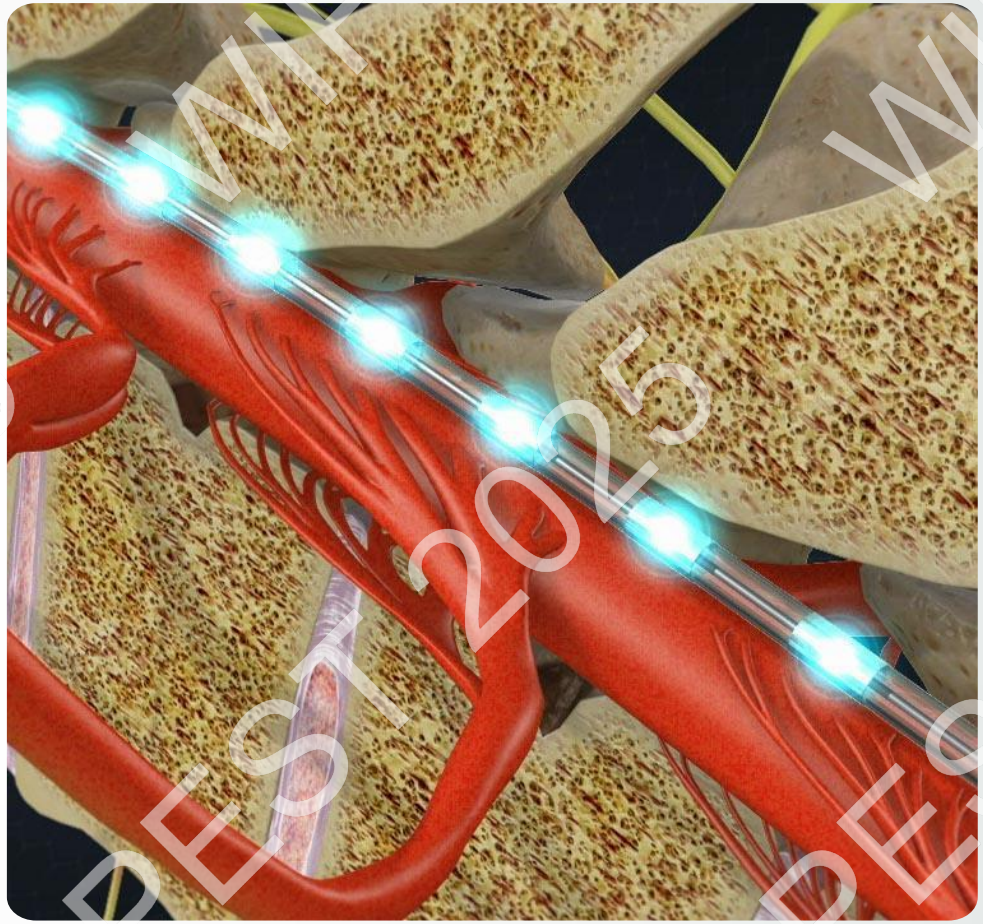


- **Immunologic reactions**
  - Contact dermatitis, granuloma, foreign body reactions
- **Seroma**
- **Hematoma**
- **Infection 3-5%**
- **Neurological injury**
- **Post dural puncture headache**
- **Wound dehiscence**
- **Visceral injury**

Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20- year literature review. *J Neurosurg* 2004;100:254–267
Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery. 2006 Mar;58(3):481-96; discussion 481-96. doi: 10.1227/01.NEU.0000192162.99567.96. PMID: 16528188.

Physiologic Complications





Hardware-related Complications

IPG-related problems:

- Twiddler syndrome
- Pocket pain
- Charging problems
- Battery failure
- Programming problems

Lead / Catheter fracture 5,9%, disconnection , occlusion

Lead / Catheter migration 5-10%

CLINICAL STUDIES

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Research Article
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Pain Management

Long-term safety of spinal cord stimulation systems in a prospective, global registry of patients with chronic pain

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Incidence of Lead Migration With Loss of Efficacy or Paresthesia Coverage After Spinal Cord Stimulator Implantation: Systematic Review and Proportional Meta-Analysis of Prospective Studies and Randomized Clinical Trials

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ABSTRACT

Objective: The objective of this meta-analysis was to approximate the incidence of overall lead migration, clinically significant lead migration, and asymptomatic lead migration in patients who have undergone spinal cord stimulator implantation.

