

IDDS for Cancer Pain



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Disclosure:

- Consulting Fee: Abbott, Avanos, Averitas Pharm, Biotronik, Boston Scientific, Nalu, Nevro, PainTeq, Saluda, Scilex Pharma, SPR Therapeutics, Vertos
- Contracted Research: Avanos, Averitas Pharm, Biotronik, Boston Scientific, Nalu, Nevro, PainTeq, Saluda, SGX Medical, SPR Therapeutics
- Stock Shareholder: Nalu, National Spine and Pain Centers



Learning Objectives:

- History of spinal anesthesia
- Introducing IDDS for cancer pain
- IDDS patient selection
- IDDS medications and evidence



Outline:

- Cancer pain overview
- History of spinal anesthesia
- Technology
- Management strategies
- Evidence IDDS for cancer pain
- Patient experience
- Coding and reimbursement



Cancer Pain Overview:

- Acute or Chronic
- Neuropathic or Nociceptive or Mixed
- Somatic and Visceral
- Constant, intermittent, breakthrough
- Cancer associated pain
- 20% to 50% of patients with cancer
- 80% of patients with advanced-stage cancer have moderate to severe pain



1. www.cancer.gov

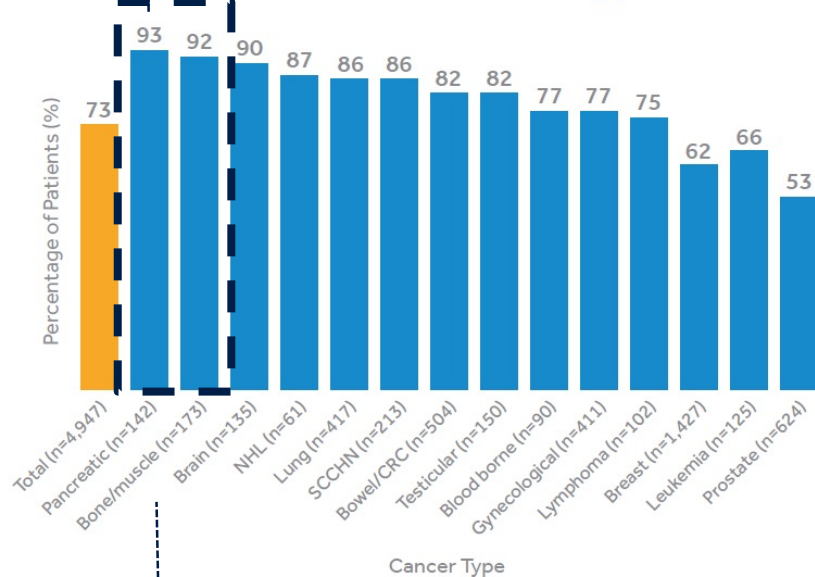
2. Fischer DJ, Villines D, Kim YO, et al. Support Care Cancer 18 (7): 801-10, 2010

3. Bruera E, Kim HN: Cancer pain. JAMA 290 (18): 2476-9, 2003

Breakdown of Pain by Cancer Type

Largest Need: Pancreatic and Bony Mets

Incidence of Pain Due to Cancer Type¹



Pancreatic cancer²

- Incurable, but treatable disease affecting **50,000 Americans per year**
- Median survival with good treatment: 8 months

Bone metastases

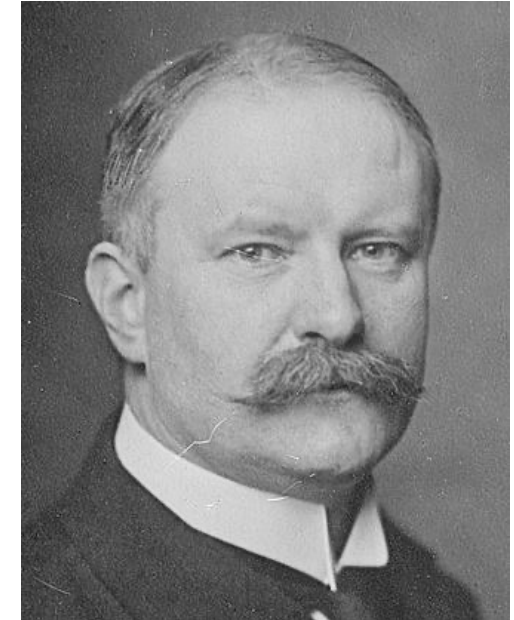
- Bone is invaded in 60-80% of patients with metastatic disease³, most frequently from **breast, prostate, and lung**⁴
- Median survival: 7 months⁵



1. Brevik H, Cherny N, et al. Ann Oncol. 2009;20(8): 1420-1433.
2. <https://pancreatica.org/pancreatic-cancer/pancreatic-cancer/>. Accessed January 2019
3. Schulman et al. American Cancer Society, 2007
4. Kurup AN, Callstrom MR. J Vasc Interv Radiol. 2010;21(8 Suppl):S242-50
5. Van der Linden YM, et al. Cancer 2005;103(2):320-8.

