Sacral Neuromodulation for Fecal Incontinence and Constipation

Toyia James-Stevenson, MD

January 6, 2015
Focus of Talk

- Discuss work-up of patients prior to SNS
- Literature review of pts with FI and Constipation
- Discuss details of SNS placement
SACRAL NEUROMODULATION IN FECAL INCONTINENCE
Definition

- Fecal Incontinence - Unintentional loss of solid or liquid stool
- Anal Incontinence - Includes leakage of gas and/or fecal incontinence
Clinical Sub-types of FI

- **Passive** – stool leakage with little or no forewarning (often have low resting pressure)
- **Urge** – occurs despite active efforts to retain stool
  - May have abnl squeeze pressure and duration
  - May have reduced rectal capacity with rectal hypersensitivity
- **Seepage** – Leakage after BM
  - Incomplete evacuation or impaired sensation
Prevalence of FI by Sex and Age

Risk Factors

- **Chronic Diarrhea**
- **Rectal Urgency**
- **Burden of Chronic Illness (Comorbid count, DM)**
- Urinary Incontinence
- Pelvic Surgery
- Caucasian Race

- Smoking (also RF for external sphincter atrophy on MRI)
- Obesity
- Instrumented Vaginal Delivery
- Decreased physical activity
- Advanced Age

**OPTIONS FOR MANAGEMENT OF FECAL INCONTINENCE**

- Conservative Management (Meds, Dietary Advice, Kegels)
- Pelvic Floor Therapy/Biofeedback
- Continence Products
- Anal Plugs
- Sphincter Repair (Overlapping Sphincteroplasty)
- Sacral Nerve Stimulation
- Posterial Tibial Nerve Stimulation (not FDA-approved)
- Injectable Bulking Agent (Sodium Hyaluronate Dextranomer Microspheres)
- Temperature-Controlled Radiofrequency Energy to Internal Anal Sphincter
- Diversion with Colostomy
- Artificial Bowel Sphincter/Magnetic Anal Sphincter
Why Is This Important?

- Can have devastating impact on quality of life
- Loss of dignity, modesty, confidence
- Many do not share with closest relatives and friends
- Fewer than 30% discuss their FI with physicians
- Caregiver burden >> urinary incontinence
- Common cause of nursing home admission
Normal Anorectal Function

• IAS- smooth muscle, 70-85% of resting tone
• Stool causes rectal distention
  – Rectal contraction
  – Urgency sensation
  – Relaxation of IAS (RAIR)
• EAS, PR and levator ani can be voluntarily contracted to maintain continence (85% of squeeze tone)
Changes in Anorectum with Age

- Lower resting and squeeze pressures (decrease by 30-40% in pts >70 yo)
- Denervation of anal sphincter
- Decreased rectal compliance (stiffer rectum)
- Decreased rectal sensation
- Perineal laxity

Fox et al, Dis Colon and Rectum, Nov 2006
At Least 8 Factors Affect Continence

1. Sphincter function
2. Anorectal sensation
3. Puborectalis function
4. Rectal compliance
5. Colorectal motility
6. Stool consistency
7. Peripheral/central innervation
8. Cognition
Suggested algorithm for evaluation and management of fecal incontinence.

Clinical evaluation including digital rectal examination

- Treat underlying disease and manage bowel disturbances
- Treat local anorectal problems

Persistent symptoms

- Anal manometry
  - Normal pressures
  - Weak pressures
    - Consider anal imaging, EMG if appropriate
- Rectal sensation
  - Reduced
- Rectal balloon expulsion
  - Abnormal
    - Evacuation disorder
    - Pelvic floor retraining
    - Persistent Symptoms
    - Consider sphincteroplasty or sacral nerve stimulation or NASHA Dx, if appropriate

Biofeedback

- A few small single-center studies have shown benefit of biofeedback over pelvic floor exercises.
- Benefit may be highest in those with urge incontinence and predominantly EAS weakness.

**FIGURE 1.** Fecal Incontinence Severity Index (FISI) scores at baseline, pretreatment (end of run-in), and at 3 months post-treatment in patients treated with biofeedback versus pelvic floor exercise (PFE). At the 3-month follow-up, patients in the biofeedback group had greater reductions in FISI scores versus patients in the PFE group (*P* = 0.01, ANOVA). *P* = 0.01, biofeedback versus PFE. Adapted from Heymen et al. 40
Overlapping Sphincteroplasty

• EAS muscles overlapped in the anterior midline
• Better outcome than end-to-end repair
• Long-term data shows suboptimal improvement