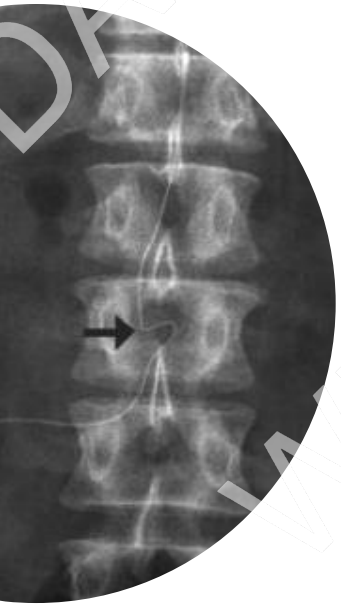
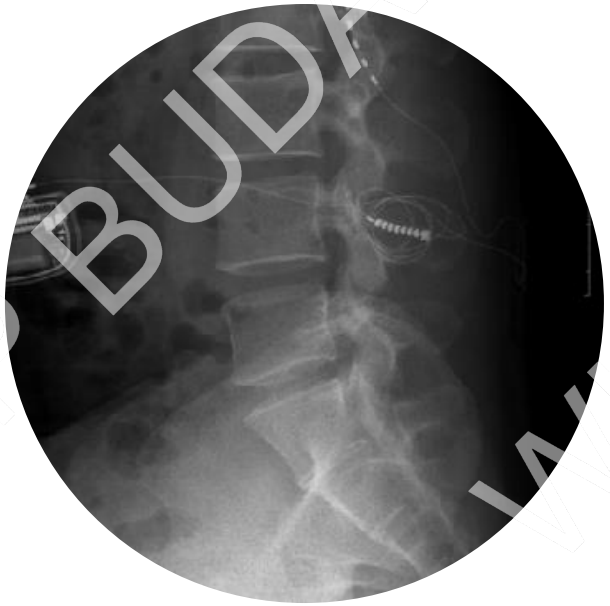
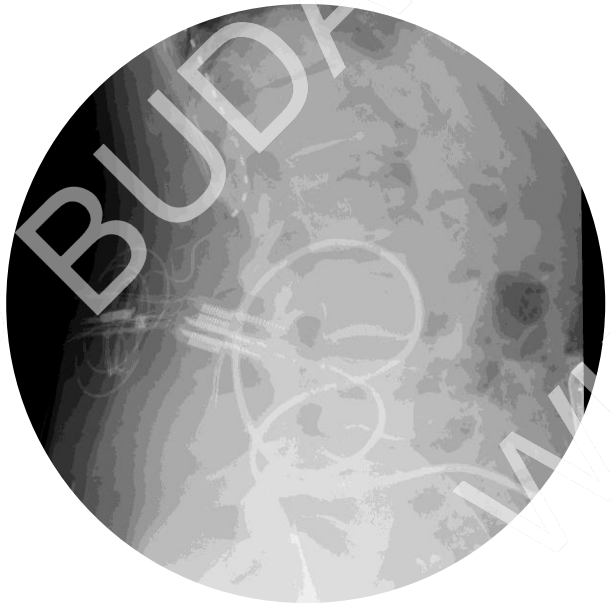
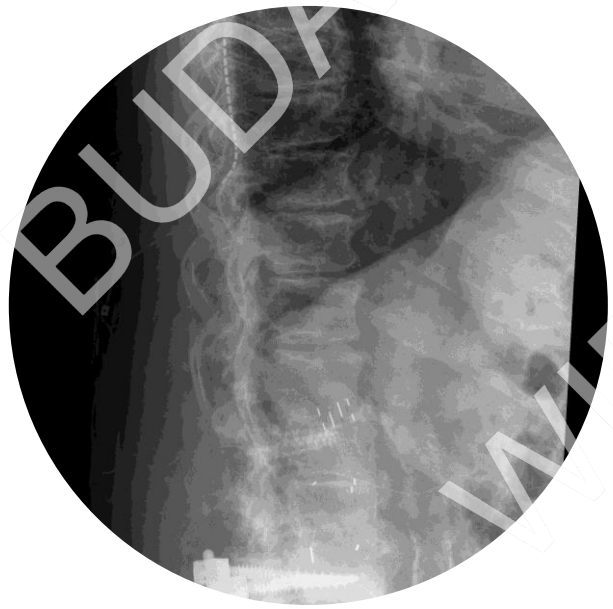
Materials and Methods: A comprehensive literature search was performed for studies published before May 31, 2022. Only randomized controlled trials and prospective observational studies with more than ten patients were included. Two reviewers analyzed the articles from the literature search for final inclusion, after which, study characteristics and outcome data were extracted. The primary dichotomous categorical outcome variables were the incidence of overall lead migration, clinically significant lead migration (defined as lead migration resulting in loss of efficacy), and asymptomatic lead migration (defined as lead migration discovered incidentally on follow-up imaging) in patients with spinal cord stimulator implant. Freeman-Tukey arcsine square root transformation for meta-analysis of proportions using random effects (DerSimonian and Laird method) was used to calculate incidence rates for the outcome variables. Pooled incidence rates and 95% CIs were calculated for the outcome variables.

Results: Fifty-three studies met the inclusion criteria, with a total of 2932 patients having received spinal cord stimulator implants. The pooled incidence of overall lead migration was 9.97% (95% CI of 7.62%–12.59%). Only 24 of the included studies commented on the clinical significance of reported lead migrations, of which every lead migration was clinically significant. In these 24 studies, 96% of the reported lead migrations required a revision procedure or explant. Unfortunately, no studies that reported lead migration commented on asymptomatic lead migrations; therefore, the incidence of asymptomatic lead migrations could not be defined.

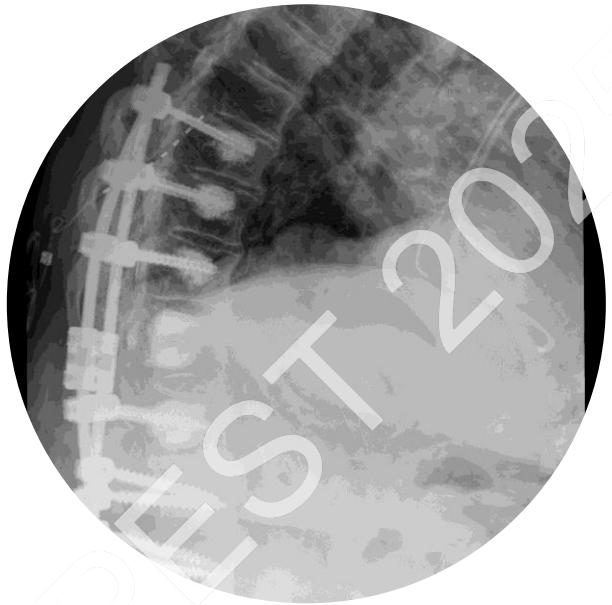
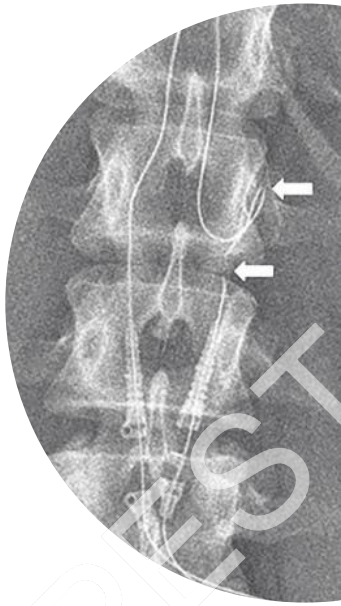
Conclusions: This meta-analysis found that the rate of lead migration in patients who have received spinal cord stimulator implants is approximately one in ten patients. This likely closely approximates the incidence of clinically significant lead migration owing to the included studies not routinely performing follow-up imaging. Therefore, lead migrations were primarily discovered owing to loss of efficacy, and no included studies clearly reported asymptomatic lead migration. The results of this meta-analysis can be used to inform patients more accurately on the risks and benefits of spinal cord stimulator implantation.

