



Perioperative Medicine Summit

Evidence Based Perioperative Medical Care

Implanted device now what?

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Financial Disclosures

None

SPAQI President

Case 1

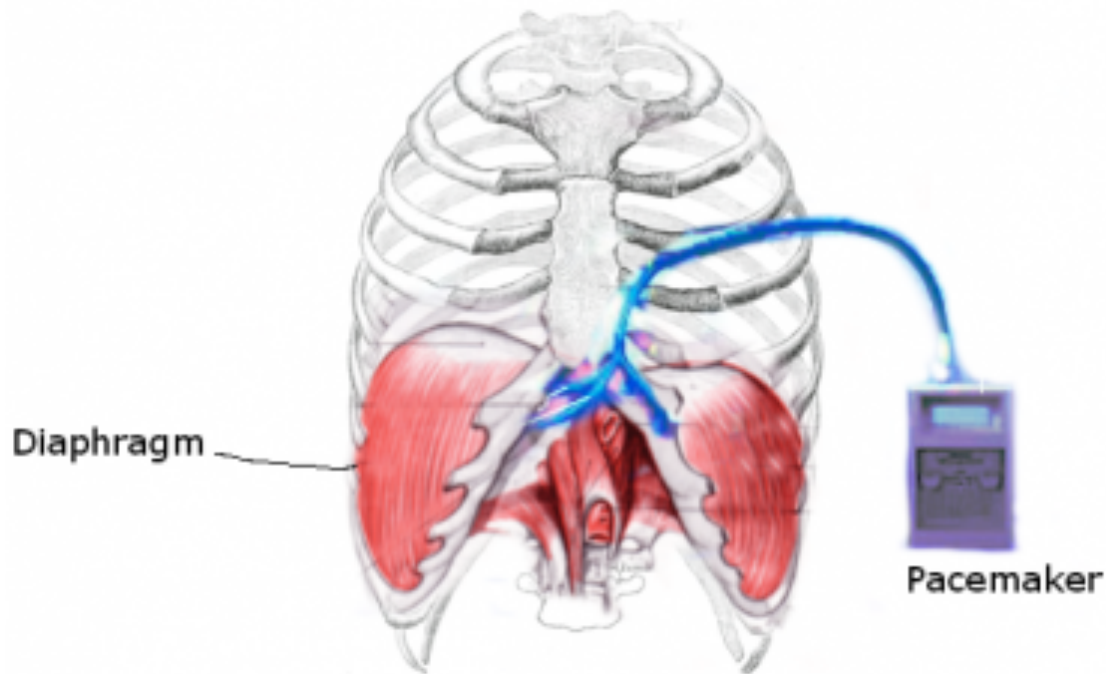
- 59 year old male with advanced ALS
 - Presents for g-tube placement
 - Ventilatory support:
 - BiPAP
 - Diaphragmatic Pacemaker

ALS – Lou Gehrig's disease

Amyotrophic Lateral Sclerosis – rapidly progressive, fatal neurodegenerative disease

- Respiratory and bulbar dysfunction are leading causes of death
- Ventilation
- Aspiration
- End of life wishes
- Device

Diaphragmatic Pacing System (DPS)



<http://emedicine.medscape.com/>

Diaphragmatic pacing

Polio patients

Diaphragmatic paralysis

- not well tolerated
- electrodes placed directly on the phrenic nerve

ALS diaphragmatic pacing model is implanted directly into the muscle of the diaphragm.

FDA approved 2011

Although still not comfortable it offers improved quality of life.

Procedure can be performed at relatively low risk.

Indications

ALS patients

- a. with **stimulatable diaphragm** as tested by either:
 - i. radiologic visualization of diaphragm movement with fluoroscopy or ultrasound
 - ii. neurophysiologic testing

and

- b. experiencing **chronic hypoventilation** as measured by one of the following:
 - i. FVC < 50% of predicted
 - ii. MIP weaker than -60 cm H₂O
 - iii. PCO₂ greater \geq 45 mm Hg
 - iv. SaO₂ less than 88% for 5 consecutive minutes during sleep

Training period

Diaphragmatic pacing in ALS patients

- Activates diaphragm to aid breathing
- Delays diaphragmatic atrophy
- Prolongs life
- Improves sleep quality

DPS

- Protecting the patient
 - Electrocautery
 - 20cm (8")
 - Antibiotics
- Protecting the device
 - Remote
- Replacing the device while inactivated
 - Ventilation

Case 2

75 year old woman for lap chole

- CAD with ischemic cardiomyopathy
- PPM
- ECG pacemaker dependent

?type of device

CAD

Symptoms:

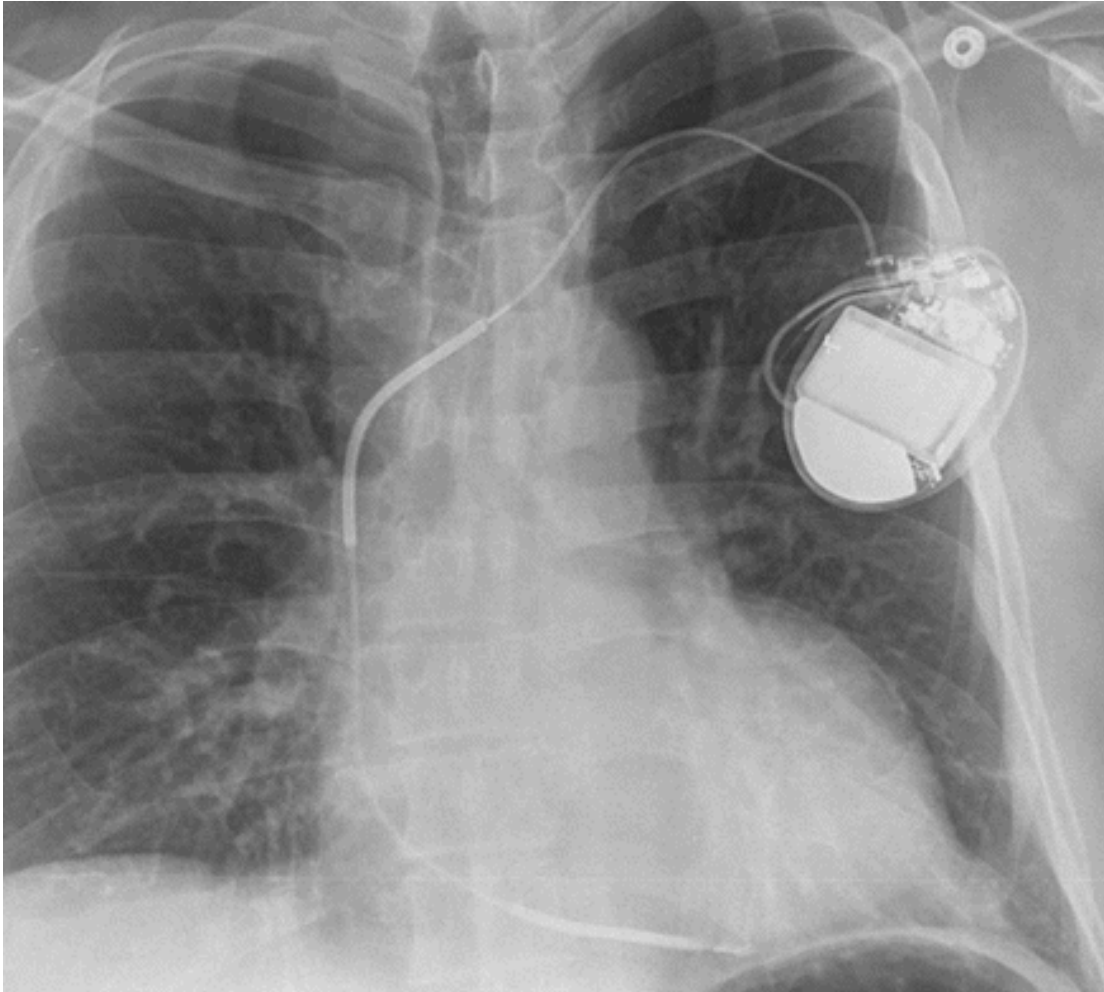
- Ischemia
- Heart failure

Optimal medical management

Stents / Antiplatelet therapy

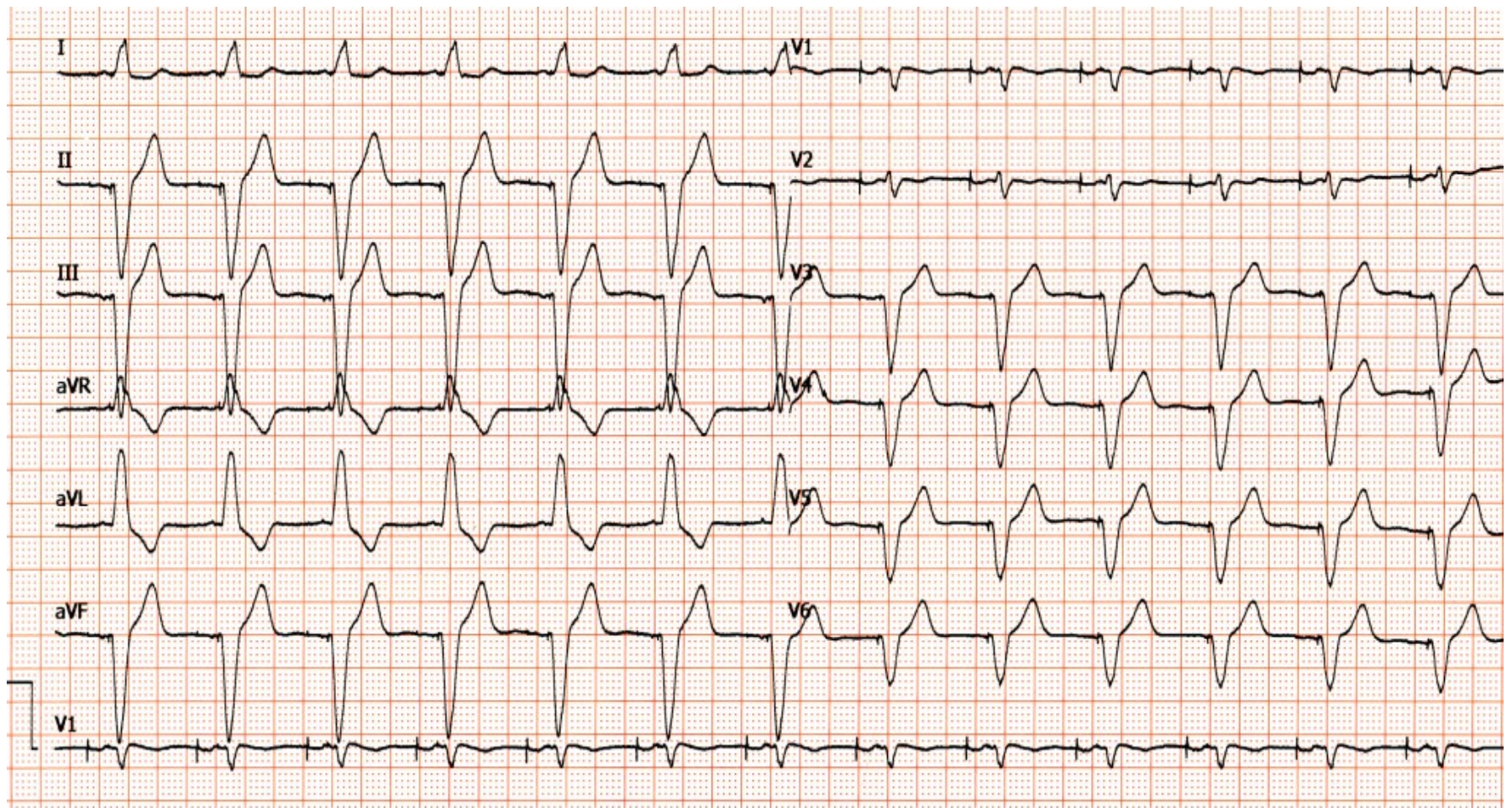
Pacemaker

CXR



Identify CIED brand

- Medtronic : “M”
- Bos Sci “ BSC” or “BOS” or “GDT”
- St Jude “SJM”



