38TH ANNUAL MEETING

Today and Tomorrow in Pain Medicine: Innovations and Practical Applications

DRG: Patient Selection and Complications

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AAPM 2022 38TH ANNUAL MEETING

UNIVERSITY of VIRGINIA HEALTH SYSTEM

Objectives

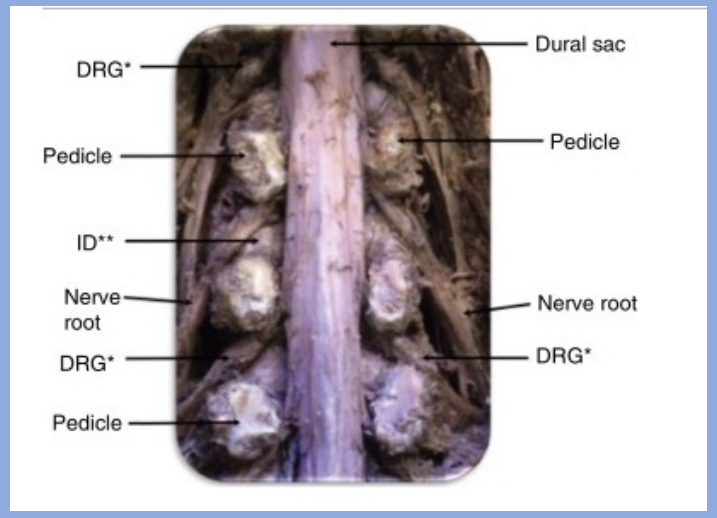
- Identify patients who may benefit from DRG stimulation
- Discuss basic preoperative evaluation for possible DRG candidates
- Recognize complications that may occur DRG stimulation

- Disclosures
  - Funded research from Avanos, NIH, FUS Foundation, FUS Mobile
  - Steering committee/honoraria from Avanos

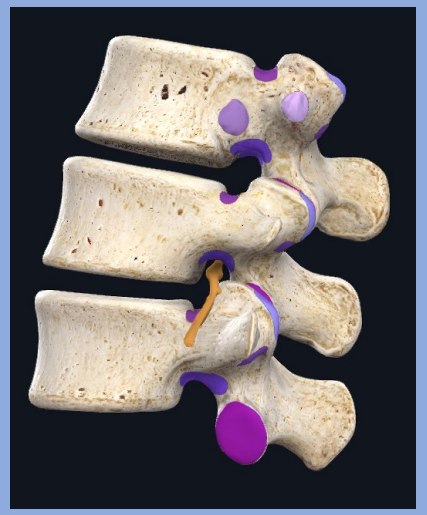
- The presentation will discuss non-FDA approved uses for DRG stimulation.

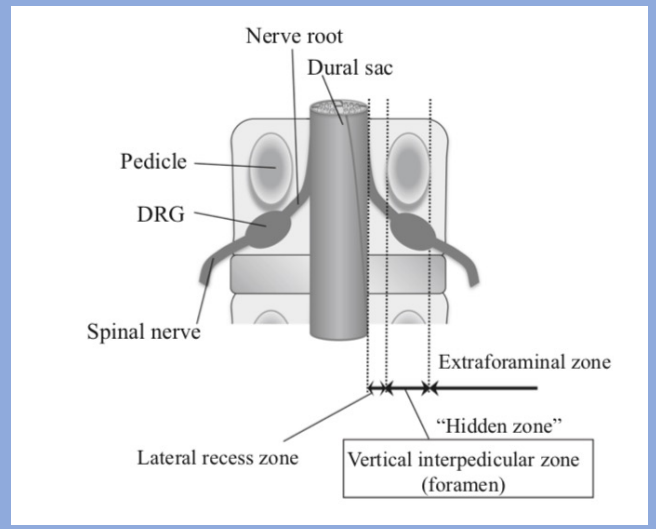
Anatomy

- DRG
  - Identified on radiologic imaging as lying at the caudal aspect of the neuroforamen between the pedicle on the AP view and posterior to the posterior portion of the vertebral body on lateral view



Vialle E. et al. Anatomical study on the relationship between the dorsal root ganglion and the intervertebral disc in the lumbar spine, Revista Brasileira de Ortopedia (English Edition) 2015:50(4):450-454.

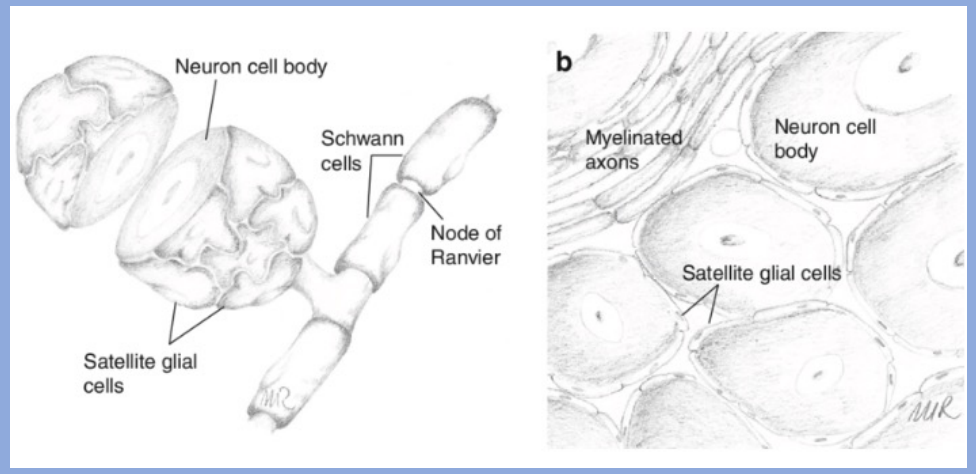


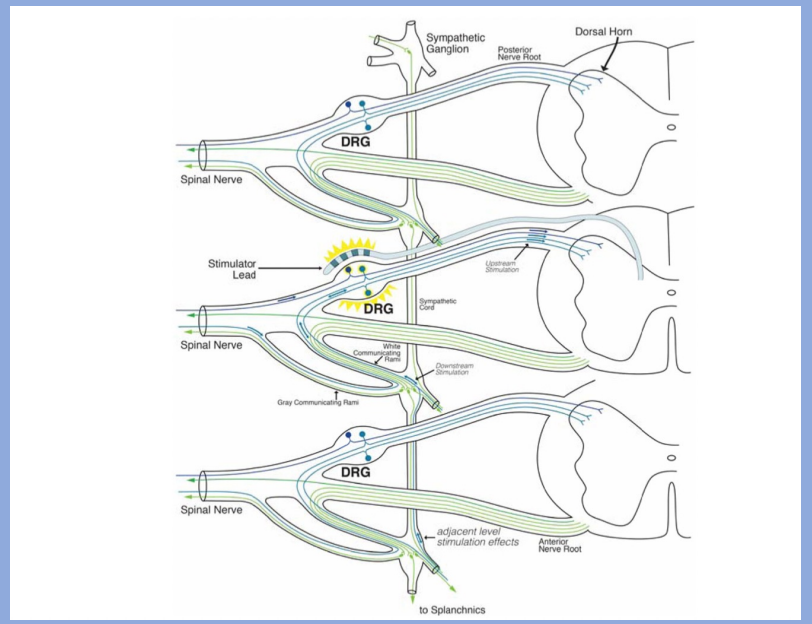


Orita, S., Inage, K., Eguchi, Y. *et al.* Lumbar foraminal stenosis, the hidden stenosis including at L5/S1. *Eur J Orthop Surg Traumatol* **26,** 685–693 (2016). https://doi.org/10.1007/s00590-016-1806-7