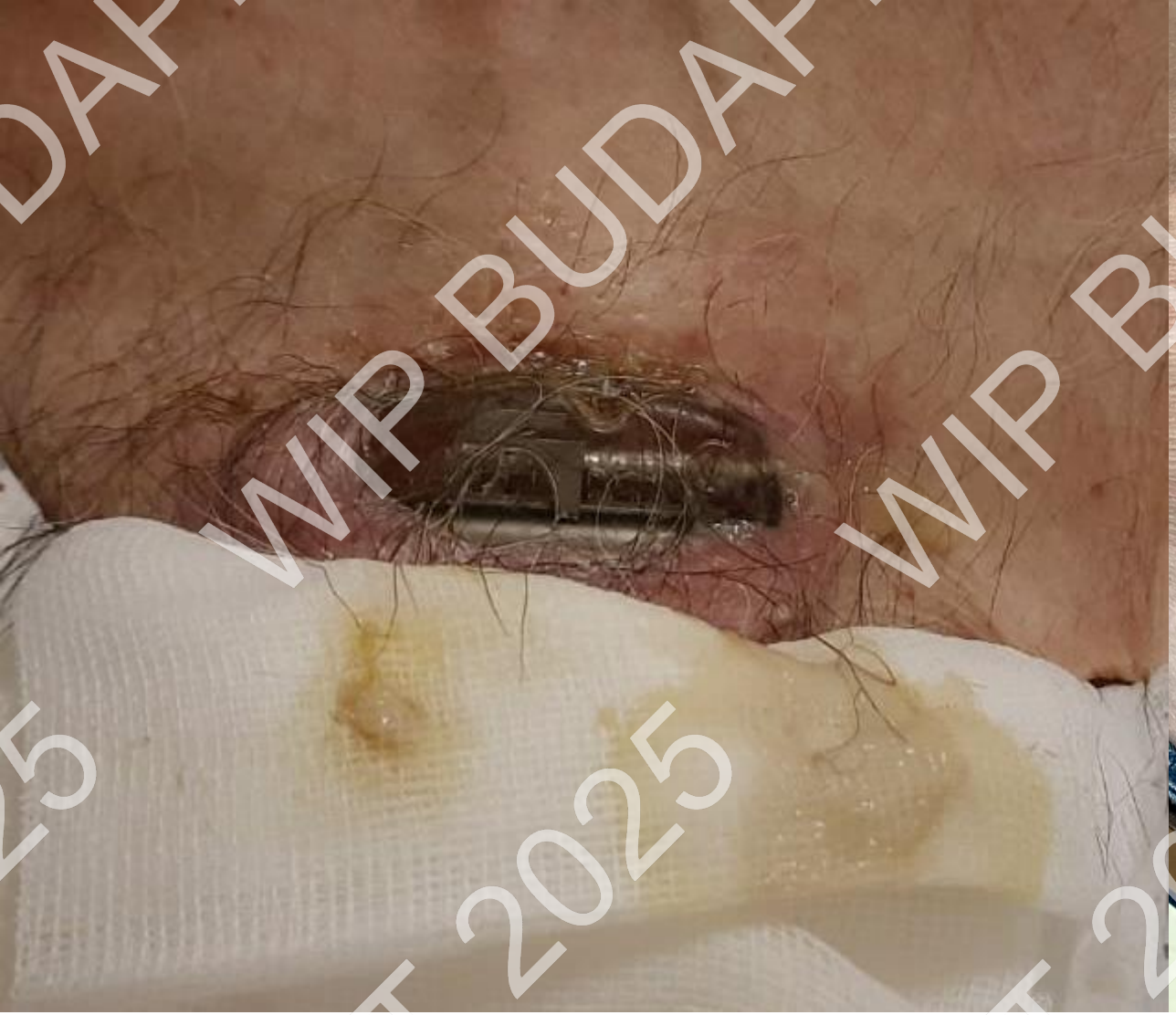
Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20- year literature review. *J Neurosurg* 2004;100:254–267

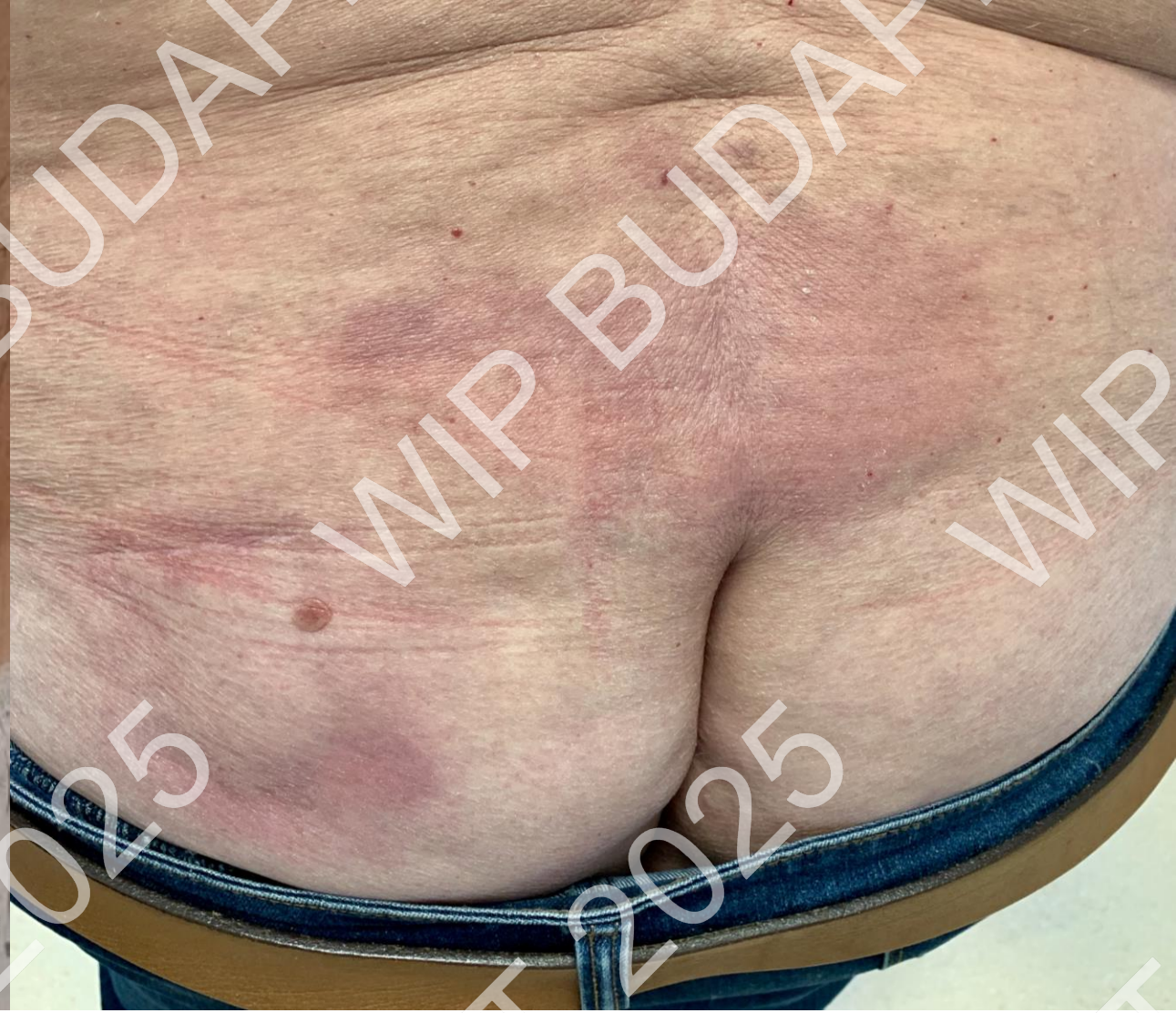
Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery. 2006 Mar;

Hardware-related complications – SCS





Hardware-related complications – SCS

AGENDA

- Introduction
- Complications in Interventional Pain Procedures
- Avoiding Complications – Spinal Cord Stimulation
- Conclusion

Risk reduction – NACC guidance

OPERATOR SKILLS

SCS ONLY AFTER FAILURE OF CMM; PRIOR TO REPEAT SURGERY AND / OR LONG-TERM OPIOID PRESCRIPTION

TRIAL WITH PROPER INTERPRETATION IS MANDATORY?

