Diaphragm Pacing
Useful Skills

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Diaphragm Pacing

• **Indications**
  – Congenital central hypoventilation syndrome (CCHS)
  – **High tetraplegia** (above C-3)
  – {Intractable hiccups}
  – {End-stage COPD}

• **Contraindications**
  – Phrenic nerve injury or paralysis
  – Spinal cord injury (SCI) to C3-5 region
  – {Primary neuromuscular disorder (ALS)}
  – Restrictive lung disease
Preoperative Evaluation

- **Chest radiograph** - elevated hemidiaphragm
Preoperative Evaluation

- **CT scan** - neck and chest
- **Fluoroscopy** - average excursion 3-5 cm, ranging 2-10 cm; sensitive when supine
- **Sniff test** - paralysis from weakness
- **Phrenic stimulation** - cervical thimble electrode with EMG
Preoperative Evaluation

ALS inclusion criteria

• Chronic hypoventilation
  – FVC < 50% predicted (>45%), or
  – MIP < 60 cmH₂O, or
  – pCO₂ ≥ 45 mmHg, or
  – SaO₂ < 88% for 5 consecutive mins during sleep

• Phrenic nerve function
  – Neurophysiology testing, or
  – Visualizing diaphragm contraction via fluoro, or
  – Radiographic technique such as U/S
Preoperative Evaluation referrals

- Lecture circuit - medical and laypersons
- Make connections - trauma, spine, intensivist, pulm, rehab pm&r, neuro
- Share the evaluation - EMG, fluoro, rehab privileges, re-programming
- Industry - supportive personnel with surgeon proctoring, websites, forums, webinars
Pacing Devices

- Avery Biomedical Devices (Commack, NY)
  - Mark IV Breathing Pacemaker System
  - Direct implantation on phrenic

- Synapse Biomedical, Inc (Oberlin, OH)
  - NeuRx Diaphragm Pacing System
  - Implants into motor point on diaphragm
Pacing Devices

• **Avery** Mark IV phrenic nerve pacemaker
  – FDA-approved since 1986
  – Class III medical device
  – Approx $48,500

• **Synapse** NeuRx diaphragm pacing system
  – FDA-approved since 2008
  – HUD/HDE with IRB protocol required
  – Approx $31,600 and less for ALS
Surgical Implantation
getting started in clinic

• Intact phrenic nerve
  – Stable spine
  – Stable ALS
• Insurance pre-approval
• Institution approval
• Purchase of device
• Sterilization routine
# Surgical Implantation

**getting started in clinic**

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>34.85</td>
<td>Implantation of a diaphragmatic pacemaker</td>
</tr>
</tbody>
</table>

## Common Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>V46.11</td>
<td>Dependence on Respirator, Status (ICD-10, Z99.11)</td>
</tr>
<tr>
<td>327.24</td>
<td>Idiopathic sleep related nonobstructive alveolar hypoventilation (ICD-10, G47.34)</td>
</tr>
<tr>
<td>327.25</td>
<td>Congenital central alveolar hypoventilation syndrome (ICD-10, G47.35)</td>
</tr>
<tr>
<td>344.01</td>
<td>C1-C4, Complete quadriplegia (ICD-10, G82.51)</td>
</tr>
<tr>
<td>344.02</td>
<td>C1-C4, Partial quadriplegia (ICD-10, G82.52)</td>
</tr>
<tr>
<td>356.8</td>
<td>Other specified idiopathic peripheral neuropathy (ICD-10, G60.8)</td>
</tr>
<tr>
<td>519.4</td>
<td>Diaphragm paralysis (ICD-10, J98.6)</td>
</tr>
<tr>
<td>748.8</td>
<td>Other specified congenital malformations of respiratory system (ICD-10, Q34.0)</td>
</tr>
</tbody>
</table>

## MS-DRG Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>163, 164, 165</td>
<td>Major chest procedures (with MCC, with CC, without CC or MCC)</td>
</tr>
<tr>
<td>907, 908, 909</td>
<td>Other OR procedures for injuries (with MCC, with CC, without CC or MCC)</td>
</tr>
<tr>
<td>957, 958, 959</td>
<td>Other OR procedures for multiple significant trauma (with MCC, with CC, without CC or MCC)</td>
</tr>
<tr>
<td>981, 982, 983</td>
<td>Extensive OR procedure unrelated to principal diagnosis (with MCC, with CC, without CC or MCC)</td>
</tr>
</tbody>
</table>