Anatomy

- Located within the dural sheath with thin layer of csf
- Housed within the neuroforamen
- Aβ, Aδ, and C fibers sensory info to the DRG
- Glial cells





Hunter al 2018

Patient Selection

- Psychologically stable
- Definitive pathology
- No active untreated SUD
- No poorly controlled medical co-morbidities
- Be properly educated
- No anticoag issues

Indications

- NACC Recommendations:
  - DRG stimulation be considered primarily for patients who have **focal neuropathic pain syndromes with identified pathology**
  - Level 1, Grade A, consensus Strong

  - Currently FDA approved for spinal level T10 and below.
    - Placement above T10 is common
  - DRG is used in Europe and Australia from C5 rostral.
  - NACC recommends leads not be placed above C5 and needle entry should be C6 or lower
  - Level II, Grade C, Consensus moderate

Deer et al 2019

Indications

- FDA indications:
  - *Moderate to severe chronic intractable pain of the lower limbs in adults with* ***complex regional pain syndrome types I and II*** *and/or* ***peripheral causalgia in the groin and lower limb***.
- Other indications:
  - Focal pain syndromes
  - PDPN
  - Peripheral neuropathies
  - Post surgical pain
  - Pelvic pain/groin pain
  - Phantom limb/stump pain
  - Post herpetic neuralgia

CRPS

- **Consensus point 2**
- The NACC recommends DRG stimulation as an effective therapy for the treatment of CRPS type I or type II of the lower extremity.
- Level I, Grade A, Consensus Strong.
- **Consensus point 3**
- DRG stimulation of the upper extremity for treatment of CRPS type I or type II requires more study.
- Level II-2, Grade A, Consensus Strong.

Deer et al 2019

PDPN

- **Consensus point 4**
- DRG stimulation in DPN may be effective based on limited data.
- There is good evidence for SCS in this condition, and, therefore, at present the NACC recommends that the use of DRG stimulation rather than SCS should be carefully justified in individual cases.
- Level III, Grade C, Consensus Strong.

Deer et al 2019

Other peripheral neuropathies

- **Consensus point 5**
- The NACC appreciates that the current evidence for non-diabetic peripheral neuropathy is limited.
- More robust prospective trials are needed to determine if the efficacy seen in the diabetic population can be extrapolated to other populations.
- The NACC recommends these patients be treated on a case- by-case basis, and that if the pain is neuropathic in nature there is a good likelihood of response.
- Level III, Grade B, Consensus Moderate.

Deer et al 2019

Post surgical pain

- **Consensus point 6**
- The NACC recommends the use of DRG stimulation in patients with chronic postoperative surgical pain.
- As data are emerging, decisions need to be made on a case-by-case basis.
- Level III, Grade C, Consensus Moderate.

Deer et al 2019

Pelvic pain

- **Consensus point 7**
- At this time, the treatment of pelvic pain with DRG should occur using strict selection criteria, including the identification of the mechanism of injury (surgical or trauma-related) and related pathology, along with the designation of visceral or somatic.
- Currently, it is suggested that proceeding with DRG stimulation should be a team effort, combining specialists in gynecology, urology, and psychology.
- Patients with significant psychological issues should be excluded or treated prior to consideration of DRG stimulation.
- A history of sexual abuse or significant psychologic comorbidity should be considered a relative contraindication until proper counseling can be established and the therapist feels that an implant is indicated.
- Level III, Grade I, Consensus Moderate

Deer et al 2019

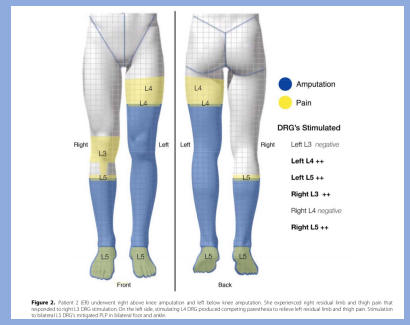
Groin pain

- **Consensus point 8**
- The NACC recommends DRG stimulation for the treatment of neuropathic groin pain.
- Level II-2, Grade B, Consensus Strong.

Deer et al 2019

Phantom limb and stump pain

- **Consensus point 9**
- The NACC acknowledges that DRG stimulation in phantom limb pain may be considered in select patients. Further study is needed.
- Level III, Grade I, Consensus Moderate.
- **Consensus point 10**
- Mapping of the appropriate DRG with sensory stimulation may be helpful in proper lead placement in specific patients with phantom limb pain. Further study is needed.
- Level III, Grade I, Consensus Moderate.



Deer et al 2019; Hunter et al 2017

Postherpetic neuralgia

- The use of DRG stimulation to treat postherpetic neuralgia is moderately supported in the literature and has better evidence than SCS.
- Since there is damage to the DRG questions remain which DRG should be targeted (at the level vs above/below)