Cardiac Implantable Electronic Developments (**CIEDs**)

CIED is an all encompassing term:

- Permanent Pacemaker (PPM)
- Cardiac resynchronization therapy device (CRT-D)
- Automated implantable cardioverter defibrillator (AICD)

History

- Columbia: 1958 external pacemaker implanted in a 70 yr old priest.
 - Internal electrodes,
 - External pacer weighing 45kg
 - 12v car battery
- Sweden 1958 – first fully implantable ppm
- 1960 – rechargeable batteries
- AICDs in the 1980s



Arne H. W. Larsson
(5/26/1915 – 12/28/2001)
26 PPMs and outlived his
cardiologist and surgeon



PPMs

- > 2000 models of PPMs
- 250 000 new/year in US
- > 3 million people have PPM
- treat bradycardia

AICDs

- >120 000 placed /yr.
(1.5% of population has an AICD)
- > 250 000 have AICDs
- defibrillate
- pacemaker functions

Perioperative concerns

- Smaller, more sophisticated, increased susceptibility to electromagnetic interference(EMI)
 - Electro-cautery
 - MRI
 - Radiofrequency ablation
 - ESWL
- Other interference
 - Electrolytes
 - Drugs
 - Fasciculations
 - Shivering

Pre-operative

*“A focused preoperative evaluation of CIED patients consists of the following:
(1) establishing whether a patient has a CIED,
(2) defining the type of device,
(3) determining whether a patient is CIED-dependent for antibradycardia pacing function,
(4) determining device function.”*

- Battery life
- Magnet responsiveness
- Most recent check
 - 3 - 6 months for AICDs
 - 6 - 12 months for PPMs

ASA practice advisory: Anesthesiology: Feb 2011, Vol 114:2, 247-261

Involve the EP service or device company throughout peri-operative period.

Perioperative management

- Not automatic turn off of device
 - Type of device
 - Patient dependence on the device
 - Site of surgery

Intraoperative management - PPM

- Monitor
 - Continuous ECG:
 - increase gain,
 - disable “artifact filter”
 - Continuous monitoring of peripheral pulse
 - Capture
 - Mechanical systole
- Magnet – converts to asynchronous pacing
- Surgical site
 - below umbilicus
 - > 8 inches (20cm)
- Pacemaker dependent?
 - If yes consider asynchronous mode

NASPE/BPEG CODE

North American Society of Pacing and Electrophysiology (NASPE)

British Pacing and Electrophysiology Group (BPEG)

Generic Pacemaker Code (NBG Code)

Defibrillator Code (NBD Code)

Position	I	II	III	IV	V
Category:	Chamber(s) paced	Chamber(s) sensed	Response(s) to sensing	Programmability, rate modulation	Anti-tachyarrhythmia function(s)
	O =None A =Atrium V =Ventricle D =Dual (A+V)	O =None A =Atrium V =Ventricle D =Dual (A+V)	O =None T =Triggered I = Inhibited D =Dual (T+I)	O =None P =Simple programmable M =Multi-programmable C =Communicating R =Rate modulation	O =None P =Pacing (anti-tachyarrhythmia) S =Shock D =Dual (P+S)
Manufacturers' designation only:	S = Single (A or V)	S = Single (A or V)	**	**	**

Bernstein AD et al, Pacing Clin Electrophysiol, 1987 Jul;10(4 Pt 1):794-9

Intraoperative management - PPM

- Monopolar cautery to be avoided
 - bipolar electrocautery
 - harmonic scalpel
 - return pad / cautery tool pathway not to cross leads/pulse generator.
- External pacing available
- Central line placement and PPM leads
- Drugs can affect capture
 - Beta blockers
 - Ca²⁺ Channel blockers
- Fluids/blood
 - pH
 - electrolytes

Intra-operative management- AICD

- Same as PPM and
- Magnet – switch shock function to off
- Reprogram
 - Not magnet responsive
 - Magnet position
 - Interferes with the surgical site
 - Prone position
 - Asynchronous pacing needed
- Transcutaneous pacing/defibrillator pads placed

Post-operatively

- Hands off communication
 - Monitor till device reprogrammed
 - Transcutaneous pads in place till re-activated
- Interrogation

General points

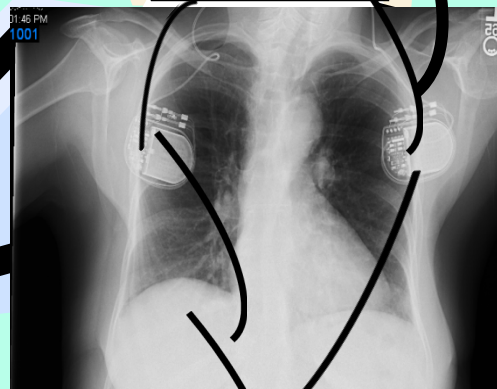
- Chest compressions done in normal manner
- External pads – anterior/posterior position
 - Avoid pulse generator
- Re-interrogate after any resuscitation
 - Shock
- CVP insertion: lead conduction / mechanical injury
- Blood transfusion/recent chemo can affect capture threshold