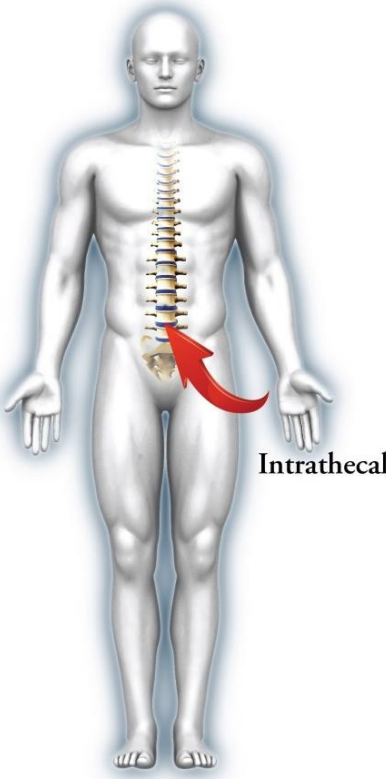
History and Spinal Anesthesia and Analgesia:

- August 16, 1898, Dr. August Bier first to inject 15 mg cocaine into the intrathecal space for ankle surgery
- 1940, continuous spinal anesthesia
- 1973, opioid receptor identified in the spinal cord
- 1979, Wang et al. intrathecal morphine for refractory cancer pain
- 1981, implantable intrathecal pump
- 1991, battery-powered IDDS pump, externally programmable, refillable



1. Bottros M, and Christo P. Journal of Pain Research, 2014
2. Wang JK, Nauss LA, Thomas JE. Anesthesiology. 1979
3. Onofrio BM, Yaksh TL, Arnold PG. Mayo Clin Proc. 1981
4. Wallace M, Yaksh TL. Reg Anesth Pain Med. 2000

Targeted Drug Delivery versus Systemic Drug Delivery:



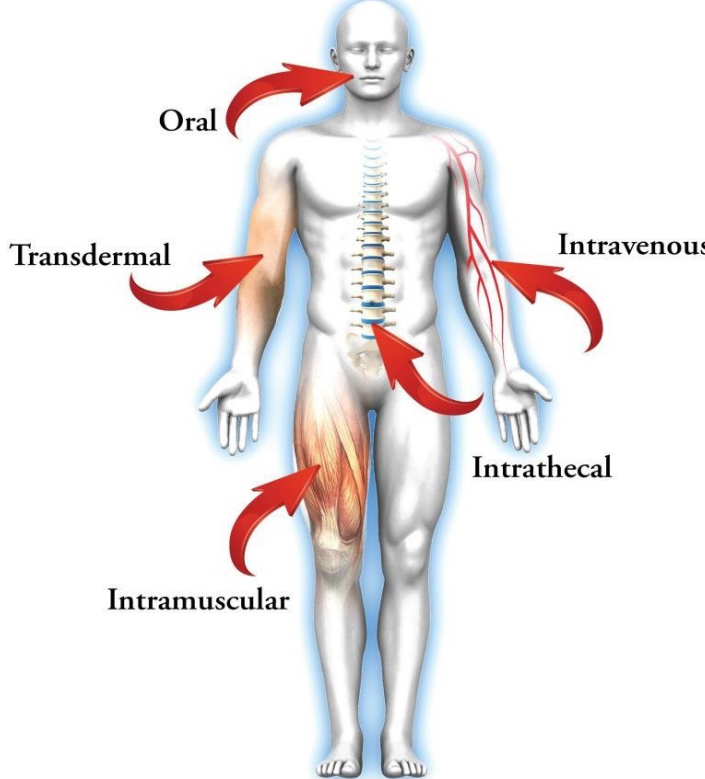
Benefits

- TDD typically results in lower blood levels of drug compared to systemic dosing
- TDD produces higher drug concentration levels at **TARGET** receptor sites in the spinal cord
- A fraction of the oral dose is usually effective
- TDD may result in fewer or more tolerable side effects than systemic dosing

