Intrathecal baclofen therapy

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- No disclosures
- No plans to discuss off-label uses
ITB: Indications

- This course addresses the surgical approaches to managing increased tone in childhood spasticity.
- It is assumed that non-surgical options are being considered.
- The choices of surgical interventions remain highly empiric, with little evidence extant which allows for an understanding of comparative effectiveness.
- However, this will change.
Surgery selection at a single institution: Gillette Children’s

- Over 100 years of care for patients with childhood-onset disability
- SDR introduced late 1980s
- First ITB pump 1996
- SDR at conus introduced 2012
Approach to surgery selection

- Ambulatory children are assessed in a single, multidisciplinary clinic (SPEV, or spasticity evaluation).
- Usually undergo motion analysis first, if possible
- Seen in clinic by pediatric orthopedist, neurosurgeon and physiatrist
So who gets a rhizotomy?

- **Between 1980s-1995:** SDR for anyone with spasticity interfering with function

- **After 1995,** ITB program began
  - Best ITB candidates were the “worst” SDR candidates
  - In other words, the subset of SDR patients with best results were identified
The “ideal” SDR candidate

- Ambulatory, diplegic CP patients
- Pure spasticity
- History of prematurity
- PVL or normal imaging
- Can cooperate with rehabilitation
- Age range (goal) 4-8, but will do later
Increased tone?

SDR candidate?

Yes

SDR

No

ITB
How did our program evolve?

- Consider GMFCS level:
  - 1-2 SDR
  - 3 We don’t know?
  - 4-5 ITB
  - (no surprises here)
By diagnosis?

- CP: see above
- Degenerative/progressive disorders: usually ITB
- Trauma (TBI, spinal cord injury): usually ITB
- Hereditary spasticity: great ITB patients (seems to be a model of “pure” spasticity)
Occasional determinants

- Some centers will not do ITB in shunted hydrocephalus (Primary Children’s, SLC)
- Access to refills may be an issue (international patients)
Do we stop evolving?

- We are doing more SDR in “good” GMFCS 3 patients than in the past.
- We will convert ITB to SDR if pump morbidity has been high.
- We will accept more deviations from the ideal candidate than in the past (e.g. a little dystonia, etc.)
Choice of SDR by type?

- Currently doing about 30 SDR/year
- One surgeon only does conus, one only does cauda, other two use both, depending on case
- Our early data suggest greater chance of persisting distal spasticity in conus patients (whether due to anatomical differences, learning curve, etc)
DON’T FORGET YOUR FLIP FLOPS
ITB: technique

- Patient selection: patient size and pump size
- Pre-operative antibiotics
- Surgical technique
- Post-operative management
- Dosing
Patient size and pump size

- Patient size does correlate with risk of infection
  - Avoid patients < 15kg or below 10th% on combined height-weight

- Length of abdomen is important
  - Does pump fit between costal margin and pelvis?

- Discuss subcutaneous vs. subfascial placement with family

- When in doubt, use 20 ml pump
Pre-operative antibiotics

- Choice of antibiotics can be based on common pathogens.
- Staph infections are still the most common, but consider the risk of Gram negative infections when an surgical ostomy is present or if the patient is incontinent.
Pre-operative antibiotics

- All patients receive intranasal mupirocin in pre-op area and for then BID x 4 days
- All patients receive vancomycin 15 mg/kg IV before incision, then 24h post-op
- All patients with increased risk of Gram negative infection receive gentamicin 2 mg/kg IV before incision, then 24h post-op
Surgical technique

- Ascenda catheter, SynchroMed II pump (20 vs 40ml size)
- Check shunt pre-op when present
- Lateral position, use fluoro and CSF flow to confirm placement
- Usually subcutaneous pocket (less painful than sub-fascial)
Surgical technique

- Insertion off-midline at L2-3 or L3-4 (less movement at these segments)
- Tip placement between T6-T10 seems to work
- Higher tip placement is inconsistent in terms of improving dosing in upper cord or affecting the arms
  - Drug distribution is a function of its density and body position
  - Concentration 4x higher in lumbar than cervical CSF samples
- Consider complex dosing options
Initial dosing

- Typically start at either 50 or 100 mcg/d
- Have a plan for weaning/stopping oral baclofen
- If this is for pump replacement (assume normal function) maintain same dose
- If dosing has been adjusted up over time and ultimately catheter issue is identified, start with a lower dose
- Start with simple continuous delivery
ITB malfunctions

- Pumps are remarkably stable, except near end of battery life
- Catheters can fail, although long-term data on Ascenda is still being collected
- Pumps can get infected
Infection Failures vs All Other Failures