Case 3

- 69 year old
- Total hip arthroplasty
- Painful osteo-arthritis



Neuro-stimulators



Deep Brain Stimulator

Hypoglossal nerve stimulator

Vagal nerve stimulator

Diaphragmatic stimulator

Spinal cord stimulator

Bladder stimulator

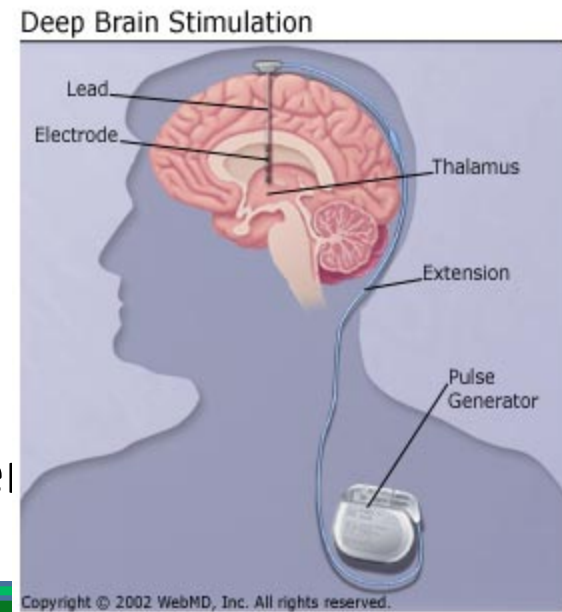
Device	Indication/s
Deep Brain Stimulator (DBS)	Parkinson's disease, essential tremor, depression
Spinal cord stimulator	Chronic pain
Carotid Baroreceptor activation therapy	Hypertension resistant to medication
Vagal Nerve Stimulator (VNS)	Intractable seizures
Occipital nerve stimulator	Headache/migraine
Gastric pacemaker	Gastroparesis
Magnetic band or bracelet	GERD
Phrenic nerve stimulator	Diaphragmatic weakness Directly into muscle in ALS
Cochlear implants (cochlear branch of acoustic nerve stimulation)	Sensorineural hearing loss
Bladder stimulator	Neurogenic bladder symptoms
Hypoglossal nerve stimulator	Obstructive sleep apnea

Deep Brain Stimulation(DBS)

- Bilateral stimulation of the internal globus pallidus or subthalamic nucleus by surgically implanted electrodes, pulse generator, extension lead, patient remote and physician programming device.
- Replaces the irreversible pallidotomy procedure of the 1950s

Indications

- Parkinson's Disease
 - Tremor
 - Rigidity
- Chronic Pain, Obsessive Compulsive Disorder, Dystonia, and Depression




DBS

- Assessing our patient:
 - co-morbidities
 - functional capacity
 - implications of Parkinson's disease (PD)
 - Mobility
 - Recovery
 - Bulbar
 - Cognitive
 - implications of PD therapies
 - DBS management

DBS management

- Indication for DBS
- PD symptom control
- Possible injuries
 - Shock/heating/burns
 - Patient
 - Device
 - Prosthetic material and infection
- Electromagnetic interference – disruption of functioning of electronic device.

General principles

By decreasing severity		Outcomes
Injury to patient	Morbidity and Mortality	Burns, infections
Damage to device	\$\$	Pain and inconvenience
Malfunction of device	Patient discomfort	No stimulation, under or over stimulation
Interference with monitoring		Missed diagnosis
Certain procedures or tests contra-indicated (ESWL/AICD/MRI/radiofrequency ablation)	Absolute Relative	Care plan modification

Peri-op Device Management

- Team approach: device rep, surgeon, anesthesia and coordination usually done by the nurses.
- Management of his Parkinson's Disease and pain
- Turning device off and back on post-procedure
 - Medical implication of holding therapy
 - Turn off and turn amplitude to zero (newer battery –no)
- Distance from surgery site
 - 20 cm
- Electrocautery
 - bipolar
- Prophylactic antibiotics
 - Prosthetic device

Case 4

45 yr old with hepatocellular ca – presents for biopsy for hip lesion.

Intra-hepatic chemotherapy pump

Implantable devices

Have pulse generator – will stimulate

Deep Brain Stimulator

Hypoglossal nerve stimulator

Vagal nerve stimulator

Diaphragmatic stimulator

Spinal cord stimulator

Bladder stimulator

Have drug – will pump

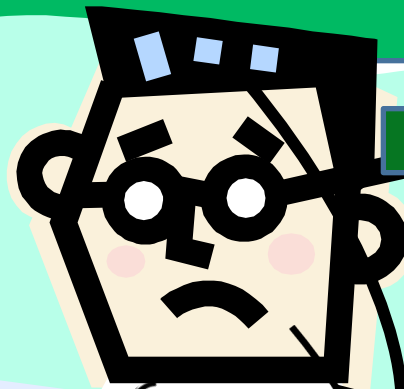
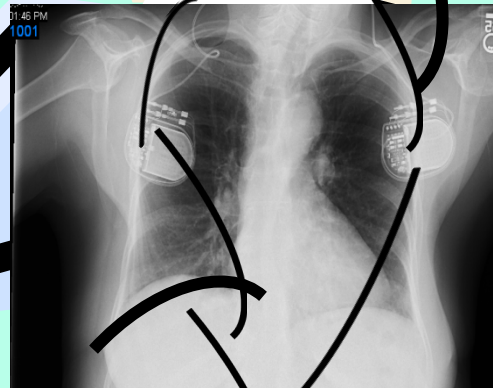
Intrathecal

Epidural

Intra-hepatic

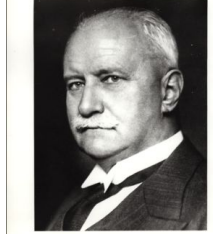
Intra-peritoneal

Subcutaneous



Device	Indications
Intrathecal pump	Chronic pain/spasticity
Intra-hepatic pump	Chemotherapy
Intra-peritoneal	Chemotherapy/Insulin
Intra-venous	Chronic DVT
Subcutaneous	Insulin
Deep Brain Stimulator (DBS)	Parkinson's disease, essential tremor, depression
Spinal cord stimulator	Chronic pain
Carotid Baroreceptor activation therapy	Hypertension resistant to medication
Vagal Nerve Stimulator (VNS)	Intractable seizures
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Bladder stimulator	Neurogenic bladder symptoms
Hypoglossal nerve stimulator	Obstructive sleep apnea

History of Implantable pumps



- Augustus Bier performed the 1st spinal on himself 1898 using cocaine. Bier A. Deutsche Zeitschrift für Chirurgie.1899
- Early 1900s investigators in Japan and the US mixed morphine with the cocaine.
- Opiate receptors were first described in the CNS in an article in Science in 1973.