Risks

- More invasive than systemic medications
- Potential for surgical complications

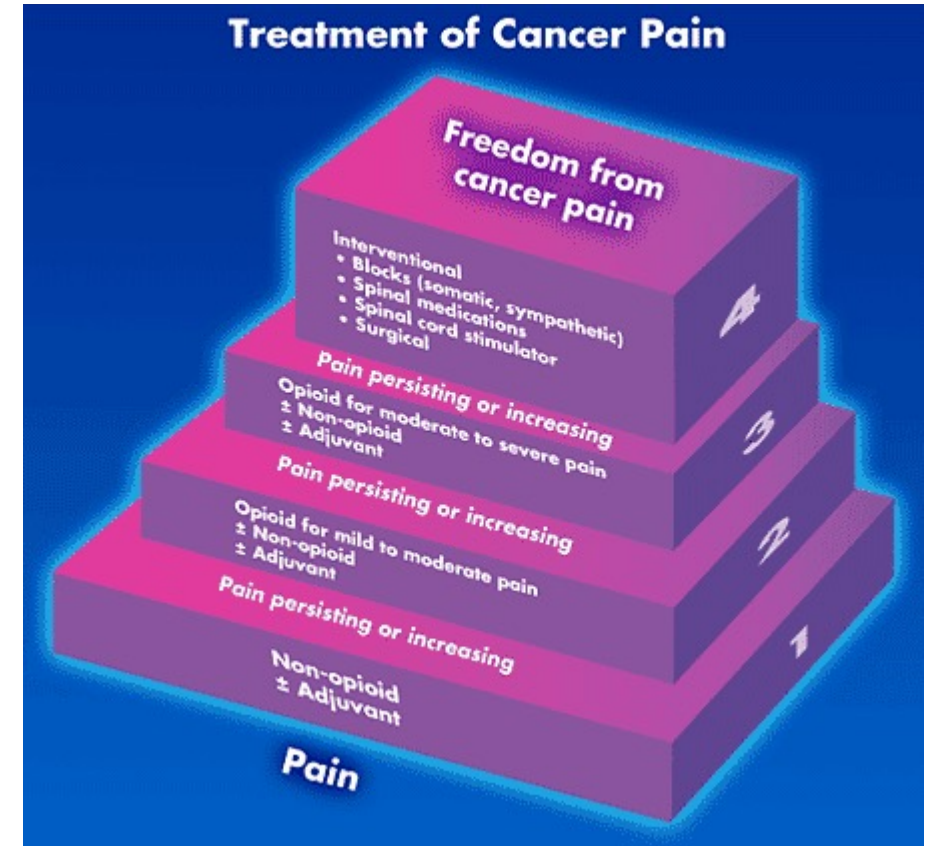
Refer to the package labeling for a complete list of risks



1. Ruan X. *Pain Physician*. 2007;10:357-366.
2. Ellis DJ, Dissanayake S, McGuire D, et al. *Neuromodulation*. 2008;11:40-49.
3. Figure courtesy of Medtronic

Targeted Intrathecal Drug Delivery

- Chronic pain refractory to conservative therapy
 - Axial Neck or Low back pain
 - Failed Back Surgery
 - Abdominal/Pelvic pain
 - Extremity pain/ CRPS
 - Trunk pain
 - Cancer pain
- Alternative to oral opioids
- Physician programmed (*patient compliance*)
- FDA: morphine, baclofen, ziconotide



<https://www.who.int/publications/i/item/9789241550390>

Patient Selection:

IDDS for Cancer Pain

- Chronic refractory cancer pain or cancer associated pain
- Refractory to conventional medical management
- Intolerance to systemic opioids
- Greater than 3-month life expectancy*, rev 2012
- Include cancer associated pain (radiation/chemotherapy)

Table 6. Disease Indications for Intrathecal Drug Delivery.

- Axial neck or back pain; not a surgical candidate
 - Multiple compression fractures
 - Discogenic pain
 - Spinal stenosis
 - Diffuse multiple-level spondylosis
- Failed back surgery syndrome
- Abdominal/pelvic pain
 - Visceral
 - Somatic
- Extremity pain
 - Radicular pain
 - Joint pain
- Complex regional pain syndrome (CRPS)
- Trunk pain
 - Postherpetic neuralgia
 - Post-thoracotomy syndromes
- Cancer pain, direct invasion and chemotherapy related
- Analgesic efficacy with systemic opioid delivery complicated by intolerable side effects

Contraindications:

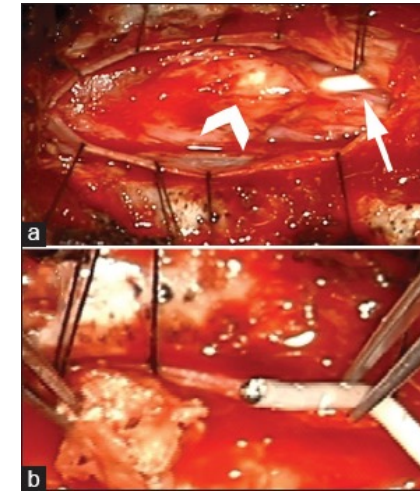
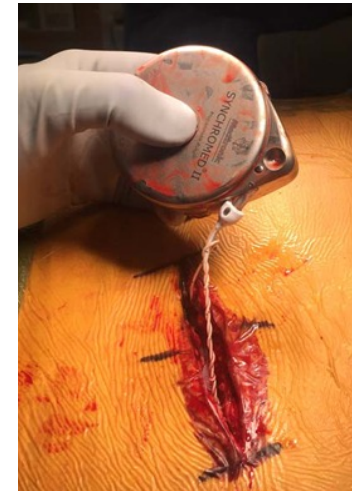
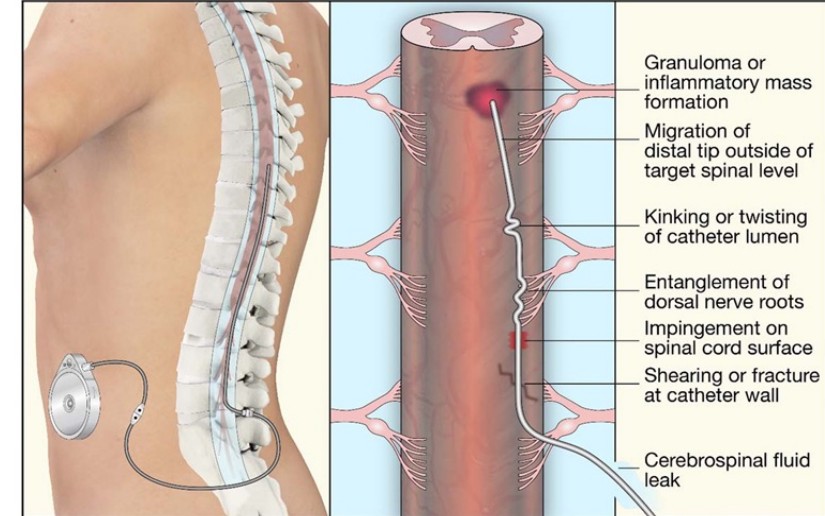
- Tumor encroachment of the thecal sac
- Poor surgical candidate
- Emaciation
- Aplastic anemia
- Systemic or occult infection
- Sensitivities or allergy to medications
- Allergy to system materials (ex. Nickel)



Krames, E. *JPSM*. 1997; 14(3S): S3-S13.

IDDS Risks and Complications:

- Surgical risks
- Medication side effects
- Catheter complications
 - Granuloma
 - Kink
 - Leak
 - Dislodgement
- Pump complications
 - Motor stall
 - Pump inversion



Nagel, SJ et al. Neuromodulation, 2017

Southwell, DG et al. Surgical Neurology International, 2017

IDDS Medications:

FDA: Morphine, Ziconotide, Baclofen

Table 1 2012 Polyanalgesic Consensus Committee recommendations for intrathecal medication in neuropathic pain management

Line 1	Morphine	Ziconotide	Morphine + bupivacaine
Line 2	Hydromorphone	Hydromorphone + bupivacaine or Hydromorphone + clonidine	Morphine + clonidine
Line 3	Clonidine	Ziconotide + opioid Fentanyl	Fentanyl + bupivacaine or Fentanyl + clonidine
Line 4	Opioid + clonidine + bupivacaine	Bupivacaine + clonidine	
Line 5	Baclofen		



Deer et al. Consensus Conference (PACC): Recommendations for Intrathecal Drug Infusion Systems Best Practices and Guideline, Neuromodulation, 2016

IDDS Management Strategies:

- Simple continuous
- Flex dosing
- On-demand (ex. PTM)
- Compounding



Simple Continuous



Individualized Dosing (Night Increase)



Individualized Dosing (Day Increase)



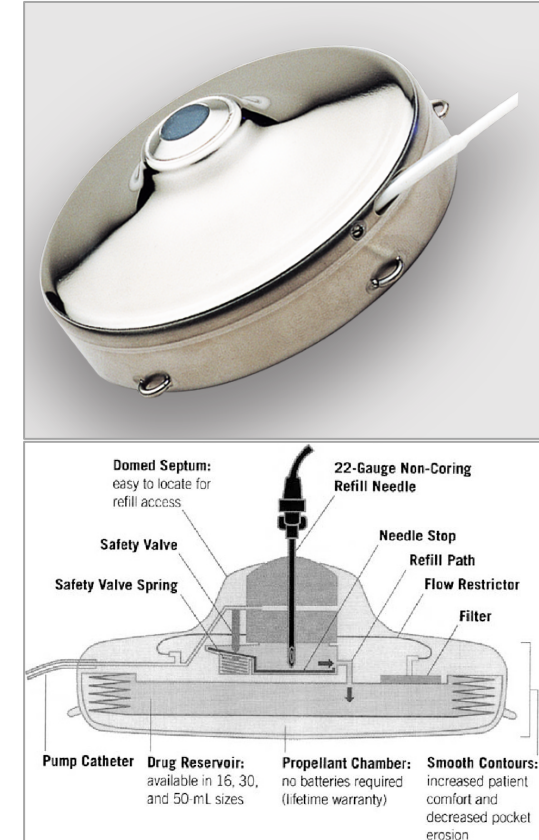
<https://lioresal.com/lioresal-intrathecal/dosing/>