Deer et al 2019

Targets

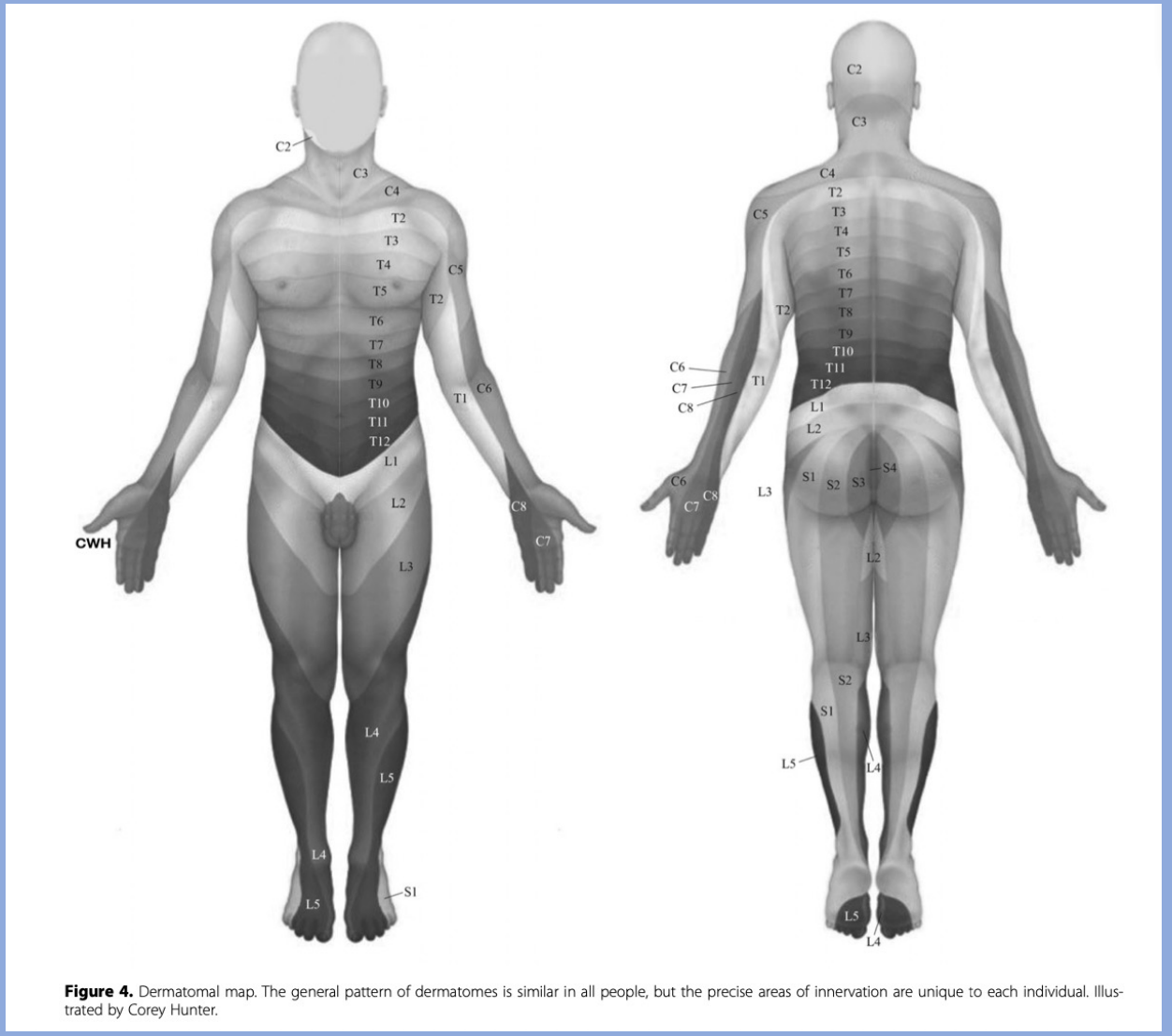


Figure 4. Dermatomal map. The general pattern of dermatomes is similar in all people, but the precise areas of innervation are unique to each individual. Illustrated by Corey Hunter.

Deer et al 2018

Targets

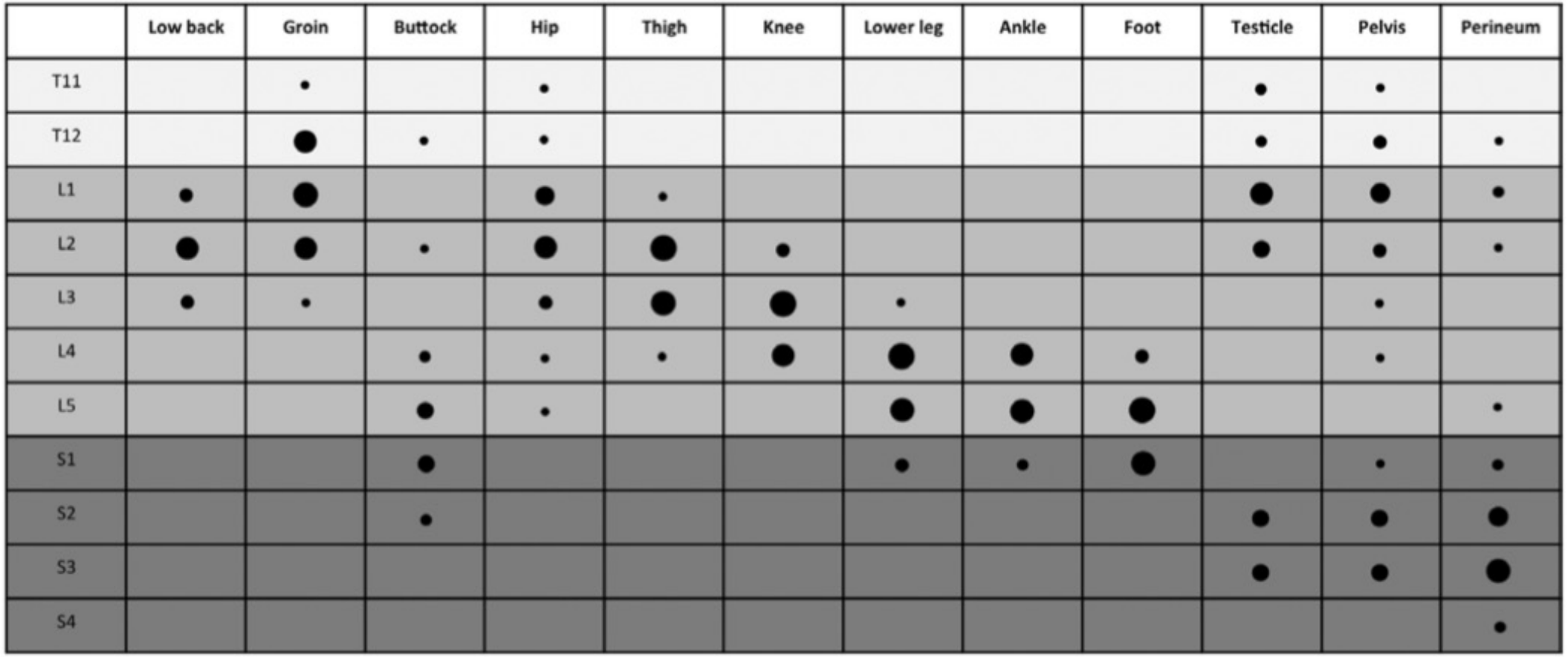
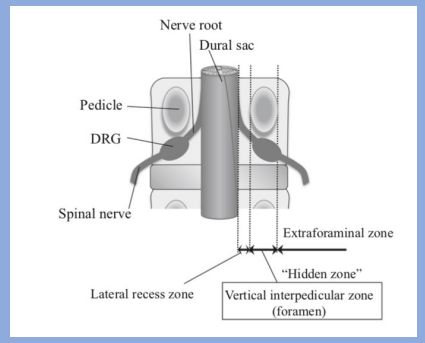


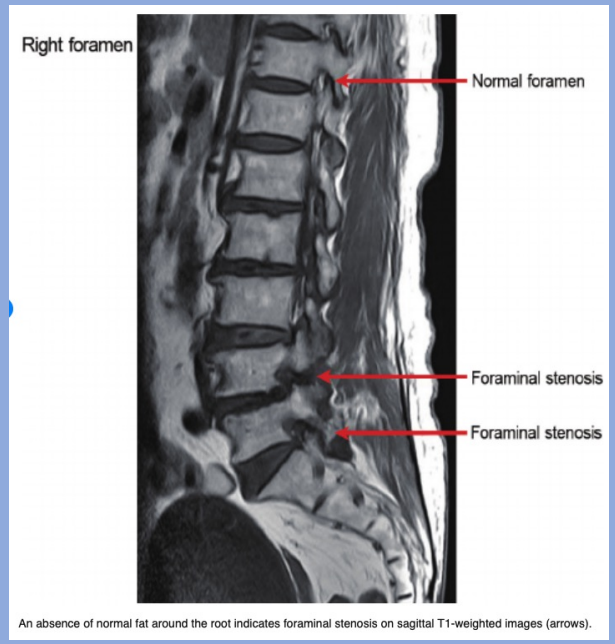
Figure 7. Suggested stimulation levels by pain location. Data compiled from a poll of the authors; area of circle represents the number of implanters recommending each level.