Pert CB, Snyder SH. Opiate receptor: demonstration in nervous tissue. Science. 1973;179:1011–4.

- 1976: “ The narcotics, acting only at the spinal level, changed cord function to block not only spinal reflexes but also the operant response to painful stimuli.”

Yaksh TL, Rudy TA. Analgesia mediated by a direct spinal action of narcotics. Science.1976;192:1357–8.

History (cont.)

- Intrathecal morphine was first used for cancer pain in 1979
- Continuous spinal
 - Described in 1940s
 - Introduced clinically for labor analgesia 1979

Wang JK, Nauss LA, Thomas JE. Pain relief by intrathecally applied morphine in man. *Anesthesiology*.1979;50:149–51.

History (cont.)

- **Implantable pain pumps were first described in 1981.**

Onofrio BM, Yaksh TL, Arnold PG. Continuous low-dose intrathecal morphine administration in the treatment of chronic pain of malignant origin. Mayo Clin Proc. 1981;56:516–20.

- Safe and effective
- Morphine was the only drug initially
- **Cancer pain and spasticity are primary indications with demonstrated good efficacy**
- Programmable pumps
- Non cancer pain treatment is less well supported
- Chemotherapy pumps followed

Implantable



- Catheter
- Pump (20cm³)
 - Hermetically sealed
 - Subcutaneous port for drug refill
 - Reservoir that needs intermittent refills
 - Enough volume (now up to 50cm²)
 - Controlled by a microprocessor: power source and electronic circuit

Microprocessor

- Microelectromechanical systems (MEMS)
 - Nanotechnology
- Remote recharging
- Programmable
- Independence
- Compliance

Implanted pumps: Indications

- Alternate routes of administration of **chemotherapy** for malignancy
 - Intra-hepatic artery infusion - primary liver malignancy / metastatic colon cancer.
 - Intra-peritoneal for ovarian cancer
- **Diabetes** Requiring Insulin
 - Insulin delivered subcutaneously or by intraperitoneal route
- Investigational use
 - Other cancers
 - DVT treatment
 - Chronic infections

Implanted pumps: Indications

- **Chronic pain** syndromes – neuroaxial
 - After oral meds no longer working or p.o. not tolerated
 - Morphine/hydromorphone
- **Spasticity** associated with cerebral palsy(CP), stroke, spinal cord injury or multiple sclerosis(MS)
 - Baclofen (approved for > 4 years of age)
 - Spasticity worsened by:
 - Pain
 - Full bladder
 - constipation

Implanted Devices: General principles

By decreasing severity		Outcomes
Injury to patient	Morbidity and Mortality	Burns, infections
Damage to device	\$\$	Pain and inconvenience
Malfunction of device	Patient discomfort	Under dose or overdose
Interference with monitoring		Missed diagnosis
Certain procedures or tests contra-indicated (ESWL/AICD/MRI/radiofrequency ablation)	Absolute Relative	Care plan modification



Care of the patients and their pumps

- The drug is usually diluted in saline.
- Sterility is important and the solutions contain bacteriostatic properties.
- Pumps are kept patent by the continuous infusion of the drug.
- Intermittent boluses instead or in addition.
- Chemo agent should be removed and
- If not in use, the pump should be flushed with a heparin bolus.

Managing the co-morbidities

Cancer

- Chemotherapy side effects
 - neutropenia
- Chemo infusion port site
- Radiation
- Immuno-compromise
- Infection
- Impaired coagulation
 - platelets

Patient education: Awareness of interactions with other devices and tests

- Strong electromagnetic interference (EMI) e.g. defibrillation, diathermy, electro-cautery, MRI, radiofrequency ablation, and therapeutic ultrasound
- Metal detectors at airports, anti-theft devices in retail stores
- Magnet in the device may damage certain items or erase information



Subsequent surgeries

Verify:

- The drug/s in use
- Site of the pump, the catheter, the port
 - The catheter can be placed intrathecal, epidural, intra-ventricular, subcutaneous, intra-peritoneal, intra-arterial (hepatic artery usually).
- Positioning of the patient for the procedure may affects pump function or cause pressure injury to the patient.
- Surgical incision and invasive monitoring need to avoid the implanted pump.

Drug Management

Δ Dose

Insulin

Take

Pain

Spasticity

Hold

Chemo

- Sedation and respiratory depression interactions
- Withdrawal – baclofen – fever, confusion, spasms
- opiate

Implanted devices - Key Points

- Indication for the device
- Associated co-morbidities
- Perioperative risks
 - Sources of electromagnetic interference
 - Patient injury
 - Device damage
 - Device malfunction
 - Interference with diagnostics
- Management

In conclusion

Coordination of care throughout the peri-operative process.

- Primary practitioners
- Surgeon and anesthesiologist
- Device company
- Application of clinical management pathways and processes in order to prevent injury to
 - Patient
 - Device

Thank you.



Society for Perioperative Assessment
and Quality Improvement

Appendix: Company Phone Numbers

Medtronic 1 (800) 723-4636 (Tachy)

1 (800) 505-4636 (Brady)

1 (800) 328-0810

St Jude Medical 800-722-3774

Guidant Medical 800-227-3422 (1-800-CARDIAC)