Intrathecal Drug Delivery Pumps

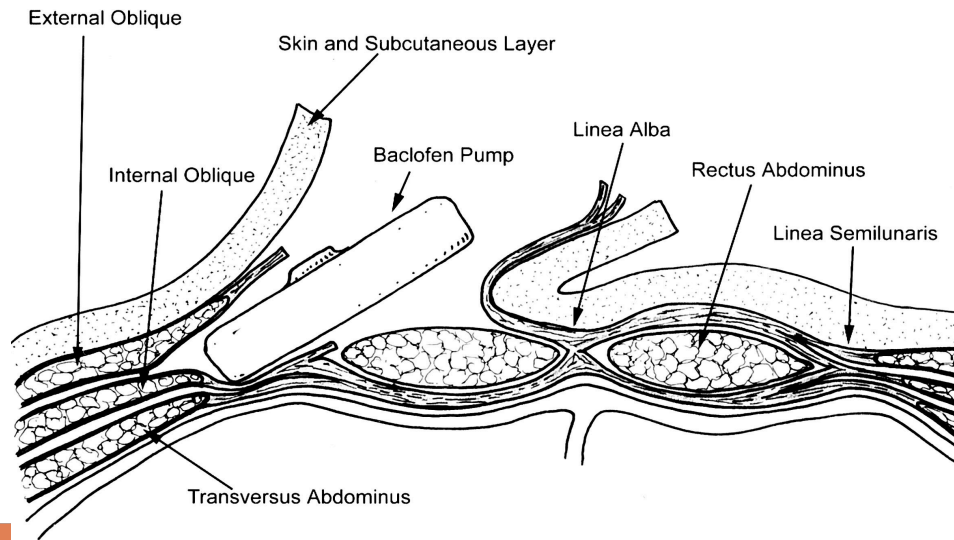
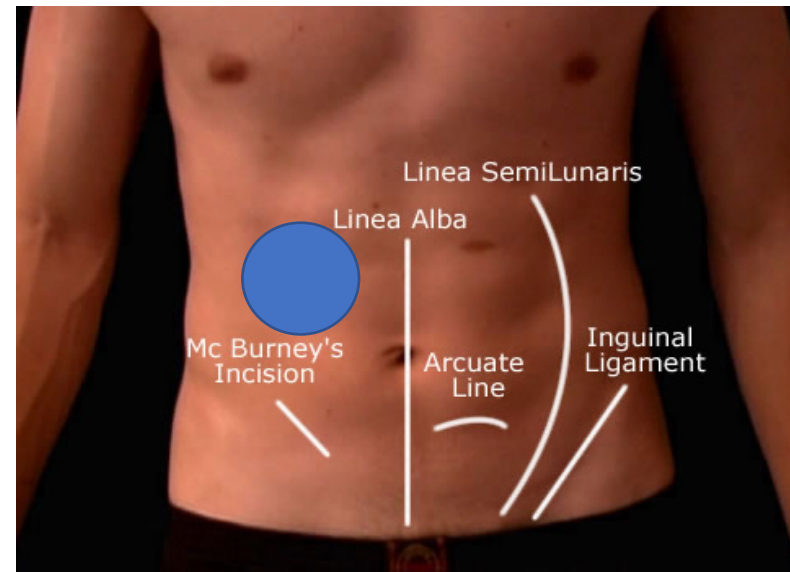
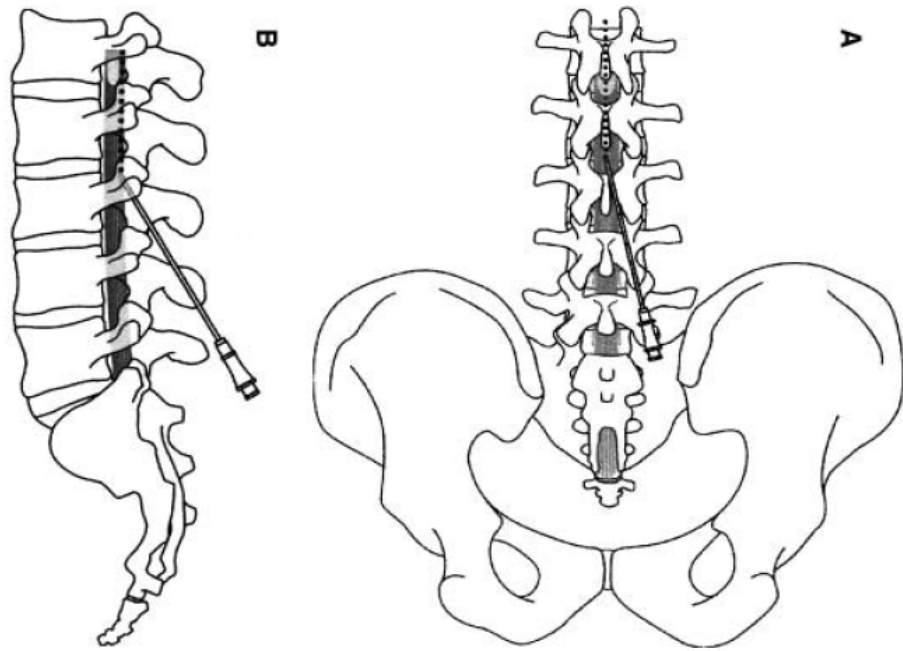
- Positive pressure Precision Dosing System
- 20 cc or 40 cc
- Pulsatile flow
- MRI conditional
- Positive pressure reservoir
- Must remove medications for MRI