## CPT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array, peripheral nerve. Use with HCPCS C1778 (CMS recommended replacement for Code 64577, which is deleted as of 1/1/2012)</td>
</tr>
<tr>
<td>64590</td>
<td>Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling. Use with HCPCS C1767.</td>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrodes. If a revision procedure, use with HCPCS C1778.</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral neurostimulator pulse generator or receiver. If a revision procedure, use with HCPCS C1767.</td>
</tr>
</tbody>
</table>

## HCPCS Codes

<table>
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<tr>
<td>C1778</td>
<td>Lead, neurostimulator (implantable). Use with CPT 64575 or CPT 64585.</td>
</tr>
<tr>
<td>C1816</td>
<td>Receiver and/or transmitter, neurostimulator. Use with CPT 64590 or CPT 64595.</td>
</tr>
</tbody>
</table>
Surgical Implantation
getting started in OR

• Intubation
  – Tracheostomy
  – Double-lumen tube

• Limited neuromuscular blockade

• Destination
  – PACU vs ICU
  – Home ventilator

• Coordinate with company rep
  – Intraoperative mapping and thresholds
  – In-service session w/ periop team, pt family/caregivers and rehab unit
Phrenic Nerve Pacemaker
external transmitter

- Transmits RF energy to the implanted receiver transcutaneously via antenna
- Two independent channels, standard 9-volt batteries
- Lightweight and small for portability
Phrenic Nerve Pacemaker antenna

- Delivers RF energy from transmitter to implanted receiver transcutaneously
- Affixes directly over the implanted receiver by tape or strap
Phrenic Nerve Pacemaker implanted receiver

- Placed in subcutaneous pocket
- Simple design, easy to locate and cover with antenna
- Adaptable version available for connection to other implants
Phrenic Nerve Pacemaker

**phrenic nerve electrode**

- Surgically placed around phrenic nerve
- Cervical or thoracic implantation
- Reliable unipolar design for long-term function
Phrenic Nerve Pacemaker
transtelephonic monitor
Phrenic Nerve Pacemaker
cervical approach

- Remove trach and intubate, cover stoma
- Transverse incision at base of neck, lateral to SCM
- Stimulate to confirm- can get brachial plexus if too deep or lateral
- Seat cup around nerve for contact, but avoid stretch
Phrenic Nerve Pacemaker
thoracoscopic approach

Courtesy Avery Biomedical Devices
Diaphragm Pacing System

device system
Diaphragm Pacing System
laparoscopic approach

- Standard 4 ports: 2-10s and 2-5s
- PEG  • Stoma  • RUQ lead exit
Diaphragm Pacing System mapping
Diaphragm Pacing System mapping

Courtesy Raymond Onders, MD
Diaphragm Pacing System
electrode insertion
Diaphragm Pacing System

electrode insertion
Diaphragm Pacing System
diaphragm stimulation

Courtesy Raymond Onders, MD
Postoperative Management
device settings

- Rate: 12-16 bpm
- Pulse intensity: threshold of excitability
  - Amplitude: 10-25 mA
  - Pulse width: 100-200 µs
- Pulse frequency: 5-20 Hz
- Inspiratory time: 1.1-1.3 s
Postoperative Management
count of pacing

• Timing: 7 days to 7 months
• Tidal volume: compromise with ventilator
• Muscle conditioning: recruit slow-twitch fibers, resist fatigue
• Downsize tracheostomy, switch to button
Postoperative Management complications

- Nerve injury
  - Stretch
  - Devascularization
- Muscle injury
  - Capnothorax
- Infection
- Device failure
  - Splice kit
  - Receiver replacement
Postoperative Results

- Decreased risk of tracheal complications with improved posterior lobe ventilation
- More natural phonation, speech, taste
- Reduced health care costs: $13,000/mo
- Increased freedom: battery, attendants
- Better quality of life
Postoperative Results
commentary

- Mark IV cervical implantation is probably the least technical approach.
- NeuRx DPS is cheaper.
- Mark IV is fully implanted.
- NeuRx DPS does not really risk injury to nerve.
- Mark IV is easier to re-program.
- NeuRx DPS seems more versatile with other applications; e.g., temporary pacing.
Diaphragm Pacing

summary

• Develop a multi-disciplinary program with other providers and institution
• Healthy relationship with industry as well
• Thorough assessment of pt and phrenic
• Proven benefits: SCI, CCHS and now emerging for ALS… marginal lung function patients (txp, acute injury, low FEV$_1$)
"It feels like I'm breathing on my own.... just like I used to!"

cducko@partners.org

www.averybiomedical.com
www.synapseebiomedical.com