PSYCHOLOGICAL EVALUATION WITHIN A YEAR BEFORE SCS

WITHHOLD OR BRIDGE ANTICOAGULATION THERAPY

ACCREDITED STERILE ENVIRONMENT, SUCH AS A HOSPITAL SURGICAL SUITE

ATRAUMATIC NEEDLE PLACEMENT, JUDICIOUS USE OF FORCE WHEN PLACING PERCUTANEOUS LEADS; GOOD HAEMOSTASIS

IN CASE OF A SUSPECTED HAEMATOMA - IMMEDIATE NEUROLOGIC EVALUATION / URGENT CT SCAN

Preoperative planning

1. Select the **indication** correctly
2. **Optimize general health** and R/O contraindications
3. **Full explanation** of the procedure/stages/outcomes/restrictions.
4. Radiological information:
   - **Recent MRI** scan
5. **Level of entry** and **final position** of the lead
6. Select the **right technolog:**
   - type of lead
   - No of contacts,
   - Type of IPG
7. Decide and **mark the site** for IPG placement based on bony landmarks, body shape, clothing preference, joint mobility and cosmesis

Perioperative problems

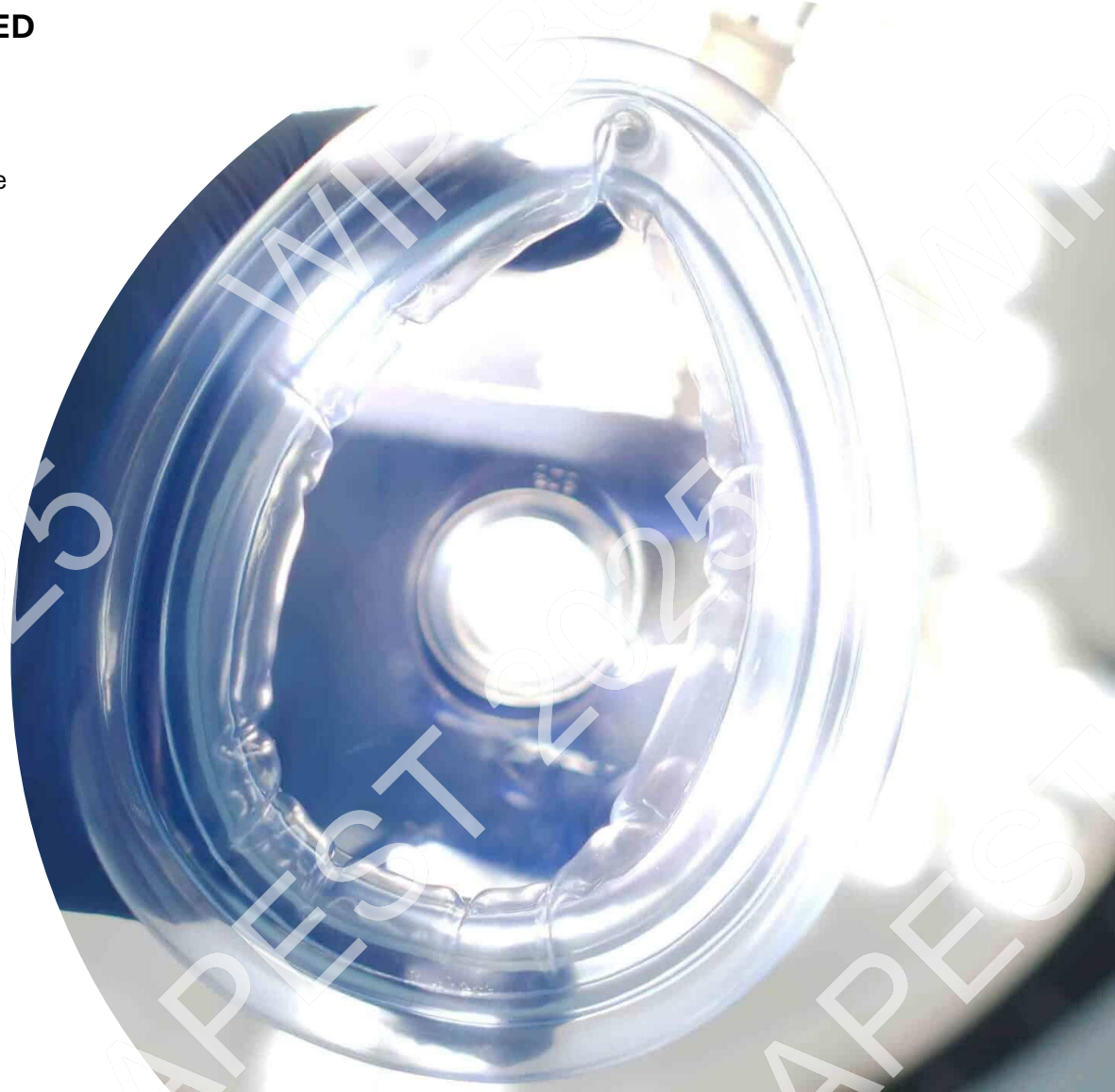
ANAESTHESIA / SEDATION RELATED

PATIENT RELATED / BIOLOGICAL

- Inability to access epidural space or reach the right target
- Inability to steer the lead to the desired target and side, ventral migration
- Inability to obtain desired concordant paraesthesia
- Epidural vein puncture
- Dural Puncture
- Haematoma
- Nerve/Spinal Cord Injury
- Infection