- Peristaltic pump w/ plastic tubing design
- 20 cc or 40 cc
- Continuous flow
- MRI conditional
- Must confirm restart of rotor after MRI

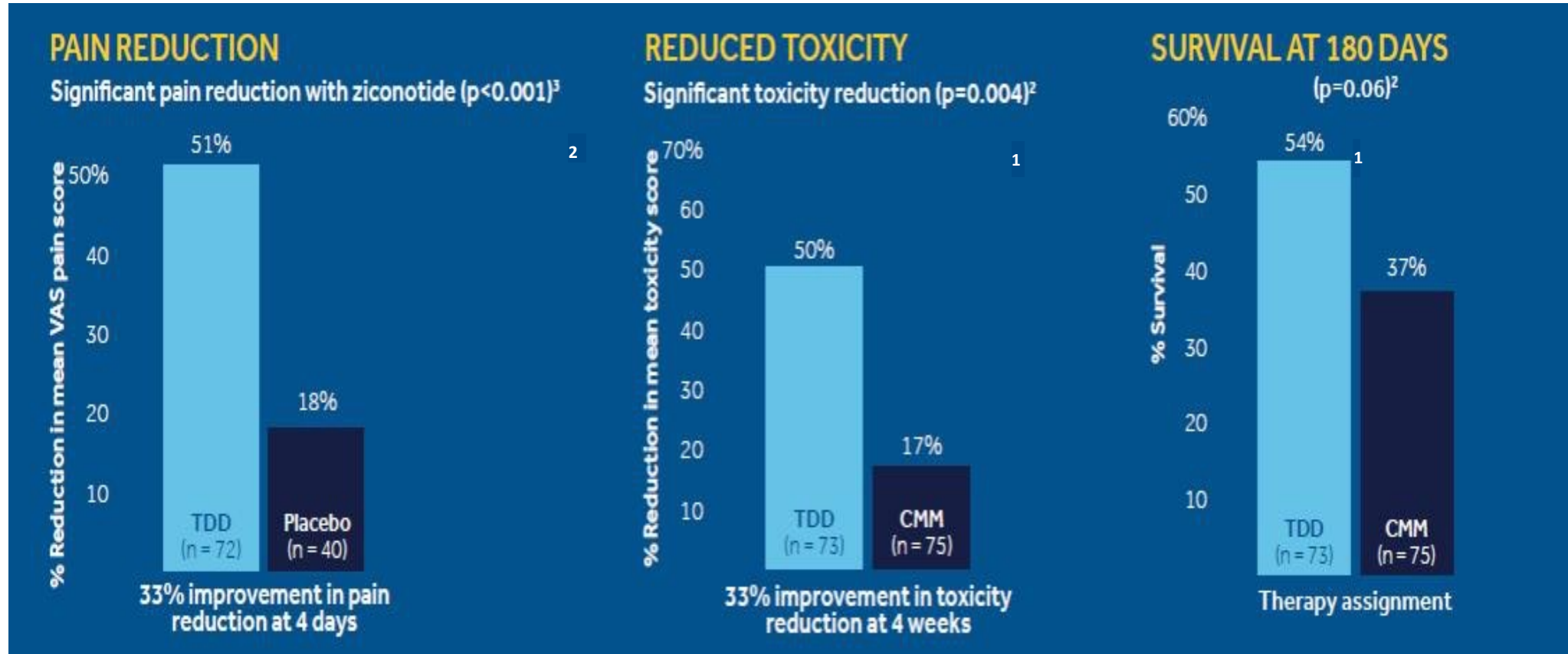


<https://flowonix.com>
<https://medtronic.com>
<https://interaoncology.com>



S. Li and P. Staats, "Permanent Implant." *Atlas of Pain Management Procedures*, 1st Ed., P. Staats and S. Diwan, Chapter 68, McGraw Hill, 2014