Deer et al 2019

Preop imaging

- Volume of space available in foramen
  - Must be able to accommodate electrodes without compromising DRG, nerve root, or other intra-foraminal structures





An absence of normal fat around the root indicates foraminal stenosis on sagittal T1-weighted images (arrows).

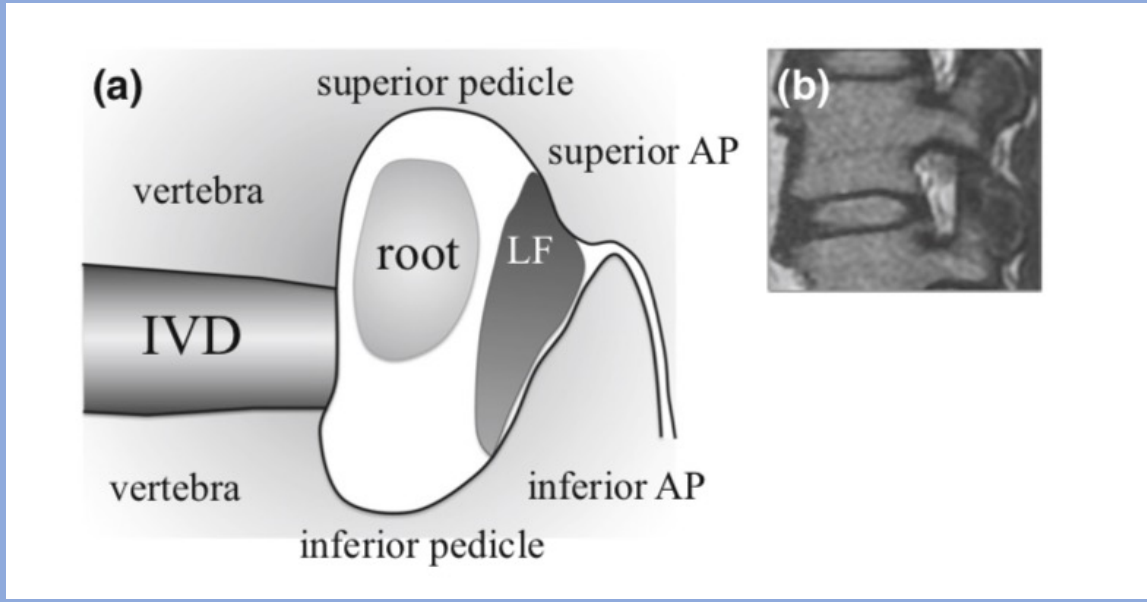
  - Sub-pedicular notch (house DRG and surrounding structures)
    - Normally occupies 30% of available foraminal area
    - Prevalence of lumbar foraminal stenosis 8-11%
    - Foraminal stenosis can be more of a concern at the vertical inter-pedicular zone (foraminal zone) or at the extra-foraminal zone—the 2 most common lumbar locations for the DRG.

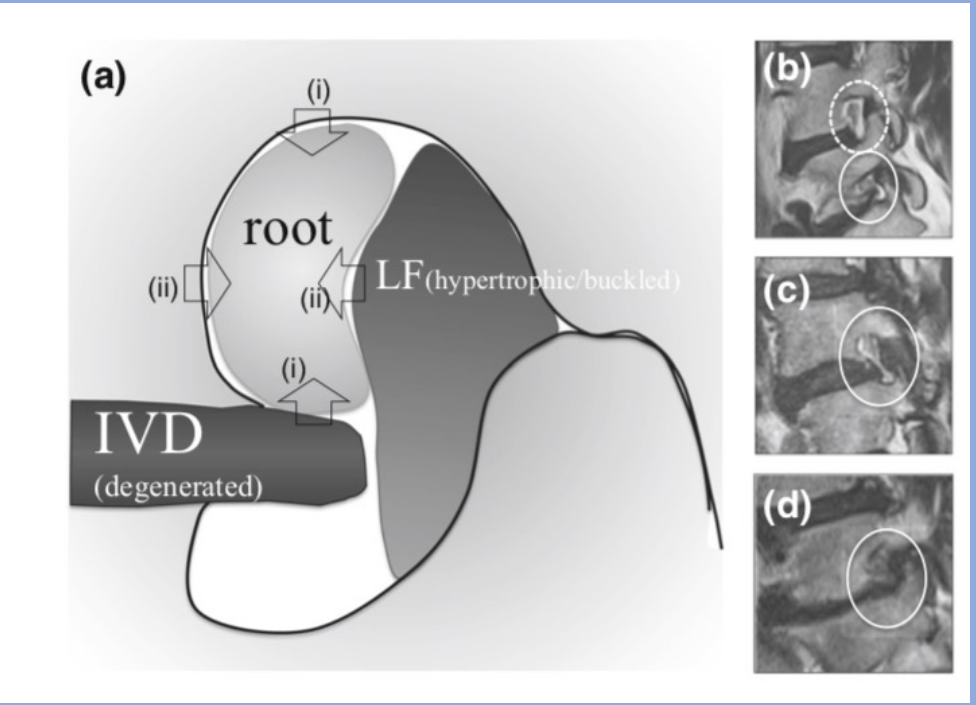
Deer et al. Neuromod 2019.

Pre-procedure planning

- Foraminal height same from L1-S1 but DRG diameter increasing (largest at L5-S1, 83 mm)
- Largest root/foramen area ratio approximates 50% at the L5/S1 foramen.
- Since the pedicle width also increased maximally at L5, the L5 nerve root has normally less space in the rostral-caudal direction and occupies a greater distance in the foramen compared to other levels

Deer et al. Neuromod 2019.





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Anticoagulation

Table 10. Anticoagulation Management Practices for Spinal Cord Stimulation as Recommended by the Neuromodulation Appropriateness Consensus Committee.