- Infection Failures
- All other Failures

Percent survival vs Months
Pump infection

- Guiding principles of surgical decision-making are similar to those applied in shunt management
- Very few infections are successfully treated with the hardware in place
- Infections which can be treated without pump removal would include Pneumococcus, Haemophilus
- All others can be suppressed with an antibiotics, but pump removal is necessary for cure
Surgery for infection

- Relocating an exposed pump can be done, assuming no fever and (-) CSF culture.
- Typical patient has presented immediately after wound failure, exposed pump is tapped and antibiotics started immediately.
- New pump placed on opposite side, can consider preserving intraspinal portion of catheter if replacement would be difficult (eg prior fusion).
Explanting an infected pump

- In most other cases, pump will need to be explanted
- Clinical meningitis may be an indication for rapid explant
- If no meningitic features, can try to wean ITB (while on antibiotics) prior to explant
- Reimplant when there is no laboratory evidence for infection, after antibiotics completed
Gee, you're right

Humans don't land on their feet
Surgical approach to pump malfunction

- Careful review of images might give guidance to where the problem is
- However, most catheter problems occur in the setting of normal images
- First, rule out infection
- Think about hydrocephalus
Pump exploration

- Start at abdominal incision
- Limited sharp dissection in order to avoid catheter injury
- Look for catheter crossing in front of pump at refill port
- Check for free fluid in pocket
- Inspect connector for puncture of catheter (especially where moving part meets non-moving part)
Pump exploration (2)

- Try to aspirate catheter: if no flow, plan on replacing catheter
- If there is back flow, clear 2-3 ml then clamp catheter in the pocket and inject it to check for leak
- Repair or replace if leak found
- If the catheter is patent and no damage detected in pocket, plan on opening back and checking for damage there.
- When in doubt, replace the catheter
Pump exploration (3)

- We do not do imaging to look for granuloma formation (not seen in baclofen therapy, usually in mixed drugs)

- Beware of shunted patients:
  - Hard to know when catheter is intrathecal (low CSF pressure)
  - Consider shunt failure presenting as apparent withdrawal
Top 10 “secrets” about ITB pump management

- I don’t really have secrets, I just wanted to acknowledge Dave Letterman’s retirement

- OK, this is actually a distillation of 20 years of pump management in a single institution…..

- I hope that it is helpful
10. ITB is reversible

- Rhizotomy is not.
- A basic consideration, but helpful when decision-making is not straightforward
9. Test doses are over-rated...

- But I would not stop anyone from doing them
- Initially required by some payers
- Previously fused patients became the first exclusion group
- In a consecutive series: 98/100 test doses had (+) responses, 1 was repeated and was (+) and 1 family declined (LE Krach, personal communication)
• A bolus test dose is not really equivalent to a functioning ITB dose, but as the ITB clears the patient “passes through” the ideal dose

• Oral baclofen has no predictive value when considering pump placement
8. Fusion is not an ITB contraindication

- A pain for surgeons, perhaps, but not a contraindication
- Either go through it (drill) or go around it (high)
- (If operating, remember that the anatomy is not normal)
7. Surgery can be combined with another procedure

- In our series, when ITB surgery was combined with injection therapies, orthopedic procedures (both extremity and spine surgery), the infection rate was not significantly different from that of isolated ITB surgery ($p=0.2$)
6. Placing a pump in a shunted patient is harder, but feasible

- Spinal fluid pressure can be negative (sub-atmospheric)
- Canal may be smaller than typical
- A small laminotomy may be required to confirm placement
5. The Ascenda catheter is hard to see

- The guidewire is helpful for placement in OR, but once removed only the tip marker is typically visible

- Caveat: this catheter might also be hard to aspirate (anecdotal experience)
4. Wean before explant, whenever possible

- Meningitis is worse than withdrawal, but not always
- Pump infections do not spread to shunts and vice versa
3. Beware of increasing dose requirements

- Frank withdrawal is obvious, but patients with normal pump function typically do not develop increasing dose requirements

- Always think about shunt malfunction and/or pain as a cause of increased tone
2. Imaging is of limited use in evaluating pumps

- Dye studies and rotor studies are not helpful, plain films might be
Pump catheter connector tear, no extravasation

Contrast entering intrathecal space
Torn pump catheter connector
1. A pathway for assessing possible withdrawal is crucial

1. Give bolus and check if due for refill

2. If no response, get films and tap sideport
   - Broken/dislodged catheter ➔ to OR
   - Cannot aspirate sideport ➔ to OR

3. Check ERI and consider replacement
Dead doctors and nurses are still on the job, researcher claims
“If you had to identify, in one word, the reason why the human race has not achieved, and never will achieve, its full potential, that word would be ‘meetings.’”

Dave Barry