Supporting Evidence for IDDS: Prospective Multicenter Data



1. Smith TJ, Staats PS, Deer T, Stearns LJ, et al. *J Clin Oncol*. 2002;20(19):4040-4049.
2. Staats PS, Yearwood T, Charapata SG, et al. *JAMA*: 2004;291(1):63-70.
3. Figure courtesy of Medtronic

Pain, QoL, Safety, and Economics:

Intrathecal Drug Delivery Systems for Cancer Pain

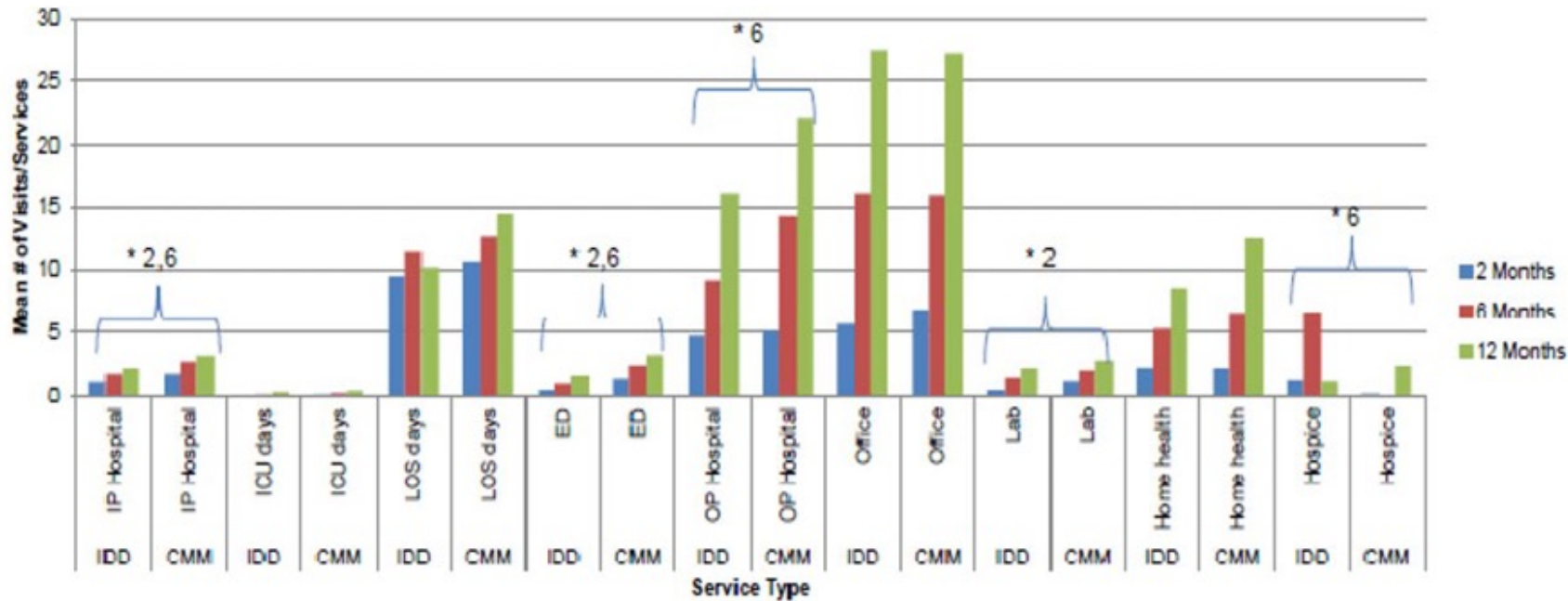
- Prospective, multicenter, registry¹
- 2003-2017, 1403 cancer patients enrolled
- Of the 283 (with baseline), improvement NRS 1.4 at 12 months
- EQ-5D, improved at 6 month, not at 12 months
- Infection 3.2%, catheter dislodgement 3.8%, pump motor stall 1.8%, catheter kink or occlusion 1.5%, catheter break 1.2%
- 4.3% exited trial due to device explant or therapy discontinuation
- Cost savings vs CMM: \$15,142@2 months, \$63,498@12 months²



1. Stearns, L. et al. Chronic Pain Medicine, 2020

2. Stearns, L. et al. JAMA Network Open, 2019

Healthcare Utilization: Intrathecal Drug Delivery Systems for Cancer Pain



- N=73 crossmatched patients
- US insurance database
- 2006-2010

Figure 1. Medical utilization by treatment group over 12 months. * Indicates a statistically significant difference at the $p < 0.05$ level for the time point(s) listed. No adjustments made for multiple comparisons. CMM, conventional medical management; ED, emergency department; ICU, intensive care unit; IDD, intrathecal drug delivery; IP, inpatient; LOS, length of stay; OP, outpatient.