Anticoagulant	Recommendation for trial	Recommendation for permanent implant
Warfarin	Discontinue 5–7 days before, INR < 1.5; if bridging required, refer to bridging medication; continue cessation during duration of trial, resume 24 hours following trial lead removal.	Discontinue 5–7 days before, INR < 1.5; if bridging required, refer to bridging medication; resume 24 hours postoperatively.
Enoxaparin (LMWH)	Hold therapeutic dose of LMWH 24 hours before procedure; hold for duration of trial; resume 24 hours following lead removal.	Hold therapeutic dose of LMWH 24 hours before procedure; resume 24 hours following surgery.
Clopidogrel (ADP receptor antagonists)	High-risk patients for cardiac events—discontinue at least 5 days before; low risk 7–10 days before; hold for duration of trial; resume 24 hours following lead removal.	High-risk patients for cardiac events-discontinue at least 5 days before; low risk 7–10 days before; resume 24 hours following surgery.
Effient (ADP receptor antagonist)	Discontinue 7–10 days prior to procedure, hold for duration of trial, resume 24 hours following lead removal.	Discontinue 7–10 days prior to procedure, hold for duration of trial, resume 24 hours following lead removal.
Ticlopidine (ADP receptor antagonists)	Discontinue 14 days prior to procedure, hold for duration of trial, resume 24 hours following lead removal.	Discontinue 14 days prior to procedure; resume 24 hours following surgery.
Abciximab, eptifibatide, tirofiban (platelet GPIIb/IIIa receptor)	Discontinue for 3 days prior to procedure, hold for duration of trial, restart 24 hours following lead removal.‡	Discontinue for 3 days prior to procedure, hold for duration of trial, restart 24 hours following the surgery.‡
Dipyridamole, aggrenox (aspirin/dipyridamole) (phosphodiesterase inhibitors)	Discontinue 7 days prior to procedure, hold for duration of trial, restart 24 hours following lead removal.§	Discontinue for 7 days prior to procedure, hold for duration of trial, restart 24 hours following the surgery.§
Naproxen, ketorolac, ibuprofen, etodolac, etc. (nonsteroidal anti-inflammatory drugs)§	Discontinue 7 days prior to procedure, hold for duration of trial, reinitiate 24 hours following lead removal.	Discontinue 7 days prior to procedure, hold for duration of trial, reinitiate 24 hours following the surgery.
Aspirin§	Discontinue 7 days prior to procedure, hold for duration of trial, reinitiate 24 hours following lead removal.	Discontinue 7 days prior to procedure, hold for duration of trial, reinitiate 24 hours following surgery.
Herbals (ginseng, ginkgo, garlic)	Discontinue 7 days prior to the procedure, hold for duration of trial, reinitiate 24 hours following lead removal.	Discontinue 7 days prior to the procedure, reinitiate 24 hours following surgery.
Pradaxa (dabigatran etexilate), Xarelto (rivaroxaban) (direct thrombin inhibitors)	Discontinue 5 days prior to procedure, hold for duration of trial, reinitiate 24 hours following lead removal.	Discontinue 5 days prior to procedure, hold for duration of trial, reinitiate 24 hours following surgery.
Heparin IV*	NA	NA
Heparin SQ†	NA	NA

*Requires inpatient hospitalization and monitoring, suggesting a special need or indication for neurostimulation, and should be assessed on case-by-case basis.
†Peaks at 2–4 hours after administration; typically thrombotic prophylaxis as inpatient and may require platelet assessment if more than 4-day dosing. Please refer to American Society of Regional Anesthesia guidelines and determine on a case-by-case basis.
‡Typically contraindicated 4 weeks following surgery. If reinitiated, careful follow-up and vigilance is suggested (50).
§Current recommendations (50) suggest variable stoppage is necessary based on clinical context and on the specific half-life of the nonsteroidal anti-inflammatory drug in question. The half-life determines the time required for discontinuation in order to limit the drug's effect on platelet function.
INR, international normalized ratio; ADP, adenosine diphosphate; LMWH, low-molecular-weight heparin; NA, not applicable.

Deer TR, Mekhail N, Provenzano D, Pope J, Krames E, Thomson S, Raso L, Burton A, DeAndres J, Buchser E, Buvanendran A, Liem L, Kumar K, Rizvi S, Feler C, Abejon D, Anderson J, Eldabe S, Kim P, Leong M, Hayek S, McDowell G 2nd, Poree L, Brooks ES, McJunkin T, Lynch P, Kapural L, Foreman RD, Caraway D, Alo K, Narouze S, Levy RM, North R; Neuromodulation Appropriateness Consensus Committee. The appropriate use of neurostimulation: avoidance and treatment of complications of neurostimulation therapies for the treatment of chronic pain. Neuromodulation Appropriateness Consensus Committee. Neuromodulation. 2014 Aug;17(6):571-97; discussion 597

8. doi: 10.1111/ner.12206. PMID: 25112891.

MRI Conditional

- 1.5 T only
- Head and extremities
- IPG not in midline
- Leads between T10-S2

Checklist

Table 3. Procedure Checklist.

Preoperative medical issues

Check for evidence of active dermal, dental, or urologic infections and treat.
Order urinalysis before procedure.
Address prior history of infection and make a plan for prophylaxis.
Review MRI imaging of cervical, thoracic, or lumbar spine in past 12 months, depending on diagnosis and planned placement of stimulator tip.
Discontinue anticoagulation with approval of treating physician for a length of time prior to procedure that is appropriate for the specific anticoagulant and surgical bleeding risk. The appropriate timing for discontinuation should be based on the medication half-life and whether the patient is taking the medication for primary or secondary prevention.
Off nonsteroidal anti-inflammatory drugs for 1 week if desired
Off acetylsalicylic acid for 7 days
Off warfarin or fondaparinux for 5 days, clopidogrel for 7 to 10 days, ticlopidine for 10 to 14 days
If patient was on warfarin, order prothrombin time testing for morning of the procedure.
Review psychological evaluation.
Obtain cardiac clearance in patients at risk for cardiac disease.
Review trial films and operative notes in preparation for permanent implant.
Evaluate the potential sites of implantation and battery pocket for infection or inflammatory process.
If there are any potential technical or patient-specific concerns, communicate with the treating physician and/or the anesthesiologist prior to implant.
Educate the patient/caregiver(s).
Obtain insurance coverage and document medical necessity.

Surgical considerations

Assess health status the day of surgery.
Have patient empty bladder preoperatively.
Obtain baseline pain score.
Review postoperative instruction sheet with patient/caregiver preoperatively.
Check that adult driver has been arranged to take patient home.
Order preoperative antibiotics and administer 30 to 60 min before incision or within 2 hours for vancomycin. Antibiotic doses should be based on the patient's weight.
Arrange for family to stay in postoperative area to observe programming and learn about recharging.
Confirm follow-up appointment before discharge.

Deer TR, Mekhail N, Provenzano D, Pope J, Krames E, Thomson S, Raso L, Burton A, DeAndres J, Buchser E, Buvanendran A, Liem L, Kumar K, Rizvi S, Feler C, Abejon D, Anderson J, Eldabe S, Kim P, Leong M, Hayek S, McDowell G 2nd, Poree L, Brooks ES, McJunkin T, Lynch P, Kapural L, Foreman RD, Caraway D, Alo K, Narouze S, Levy RM, North R; Neuromodulation Appropriateness Consensus Committee. The appropriate use of neurostimulation: avoidance and treatment of complications of neurostimulation therapies for the treatment of chronic pain. Neuromodulation Appropriateness Consensus Committee. Neuromodulation. 2014 Aug;17(6):571-97; discussion 597