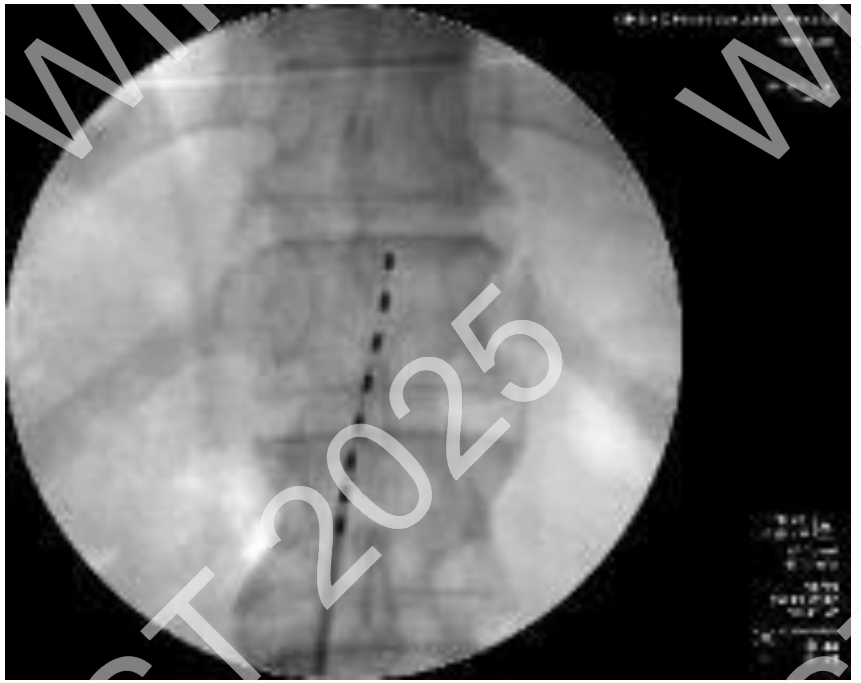
TECHNOLOGY RELATED

- Lead distortion or fracture
- Malfunction of screener
- Connection failure



Intraoperative issues: tips and troubleshooting

- Recheck all implant and equipment
- Proper patient position
- Meticulous asepsis
- Thorough anchoring to deep fascia and strain relief loop →
- Use permanent lead for trial when possible to avoid repeating the same process →
- Careful tunnelling →
- Proper layered closure to minimize dead space →
- Sterile occlusive dressing →



Consensus Point 20:

A surgical or single-stage trial may be safely considered because **the risk of SSI appears low.**

Permanent Trial

Incision

Incision (transverse vs. vertical) does **not** affect postoperative outcomes

Langer's lines may not be the best guide for incisions

Making incisions **as small as possible** to start & then extending as needed

Anchoring

Consensus Point 13:

- Familiarity with the **manufacturers' directions** for use.
- Recommendation grade **A**; level of certainty **high**; level of evidence **I**.

Consensus Point 14:

- **SCS leads**, either percutaneous or paddle, should be **anchored** to avoid migration.
- Recommendation grade **A**; level of certainty **high**; level of evidence **I**.

Consensus Point 15:

- Anchoring by using a **nonabsorbable** mechanism or suture.
- Recommendation grade **A**; level of certainty **high**; level of evidence **I**.

Consensus Point 16:

- Consideration of **mechanical anchors,** absence of high-level evidence.
- Recommendation grade **A**; level of certainty **high**; level of evidence **IC**.

Tunneling

The trocar should be inserted into either pocket at the level of the **floor of the pocket** & not in the middle of the subcutaneous tissues.

Placing a slight **bend in the shaft** will allow the operator to easily rotate the device & palpate the tip of the trocar to ensure appropriate depth.

Enter at the base of the pocket at an **angle** created to provide for a smooth exit of the leads out of the midline incision.

A **loop** of the electrode wires should be left in the lead incision.

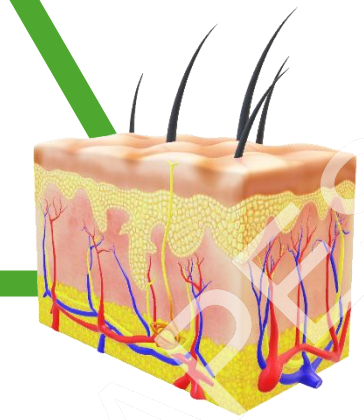
Tissue Dissection

Proper handling of instruments

Understanding of tissue planes

Skills of suturing & knot tying

Appropriate tissue handling & wound management



Consensus Point 12:

- Handle surgical tissue gently, identify appropriate tissues, limit tissue trauma, maintain hemostasis, avoid excessive electrocautery, & eliminate wound dead space.

Surgical Site Infection (SSI)

SSIs-An infection in the region of an implantable device within one postoperative year

80% is from body's own flora

Incidence – 4 - 10% Pocket vs Lead – 9:1

Superficial SSIs: the skin and subcutaneous tissue occur within 30 days after operation

Deep SSIs: the deep soft tissue (muscle and fascia) and epidural space-within 1 year

Organisms: Staphylococcus aureus and coagulase - negative staphylococci (e.g., Staphylococcus epidermidis), with Escherichia coli, and Pseudomonas aeruginosa being less common

Deer T.R., Provenzano D.A., Hanes M., Pope J.E. Mekhail N. 2017. The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management. Neuromodulation 2017

Surgical Site Infection

Patient - related Factors: Preexisting infection, patient population with risk factors

Surgical Preparation and Preoperative Planning!

Surgical and Operating Room Management - Antibiotics / Asepsis / Sterile dressing

Meticulous technique with reduced operative time

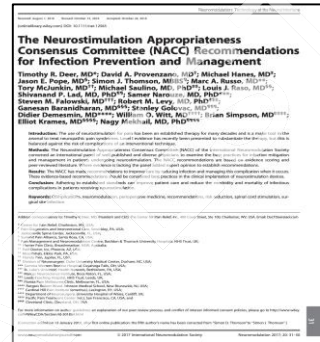
Contributors to spinal and multiple-site infections:

- **Duration and complexity of the lead implantation procedure**
- Use of a **percutaneous lead** / extension during a trial period (>DAYS-WEEKS) Need for a second-stage Implant operation
- **Trial duration**!!

Deer T.R. Et al. Prevention and Management of Intrathecal Drug Delivery and Spinal Cord Stimulation System Infections; Anaesthesiology 2004; 100:1582–94

Infection-management practices – Preoperative

Statements	Origin of recommended practice*	Evidence levels†	Recommendation strength	Consensus strength
Preoperative practices				
Identify and treat all remote infections for neuromodulation trials and implants	CDC IA	II-2	B	Strong
Optimize glucose control for neuromodulation implants	CDC IA	II-2	B	Strong
Discontinue tobacco use for neuromodulation implants	CDC IB	II-2	B	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	A	Strong
Use preoperative weight-based antibiotic dosing for neuromodulation trials and implants	CDC IB and NICE	I	A	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	B	Strong
Remove hair (when required) with electric clippers immediately before the surgical procedure	CDC IA and NICE	I	A	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	B	Strong
Keep nails short and do not wear artificial nails for neuromodulation trials and implants	CDC IB and NICE	II-3	B	Strong
Do not wear hand or arm jewelry for neuromodulation trials or implants	CDC IB and NICE	III	B	Strong

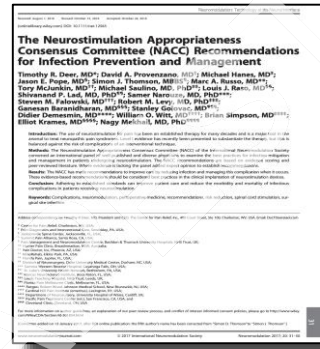

The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management

Infection-management practices – Preoperative

Table 5. Prophylactic Antibiotic Recommendations.