The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practices and Guidelines

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Introduction: Pain treatment is best performed when a patient-centric, safety-based philosophy is used to determine an algorithmic process to guide care. Since 2007, the International Neuromodulation Society has organized a group of experts to evaluate evidence and create a Polyanalgesic Consensus Conference (PACC) to guide practice.

Methods: The current PACC update was designed to address the deficiencies and innovations emerging since the previous PACC publication of 2012. An extensive literature search identified publications between January 15, 2007 and November 22, 2015 and authors contributed additional relevant sources. After reviewing the literature, the panel convened to determine evidence levels and degrees of recommendations for intrathecal therapy. This meeting served as the basis for consensus development, which was ranked as strong, moderate or weak. Algorithms were developed for intrathecal medication choices to treat nociceptive and neuropathic pain for patients with cancer, terminal illness, and noncancer pain, with either localized or diffuse pain.

Results: The PACC has developed an algorithmic process for several aspects of intrathecal drug delivery to promote safe and efficacious evidence-based care. Consensus opinion, based on expertise, was used to fill gaps in evidence. Thirty-one consensus points emerged from the panel considerations.

Conclusion: New algorithms and guidance have been established to improve care with the use of intrathecal drug delivery.

IDDS for Cancer Pain

Patient experience to treatment



- Consultation
- Neuropsychologic evaluation*
- IT medication trial (catheter, single shot)
- Pump implantation
- Routine pump programming and medication refill

Coding and Reimbursement:

ASC Coding and Payment — Effective January 1, 2022 – December 31, 2022

CPT® Procedure Codes

ASCs use CPT codes for their services. Medicare payment for procedures performed in an ambulatory surgery center is generally based on Medicare's ambulatory patient classification (APC) methodology for hospital outpatient payment, although Comprehensive APCs (C-APCs) are used only for hospital outpatient services and are not applied to procedures performed in ASCs. Alternately, ASC payment for some CPT codes is based on the physician fee schedule payment, particularly for procedures commonly performed in the physician office.

Each CPT code designated as a covered procedure in an ASC is assigned a comparable relative weight as under the hospital outpatient APC system. This is then converted to a flat payment amount using a conversion factor unique to ASCs. Multiple procedures can be paid for each claim. Certain ancillary services, such as imaging, are also covered when they are integral to covered surgical procedures, although they may not be separately payable. In general, there is no separate payment for drugs and devices; their payment is packaged into the payment for the procedure.

Procedure	CPT Code and Description ¹	Payment Indicator ^{2,3,4}	Multiple Procedure Discounting ⁵	Relative Weight ^{2,4}	Medicare National Average ^{2,4,6}
Screening Test ^{7,8,9}	62322 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	G2	Y	6.5887	\$329
	62323 Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)	G2	Y	6.5887	\$329
	62326 Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance	G2	Y	8.5415	\$426
	62327 Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)	G2	Y	8.5415	\$426
	62350 Implantation, revision, or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy	J8	Y	72.4098	\$3,614
Implantation or Replacement of Pump ^{10,11}	62362 Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming	J8	Y	289.8988	\$14,471

ASC Coding and Payment — CPT Procedure Codes *continued*

Procedure	CPT Code and Description ¹	Payment Indicator ^{2,3,4}	Multiple Procedure Discounting ⁵	Relative Weight ^{2,4}	Medicare National Average ^{2,4,6}
Removal of Catheter or Pump ^{10,11}	62355 Removal of previously implanted intrathecal or epidural catheter	A2	N	16.5419	\$826
	62365 Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion	A2	N	50.0454	\$2,498
Drug ^{12,13}	J2274 Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg	N1	N/A	N/A	N/A
	J2278 Injection, ziconotide, 1 microgram	K2	N/A	N/A	ASP+6%
Refill/ Analysis/ Reprogramming ^{14,15}	62367 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill	P3	N	N/A	\$13
	62368 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming	P3	N	N/A	\$18
	62369 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill	P3	N	N/A	\$67
	62370 Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)	P3	N	N/A	\$60
	61070 Puncture of reservoir for injection procedure	A2	Y	6.5887	\$329
Catheter Dye Study ^{16,17}	75809 Shuntogram for investigation of previously placed indwelling non-vascular shunt (eg, indwelling infusion pump)	N1	N/A	N/A	N/A

Courtesy of Medtronic

Incorporating IDDS Therapy to Your Practice

Joining the fight in treating cancer...

- Time commitment
- Providing IPM skills to cancer patients
- Highly rewarding

1. IDDS medication trial
2. IDDS pump implantation
3. Medication/pump management
4. Adoption of partners, APP
5. Home infusion services



Thank You

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