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Complications

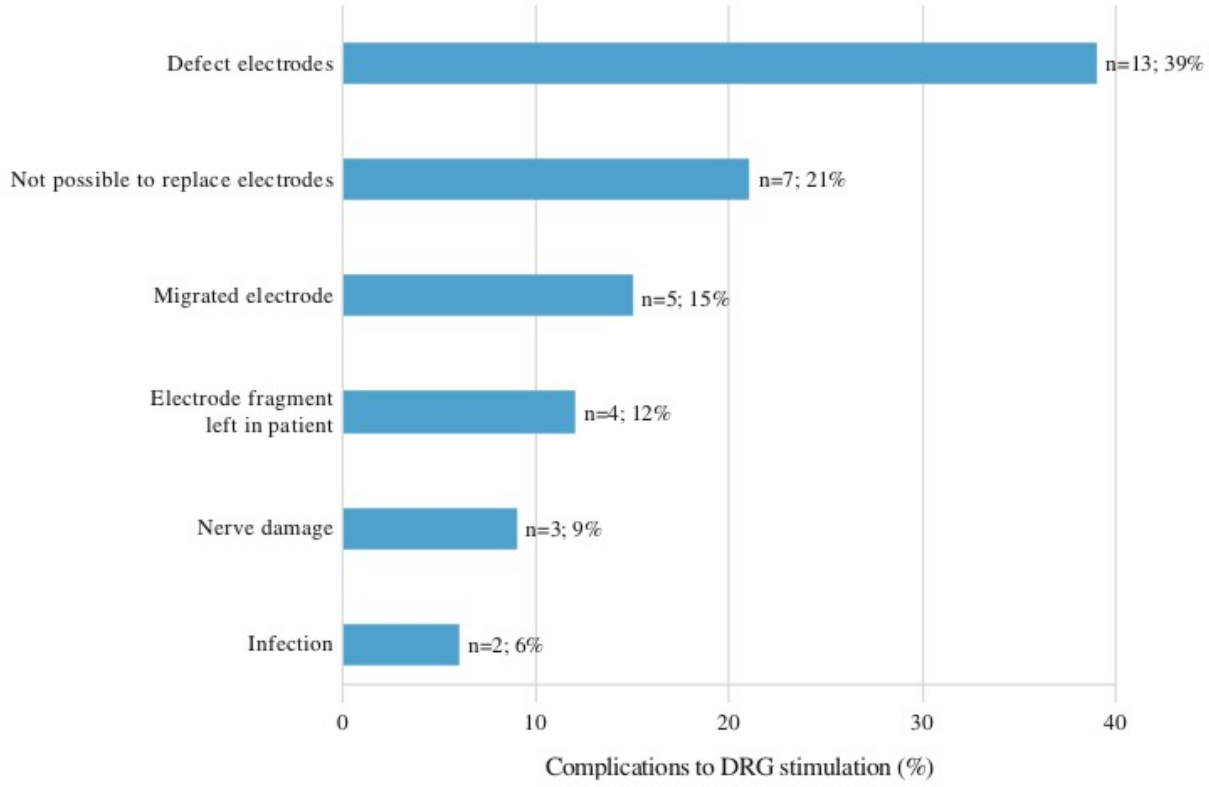

Figure 4 Complications to DRG stimulation. Number of patients (*n*) with complication by category. Percentages are of fully implanted systems (see Fig. 1). The two infections were subcutaneous infections at the implanted pulse generator (IPG)-pocket. [Color figure can be viewed at wileyonlinelibrary.com]

Horan M, Jacobsen AH, Scherer C, Rosenlund C, Gulisano HA, Søe M, Sørensen JCH, Meier K, Blichfeldt-Eckhardt MR. Complications and Effects of Dorsal Root Ganglion Stimulation in the Treatment of Chronic Neuropathic Pain: A Nationwide Cohort Study in Denmark. Neuromodulation. 2021 Jun;24(4):729-737.

Table 4

Complications Due to the Device or Procedure in the Pooled Studies.

Complications related to device or procedure	Number of events
Pain at IPG site	26
Lead Fracture	15
Lead Migration	15
Infection	13
Temporary motor stimulation	12
Dural puncture	11
Increased lead impedance	5
Loss of stimulation	2
Buzzing sound in one ear	1
Changes in sensation related to stimulation	1
Disconnection of the external trial stimulator	1
Increased pain after the trial implant procedure	1
Fell due to weakness in one leg	1
Transient motor deficit	1

Huygen FJPM, Kallewaard JW, Nijhuis H, Liem L, Vesper J, Fahey ME, Blomme B, Morgalla MH, Deer TR, Capobianco RA. Effectiveness and Safety of Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain: A Pooled Analysis. Neuromodulation. 2020 Feb;23(2):213-221. doi: 10.1111/ner.13074. Epub 2019 Nov 15. PMID: 31730273; PMCID: PMC7079258.

Lead Fractures

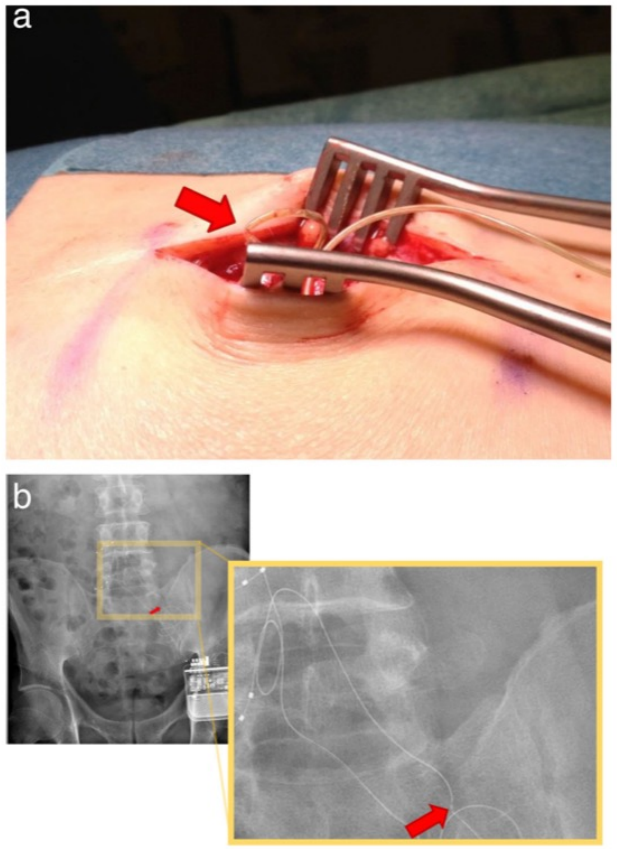

Figure 5 Examples of lead fractures. a. Broken lead. 46-year-old female, treated for neuropathic abdominal pain syndrome with almost complete pain relief. Revised due to two broken leads. b. Broken lead. 59-year-old male, treated for neuropathic pain in the foot and lower leg. Lead broke two years after implantation. It has not been replaced because of risk of lead breakage during removal, and contacts are left in the root canal as a result. The patient has one functioning lead and therefore partial pain relief. [Color figure can be viewed at wileyonlinelibrary.com]