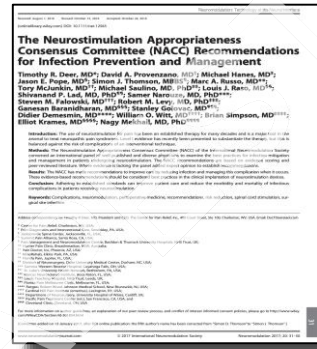
Antibiotic	Standard intravenous dosing	Timing before incision	Redosing interval	Indications
Cefazolin*	1 g ≤ 60 kg 2 g > 60 kg 3 g > 120 kg	Within 30–60 min	3–4 h (CrCl > 50 mL/min) 8 h (CrCl 20–50 mL/min) 16 h (CrCl < 20 mL/min)	First-line
Clindamycin	600 mg ≤ 80 kg 900 mg > 80 kg 1200 mg > 120 kg	Within 30–60 min	6 h (CrCl > 50 mL/min) 6 h (CrCl 20–50 mL/min) 6 h (CrCl < 20 mL/min)	β-Lactam allergy
Vancomycin	15 mg/kg	Within 60–120 min	8 h (CrCl > 50 mL/min) 16 h (CrCl 20–50 mL/min) None (CrCl < 20 mL/min)	β-Lactam allergy Known MRSA colonization

CrCl, creatinine clearance.
*To simplify cefazolin weight-based dosing, the American Society of Health-System Pharmacists recommends 2 g for individuals weighing <120 kg and 3 g for individuals weighing ≥120 kg.
Adapted from Deer et al.[43]


The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management

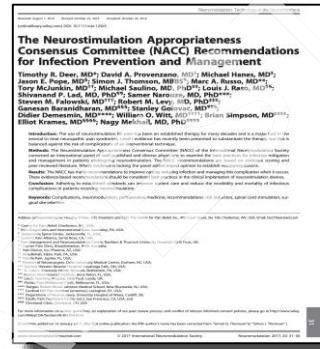
Infection-management practices – Intraoperative

Intraoperative practices				
Wear a surgical mask for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Wear a cap or hood to fully cover hair for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Use sterile gown and gloves for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Double glove	CDC II and NICE	II-1	B	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	A	Strong
Use laminar flow and HEPA filters in OR for neuromodulation implants	CDC IB	I	A	Strong
Limit procedure room traffic for neuromodulation trials and implants	CDC II and NICE	I	A	Strong
Keep procedure room doors closed during neuromodulation trials and implants	CDC IB	II-3	B	Strong
Limit tissue trauma, maintain hemostasis, eradicate dead space, and avoid electrocautery at tissue surface	CDC IB and NICE	III	B	Strong
Irrigate with saline through a bulb syringe before closure of surgical wound	NICE	I	B	Moderate
Use implant strategies to limit operative time		II-2	B	Strong


The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management

Infection-management practices – Postoperative

Postoperative practices				
Apply an occlusive dressing following neuromodulation trials and implants for 24 to 48 h	CDC IB and NICE	II-2	B	Strong
Do not routinely use topical antimicrobial agents for surgical wounds that are healing by primary intention	NICE	I	B	Strong
Understand maximum time criterion for defining a deep SSI of an implantable device (1 y post implant)	CDC	III	B	Strong
Do not continue antibiotics into the postoperative period for neuromodulation trials and implants beyond 24 h	SCIP	I	A	Strong
Educate patient and family on proper incision care, symptoms of SSI, and importance of reporting symptoms	CDC II and NICE	III	B	Strong
Wash hands before and after dressing changes	CDC IB	III	B	Strong
Use sterile technique for dressing changes	CDC II and NICE	III	B	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	III	B	Strong



The Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations for Infection Prevention and Management

Epidural Abscess

Mortality high: 10 – 23 %

4 Phases:

- **PHASE I**

Presents as backache and local tenderness

- **PHASE II**

Radicular pain, fever, neck stiffness & rigidity occurring 48 – 72 hrs later

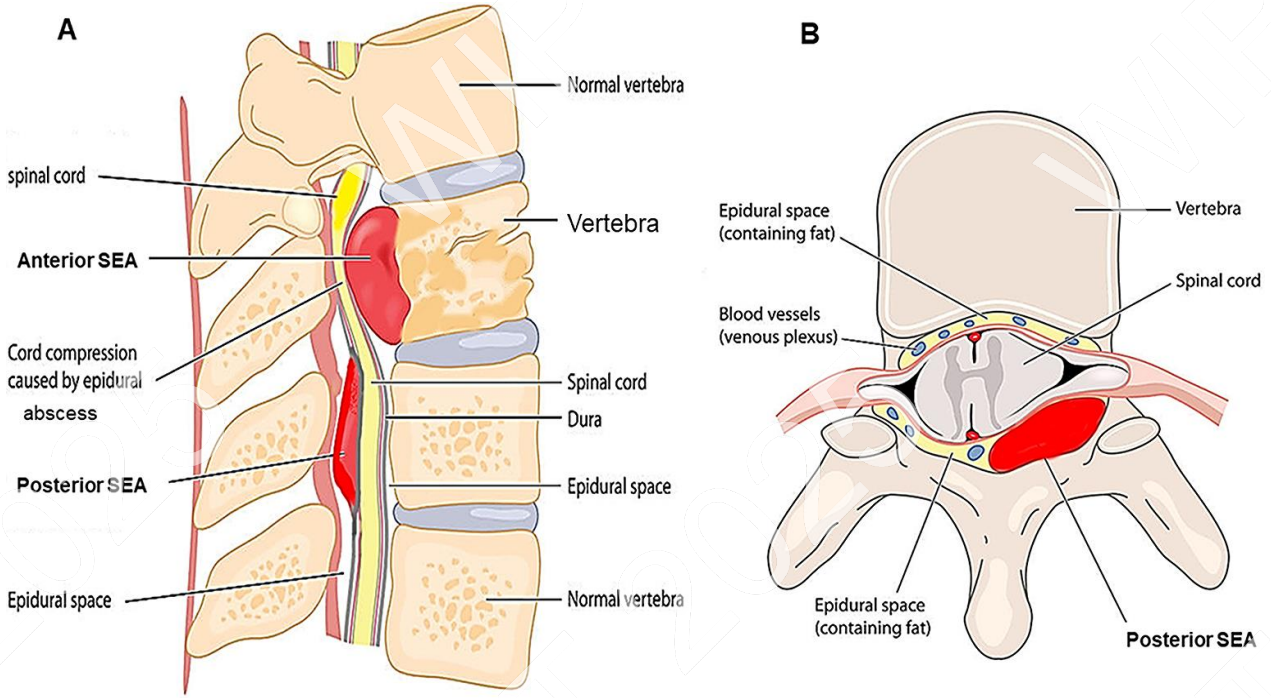
- **PHASE III**

Presents with motor, sensory or reflex depression (3 – 4 days later)