Biotronik 800-547-0394

ELA Medical 800-352-6466

Intermedics (Guidant Medical) 800-227-3422

Pacesetter (St Jude Medical) 800-722-3774

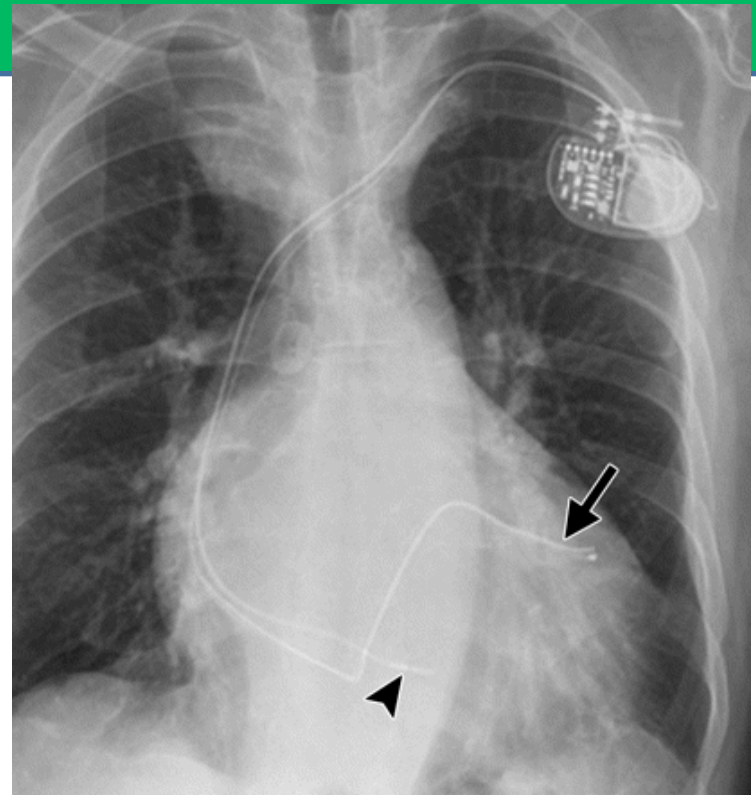
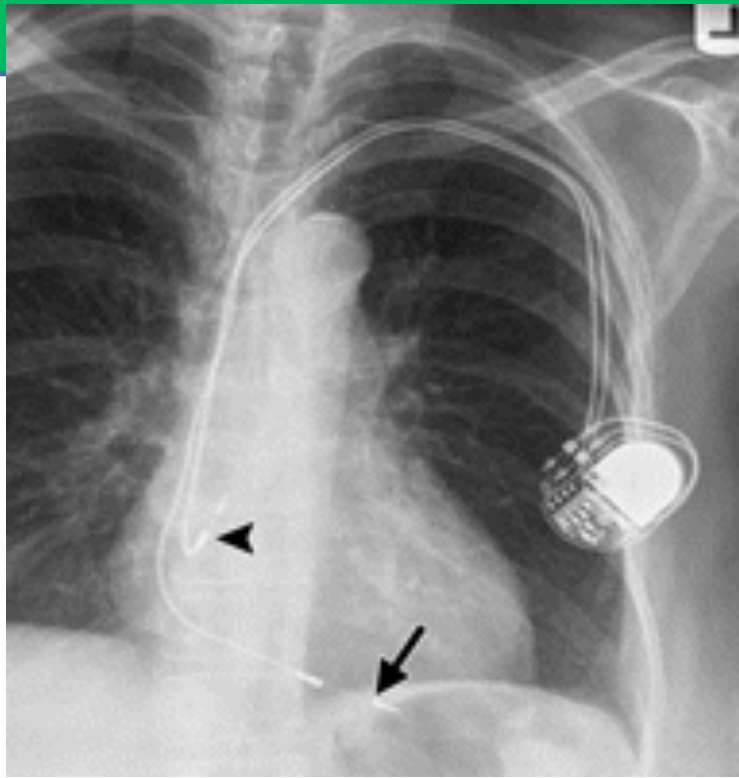
Telectronics (St Jude Medical) 800-722-3774

Ventritex (St Jude Medical) 800-722-3774

Vitatron (Medtronic) 800-328-2518

References

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<https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>
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16. Meng E et al. *Advanced Drug Delivery Reviews*, Volume 64, Issue 14, 2012, 1628 – 1638
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Spinal cord stimulator

Subcutaneous neurostimulator in lower abdomen or gluteal region.

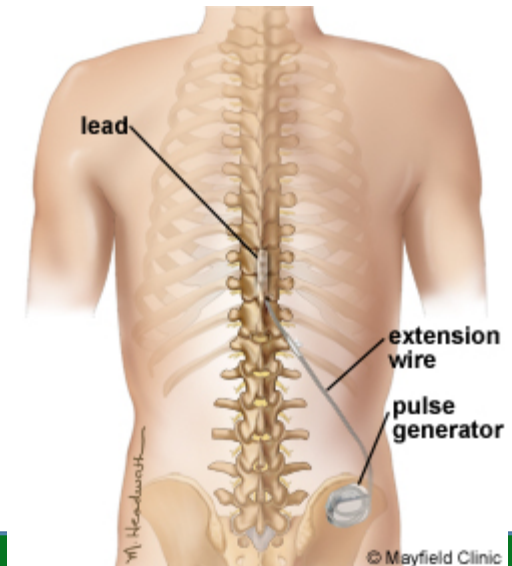
- Electrode in lumbar, cervical, or thoracic spine.
- Remote control.
- Physician/ rep control

Indications

- Chronic pain
 - Moderately effective for back pain after failed surgery
 - RSD
 - Ischemic
- Spasticity
- Arachnoiditis
- Neuropathy

Mechanism of action – based on the gate theory.