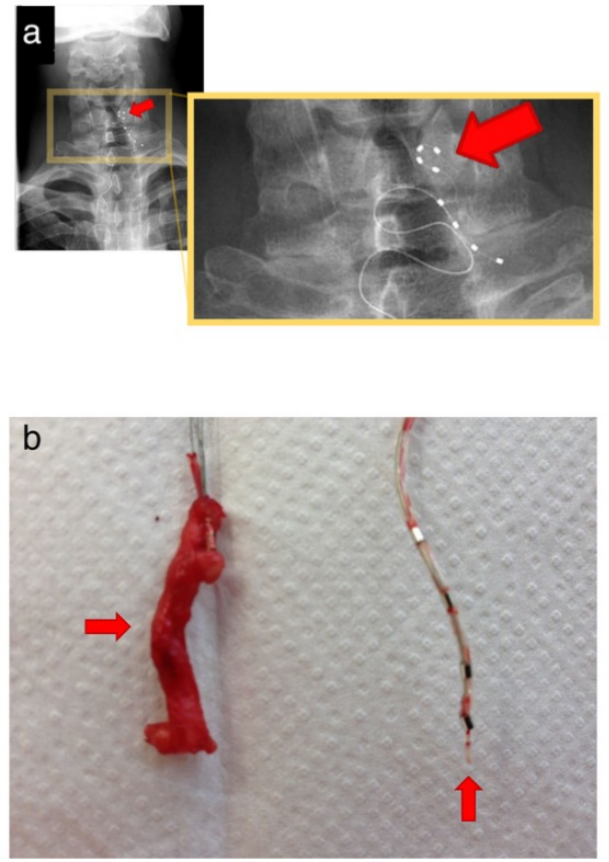

Figure 6 Examples of dysfunctional leads. a. Lead tip, with four contacts left in the patient's epidural space and root canal. 48-year-old male, treated for neuropathic pain in the left arm. Revised due to dysfunctional stimulation. Lead broken during revision. The patient has part of the painful area covered by the remaining lead. b. Lead with adhering scar tissue. Same patient as Fig. 5a. [Color figure can be viewed at wileyonlinelibrary.com]

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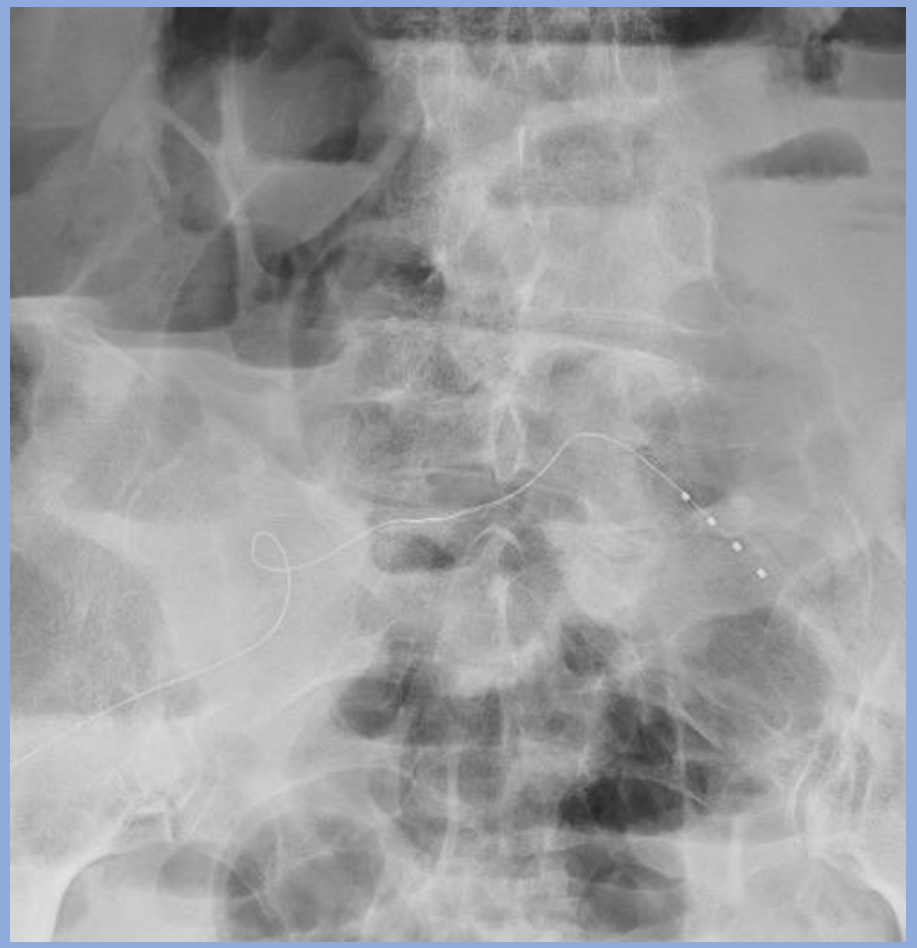
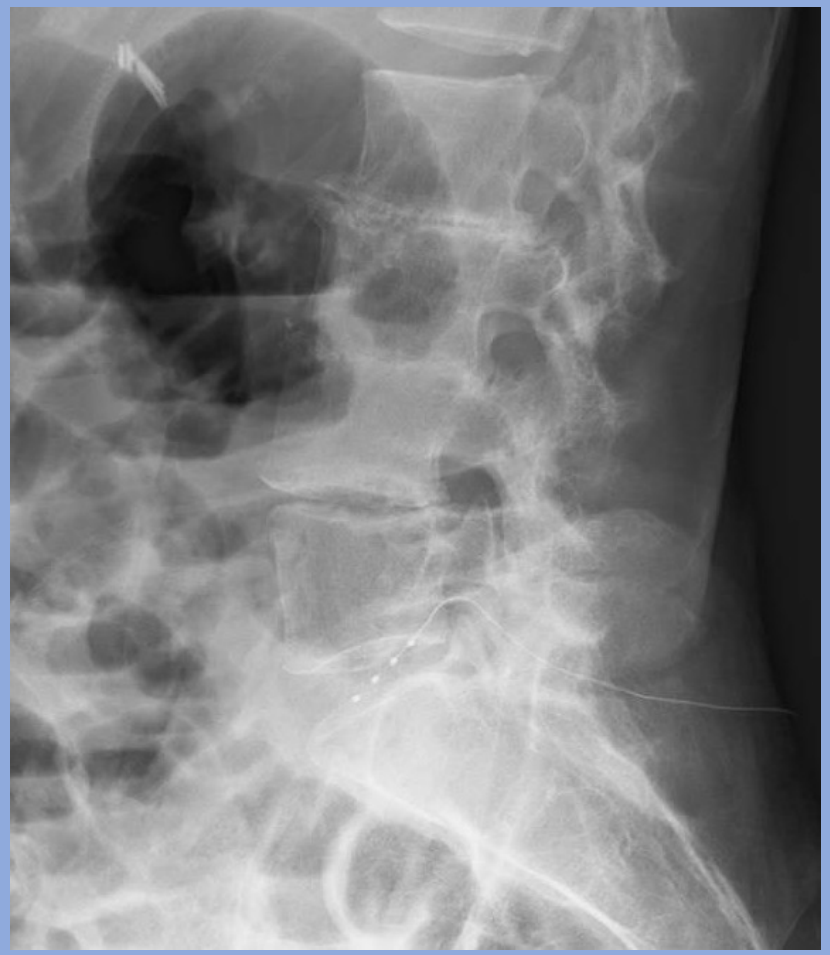
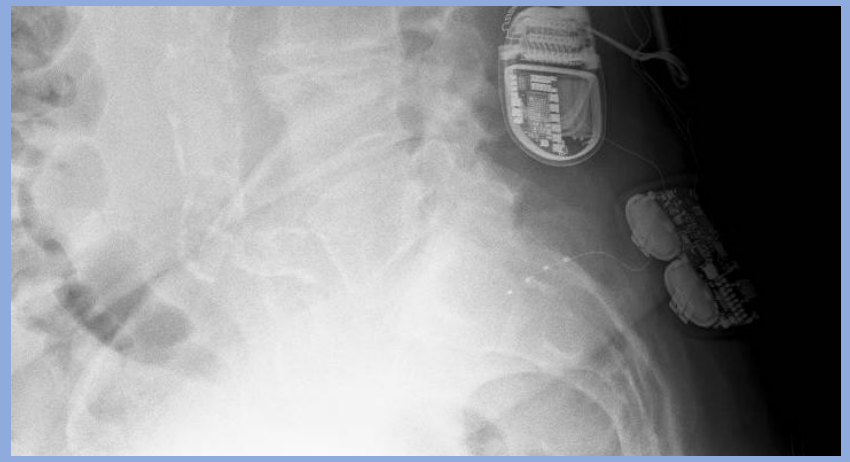
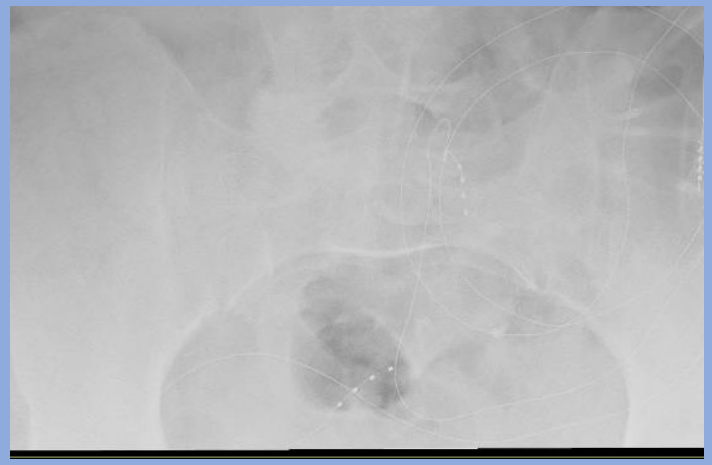
Post implant xray lead migration