- **PHASE IV**

Paralysis

Need emergency evacuation after diagnosis



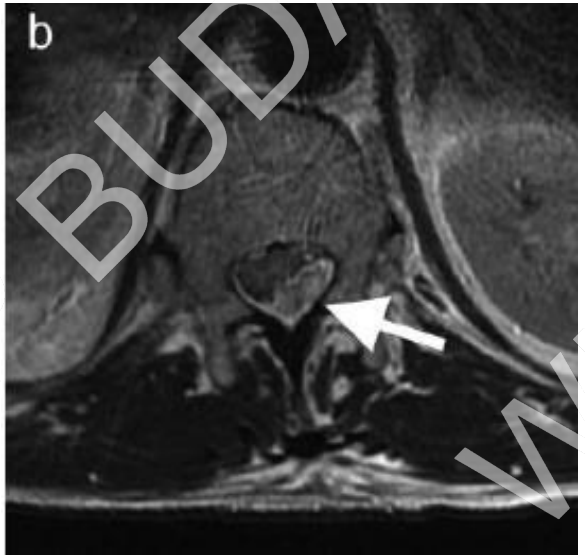
Bleeding risk

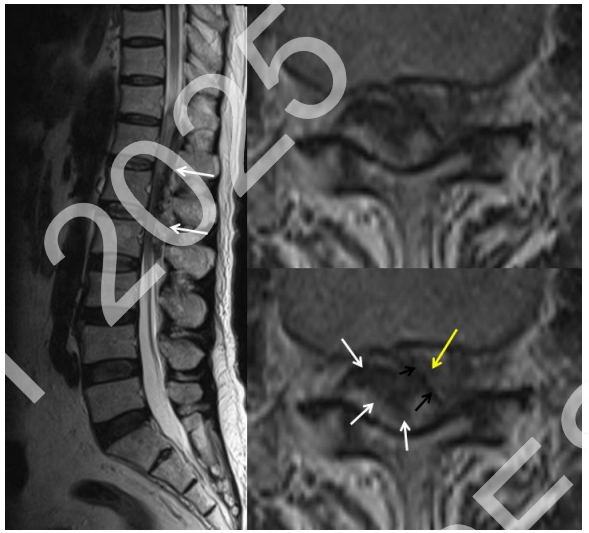
Risk of epidural hematoma - 0.3% and paralysis - 0.03%

Bleeding can occur from placement of needle, lead or IPG placement; can also occur during removal

Hematoma: Mild discomfort to significant pain, rarely may cause nerve compression

Hematoma can lead to wound dehiscence and potentially can act as a nidus for infection.





Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. J Neurosurg 2004;100:254–267.

Recommendations to reduce bleeding

Identify risk factors and address in the peri- implantation period

NSAIDs, antiplatelet, anticoagulant drugs: balance risks (bleeding/significant sequelae) vs benefits (potential cardiovascular or neurological event) for each individual patient!

The NACC recommends a minimum of five half – life interval between discontinuation of any of the new anticoagulants before intermediate - and high - risk pain procedures such as SCS

Deer T.R., Narouze S., Provenzano D.A., Pope J.E. 2017.The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations on Bleeding and Coagulation Management in Neurostimulation Devices.N euromodulation 2017; 20: 51–62

Post Dural Puncture Headache (PDPH)

Dural puncture with a 14 G needle

0.2 % - 3 %

Not everybody gets headache (<1%)

- Severe debilitating headaches, but persistent leak with intracranial hypotension: tinnitus, cervicalgia, diplopia, photophobia, rarely subdural hematoma

Prevention: Careful

Management:

Abandon	Different level approach	Fluids	Reassurance and bed rest	Blood patch

Thomas T. et al. The Incidence and Management of Postdural Puncture Headache in Patients Undergoing Percutaneous Lead Placement for Spinal Cord Stimulation. 2016; Neuromodulation: 19: 738–743

Severe neurological injury

Spinal Cord Injury – Hypoesthesia to irreversible neurologic deficits (paralysis and incontinence).

POTENTIAL CAUSES: Direct trauma, Ischemia, compression from bleeding or device volume, infection, dural puncture or other latrogenic mishaps.

Injury may occur due to:

- Needle / introducer device placement
- Lead placement / manipulation
- Lead removal

Deer T.R. et al. The Neurostimulation Appropriateness Consensus Committee (NACC) Safety Guidelines for the Reduction of Severe Neurological Injury. Neuromodulation 2017; 20: 15–30

Pain related to device components

PAIN AROUND THE IPG SITE - LEAD-ANCHOR SITE - LEAD-EXTENSION JUNCTION

Publication	Therapy type	N	Pain over implant (%)	Publication type
Cameron 2004 [20]	SCS	2,753	0.9	Review Article
Turner 2004 [35]	SCS	830	5.8	Systematic Review
Kumar 2006 [23]	SCS	410	1.2	Retrospective Analysis
Kumar 2008 [24]	SCS	42	12	RCT
Mekhail 2011 [13]	SCS	707	12	Retrospective Analysis
de Vos 2014 [28]	SCS	40	5	RCT
Total	SCS	4,782	Range 0.9–12 Mean 6.15 95 CI 0.97–11.33	
Brazzelli 2006 [30]	SNS	653	25	Systematic Review
Saper 2011 [19]	ONS	51	6	RCT

Sam Eldabe, Eric Buchser, DEAA ,Rui V. Duarte. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature. Pain Medicine 2016; 17: 325–336