Trial period



Spinal Cord Stimulator

- Increasing sophistication
 - Rechargeable batteries
 - Positional stimulation
 - High power RF for challenging pain syndromes
- Trial period – staged implantation

Spinal cord stimulator

Co-morbidities

- Pain/pain meds
- Anxiety /depression
- Muscle weakness
 - Neuromuscular blockers
 - Respiratory function
 - Bulbar function

Interaction with other devices and tests

- Strong electromagnetic interference (EMI) e.g. defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound
- metal detectors at airports, anti-theft devices in retail stores
- magnet on the stimulator control device may damage certain items or erase information

Intrathecal Drug Delivery Systems (IDDS) a.k.a. Pain pump

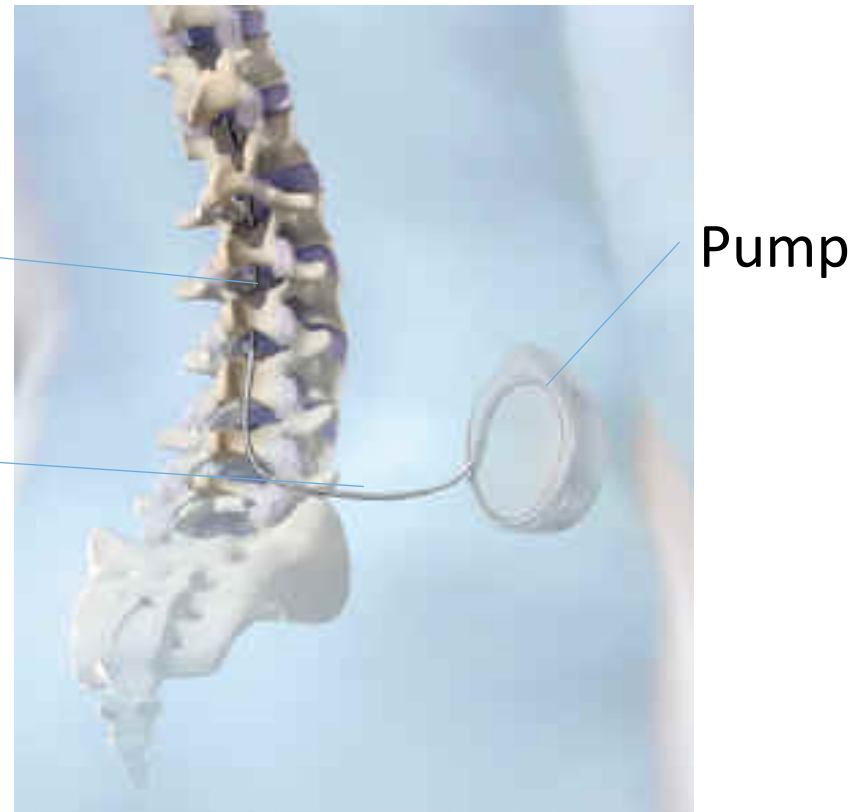
Drug delivered at receptors

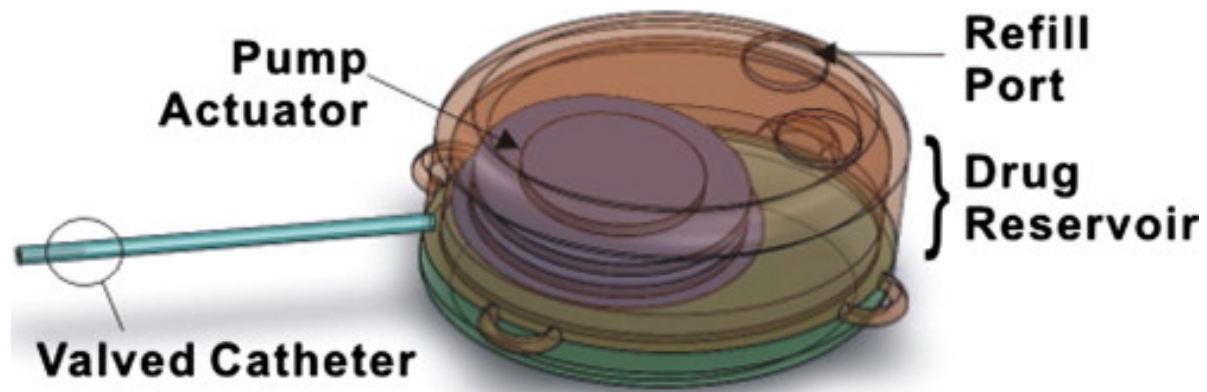
Fraction of dose for effect

Intrathecal catheter

Tunneled catheter

External programmer





Ellis Meng , Tuan Hoang

MEMS-enabled implantable drug infusion pumps for laboratory animal research, preclinical, and clinical applications

Advanced Drug Delivery Reviews, Volume 64, Issue 14, 2012, 1628 - 1638

<http://dx.doi.org/10.1016/j.addr.2012.08.006>

Driving mechanism

- Peristaltic rollers or piezoelectric discs
 - Programmable
 - Battery operated – 4-7 year battery life
- Magnetic piston
 - Minimizes battery use by partially driven by magnetic forces
 - Fills by withdrawing
 - Pumps by opposite direction move
 - One way valves
- Fluorocarbon propellant - vapor pressure mechanism
 - Fixed rate
- Osmotic pressure
- Combination of above

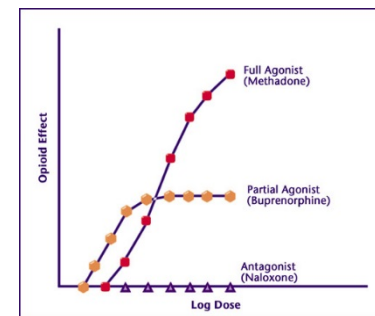
Managing the co-morbidities

Chronic pain

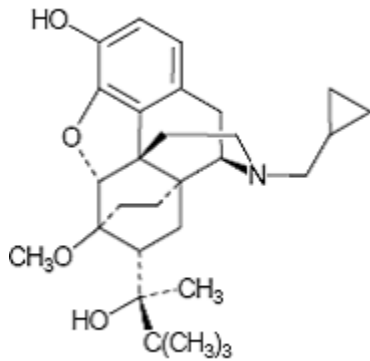
- Tolerance
- Low pain tolerance
- Anxiety
- Abuse and addiction
- Self absorbed
- RSD
- Acute pain service consults – accurate history of pain medications – opiate and non-opiate, risk factors for side effects (e.g. OSA)