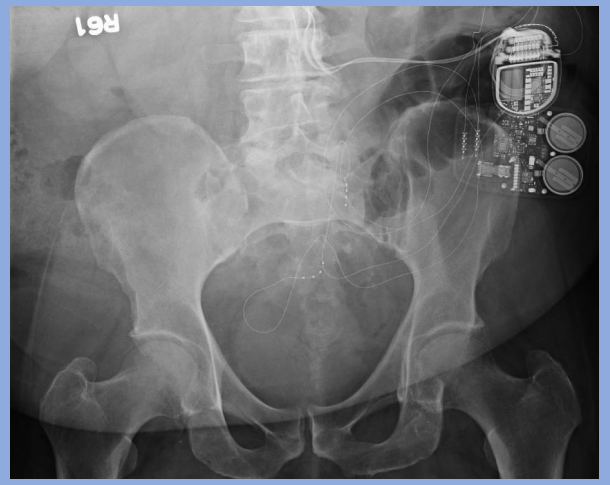


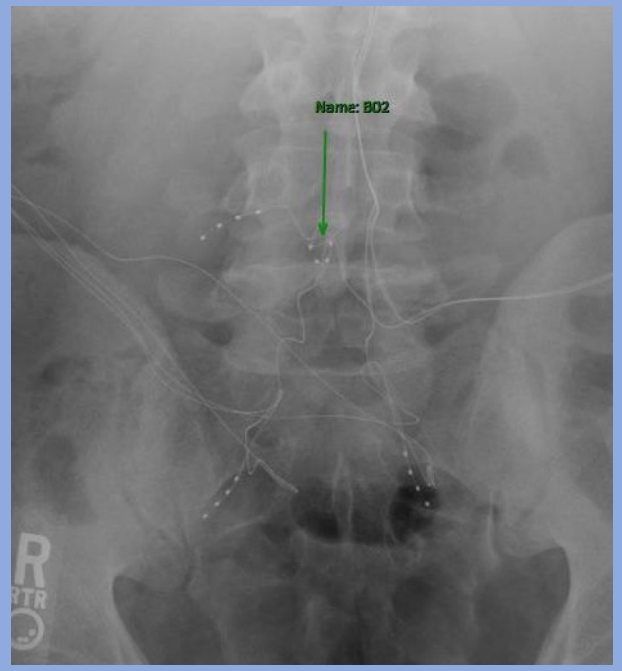


Post procedure lead migration









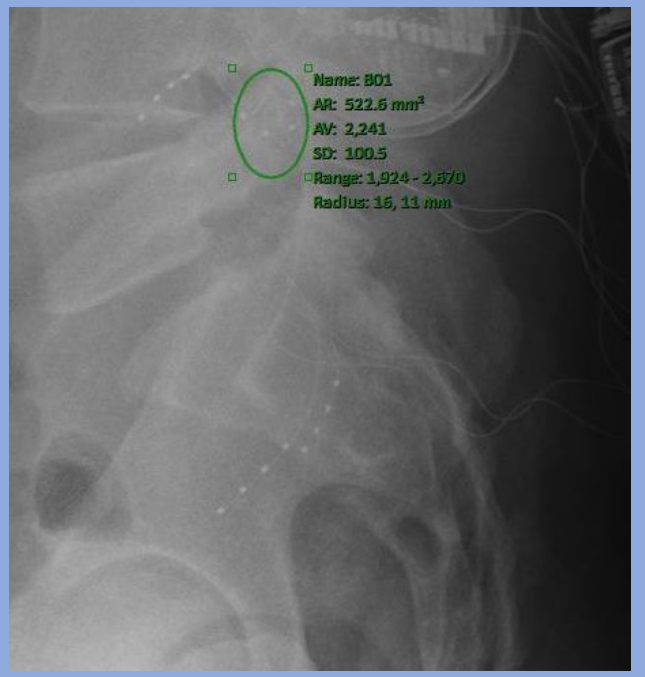


Table 23. Risk Mitigation of Possible Complications From DRG Therapy.

Complication	Mechanism of complication	Mitigation technique
Nerve injury	Needle puncture	Appropriate angle, landmarks and pre-procedure imaging
Nerve injury	Lead or sheath trauma	Gentle technique, pre- procedure imaging, patient conversation or neuromonitoring
Dural puncture or CSF leak	Needle puncture	Shallow angle, appropriate pathway to space. Loss of resistance with lateral view
Lead migration	Lack of proper strain relief, not piercing the ligaments	S-loop strain relief, assure sheath is through ligaments
Infection	Surgically acquired	Follow NACC guidance (8)
Bleeding	Perioperatively	Follow NACC guidance (9)
Lead fracture	Fracture at the ligament or at the anchor	Modify needle angle, modify tunneling angle, modify anchoring method
Lead retention	At time of removal, revision or indwelling	Remove the lead under fluoroscopy if resistance occurs; if retained consult neurosurgery. Usually no need to surgically remove the lead unless causing impingement
Pocket pain	Shallow implant, recharging, body contour	Implant as deep as possible, use non-rechargeable devices if possible, assess contour preoperatively

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Conclusions

- Patients should be carefully selected based on definitive pathology, appropriate anatomy, and who are optimized medically
- Complications can occur including lead related, IPG related, reduced efficacy, infection, weakness, amongst others

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