Pocket pain

Common with varying prevalence: 0.4 - 25%

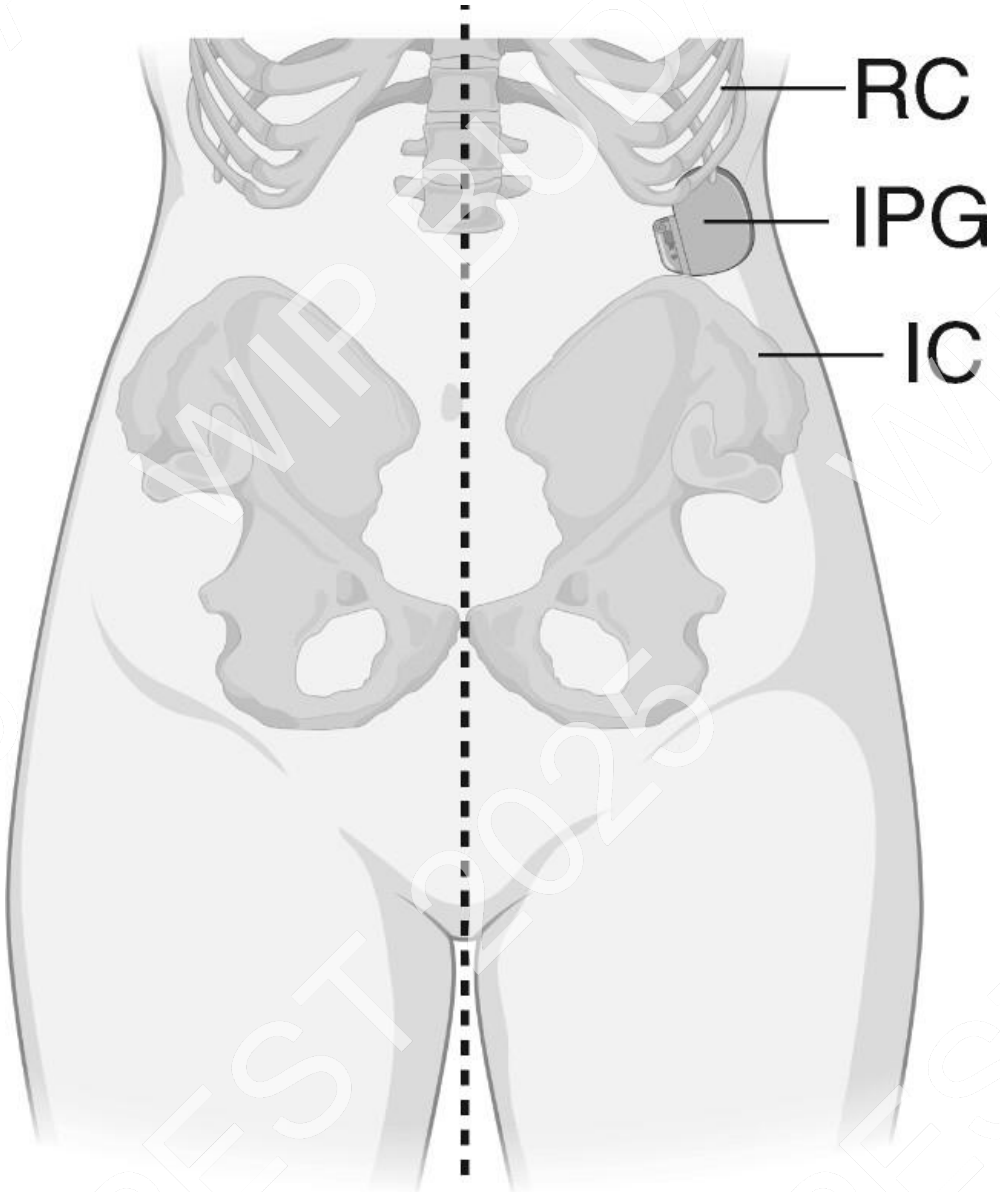
Study on cohort (n= 554): Severe pocket pain - 8%; Explant 0.9%

Predisposing factors:

- Size
- Rechargeable batteries (superficial) / Gluteal region

Management:

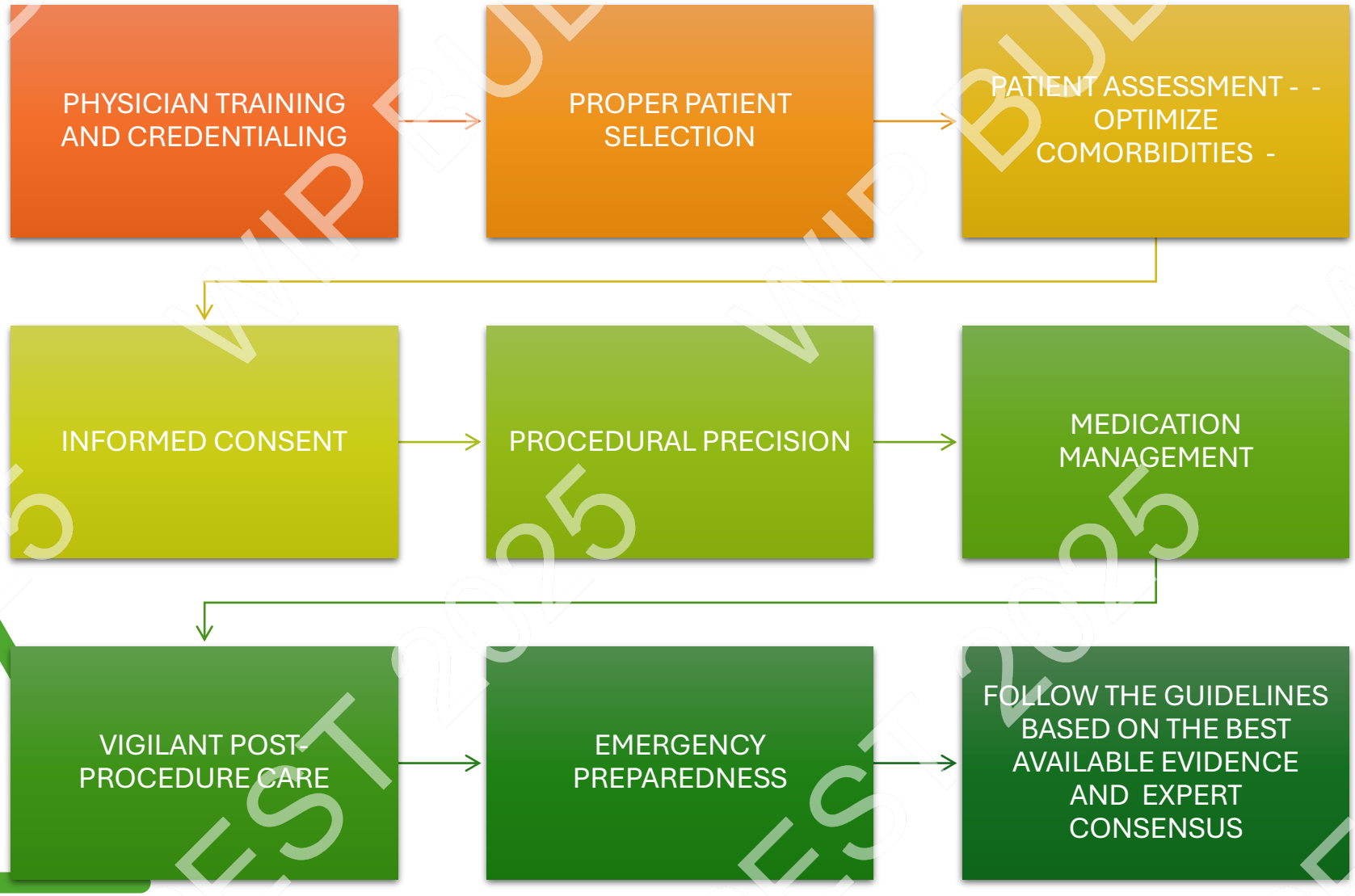
- Topical/Anti neuropathic drugs
- Surgical Revision – Change site



AGENDA

- Introduction
- Complications in Interventional Pain Procedures
- Avoiding Complications – Spinal Cord Stimulation
- Conclusion

Conclusions



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