Buprenorphine

- Buprenorphine - FDA approved 2000
 - available as: Buprenex[®]; Butrans[™]; Subutex[®]
- Schedule 3 narcotic (methadone is 2)
- Partial agonist
- Partial agonist - Treating mild to moderate pain (chronic)
- Detoxification (buprenorphine alone)
- Buprenorphine/Naloxone 2002
 - Suboxone[®]
- Why combination?
 - to prevent other than sublingual use.
- Managing opiate addiction



www.naabt.org

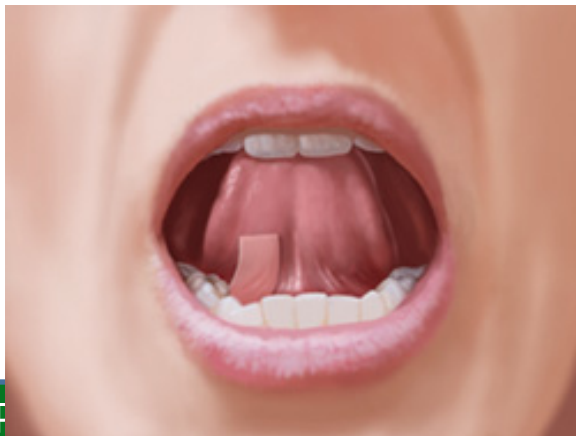


• HCl

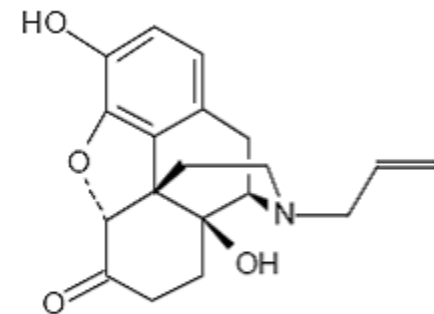
buprenorphine HCl is (2S)-2-[17-Cyclopropylmethyl-4,5 α -epoxy-3-hydroxy-6-methoxy-6 α ,14-ethano-14 α -morphinan-7 α -yl]-3,3-dimethylbutan-2-ol hydrochloride.

$C_{29}H_{41}NO_4 \cdot HCl$

- semisynthetic opioid thebaine derivative
- extremely high binding affinity at the μ -opioid (ag) and κ -opioid receptors (antag)

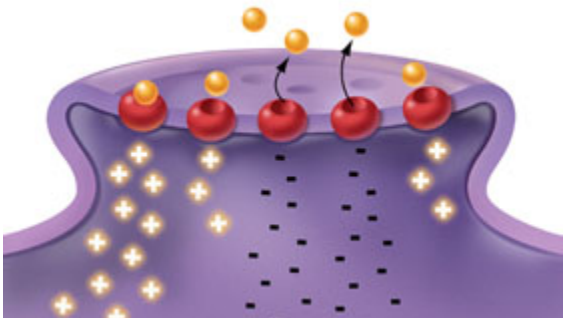
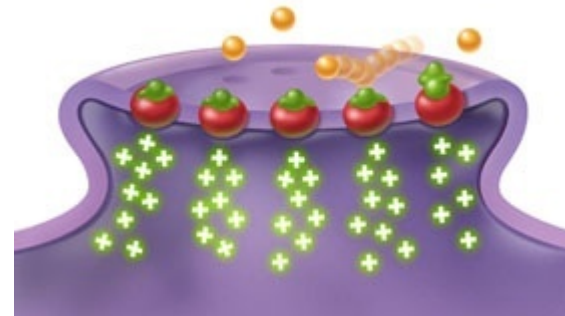
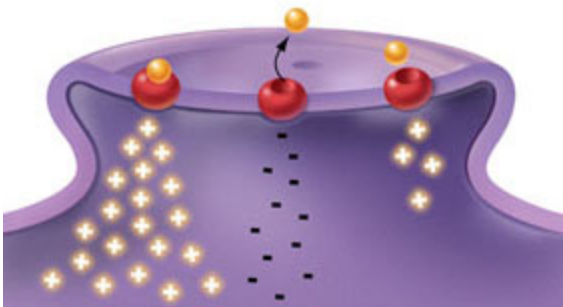
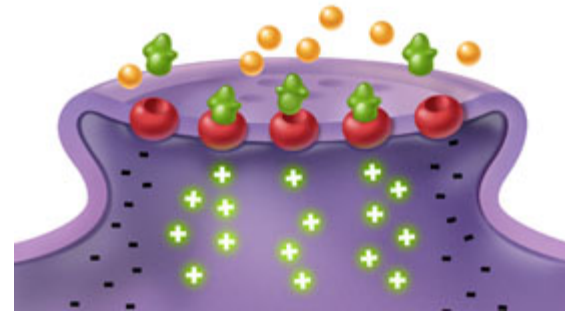
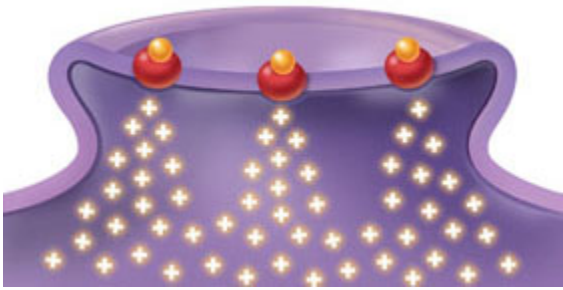


naloxone HCl






HCl • 2H₂O





Buprenorphine – 50 x higher affinity with receptor than morphine

-  Morphine molecule
-  Mu receptor
-  Buprenorphine

Side Effects of Buprenorphine

- **At risk for poor pain control perioperatively**
- Abuse
- Diversion
- Respiratory depression
- CNS depression
 - synergistic with sedatives especially benzodiazepines
- Withdrawal
- Pediatric
- Hepatitis

Buprenorphine -perioperative management

Controversial - Discuss with prescribing physician

$t_{1/2}$ 24-42 hours

Hold, and replace with alternative:

- 2 doses
- 3 days
- 5 half lives
- 1 week

Hold for 2 days

Continue:

- Use high dose buprenorphine
- Or /Add: High dose morphine
- Regional block – if necessary continuous and admit

Involve the Acute Pain Service

Not usually appropriate for ambulatory surgery centers

Patients want to avoid opiates and recurrence of addiction