<table>
<thead>
<tr>
<th>Year</th>
<th>Author</th>
<th>N</th>
<th>Months follow-up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>Karoui et al.</td>
<td>74</td>
<td>40</td>
<td>45% Continent to solid and liquid</td>
</tr>
<tr>
<td>2002</td>
<td>Halverson and Hull</td>
<td>49</td>
<td>69</td>
<td>4 Stomas</td>
</tr>
<tr>
<td>2006</td>
<td>Barisic et al.</td>
<td>65</td>
<td>60</td>
<td>46% Continent to solid and liquid 48% “Good or excellent”</td>
</tr>
<tr>
<td>2009</td>
<td>Oom et al.</td>
<td>120</td>
<td>69</td>
<td>37% “Good or excellent”</td>
</tr>
</tbody>
</table>
SNS Indication in FI

• Most appropriate in those who have failed conservative management and NOT having diarrhea:
  – Medications (Fiber, Imodium, Laxatives)
  – Dietary Advice (Low FODMAPs, lactose free)
  – Biofeedback
Proposed Mechanism of Action

• Stimulation of the anterior ramus of the sacral spinal nerves S3 or S4

• Why do patients improve?
  – Pelvic afferent and/or central level
  – Peripheral motor stimulation is not primary mechanism of action

Carrington et al, Neurogastroenterol Motil. 2014 Sep;26(9):1222-37
Pretreatment Evaluation

- **Anorectal Manometry with Compliance and Sensation**
  - Can help identify patients with dyssynergic defecation
  - Can identify patients with rectal hyposensitivity, which can improve with SNS

- **Endoanal ultrasound**

- **Neither test has been shown to predict who will have best outcomes**

- **Plain Xray identified skeletal abnormalities**
  - Imperforate anus
  - Spina bifida (MRI first as potential skeletal deformity)
  - Meylomeningocele
  - Previous Spinal surgery
# Evaluating FI When Conservative Measures Fail

<table>
<thead>
<tr>
<th>Tests for Fecal Incontinence</th>
<th>Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anorectal Manometry with Sensation and Compliance (ARM)</td>
<td>Evaluates for: a) Weakness of IAS/EAS b) hyper- and hyposensitivity c) stiff or overly lax rectum d) paradoxical sphincter contraction, which can lead to overflow incontinence/fecal seepage e) intact reflexes</td>
</tr>
<tr>
<td>Balloon Expulsion Test (BET)</td>
<td>Prolonged times indicates obstructive defecation (most frequently due to dyssynergic defecation; can also be caused by anatomic issues like rectoceles)</td>
</tr>
<tr>
<td>Defecography (MR or Barium)</td>
<td>Evaluates anatomy of pelvis and sphincters</td>
</tr>
<tr>
<td>Endoanal Ultrasound</td>
<td>Evaluates for sphincter disruption or thinning</td>
</tr>
<tr>
<td>EMG</td>
<td>Assesses sphincter activity using surface electrode or concentric needle; may help distinguish neurogenic from myogenic injury</td>
</tr>
</tbody>
</table>
Why do ARM and Balloon Expulsion?

• In pts referred to IU Motility Lab for FI
  – 35 (18%) had obstructive defecation
  – 14 (10%) fulfilled criteria for dyssynergic defecation (abnl BET + paradoxical sphincter contraction/incomplete sphincter relaxation)

• Pts with fecal seepage may have abnl sphincter relaxation → ~70- 80% respond to biofeedback
Endoanal Ultrasound in FI

- Assesses structural integrity and morphology of anal sphincters
- Reliable for detecting IAS defects
- EAS assessment can be operator dependent (nl variation such as EAS gaps possible)
- Can have low specificity as degree of separation may not correlate with symptom severity


Indiana University Health
Sphincter Defect in SNS

• NOT a contraindication

• Little data on whether pts with smaller defects do better

• Largest studies included only patients with defects of less than 120°
Percutanous Nerve Evaluation (PNE)

- Temporary electrode or a tined (quadrupolar) lead which would be definitive in the event of > 50% improvement in symptoms.
- Evaluation can last from 1-4 weeks (longer duration better in those not having daily symptoms).
- Patients with >50% symptom improvement can go on to have permanent stimulator placed.
- Data suggests that those with greater improvement may do better long-term.
Peripheral Nerve Evaluation

• Basic evaluation
  – Up to 7 days
  – Office or ASC
  – +/- fluoro or ultrasound
  – Local Anesthesia
  – Flexible thin wire
  – One electrode contact (typically switched to opposite side in 3 days)
  – Infection rare so no Abx
  – Positive result $\rightarrow$ permanent device
  – Inconclusive result $\rightarrow$ ? Stage 1 device

• Stage I device
  – Up to 14 days
  – ASC or OR
  – + fluoroscopy
  – MAC or general anesthesia
  – Flexible lead with tines that anchor in place
  – Stays in place after positive evaluation
  – 4 electrodes
  – Abx prophylaxis
  – Positive result $\rightarrow$ permanent device
  – Inconclusive results $\rightarrow$ consider other therapies
Permanent Lead Placement

• Done under fluoroscopy
• 1.7X2.0 inches
• Weighs .77oz
• Implanted under the skin of the upper buttocks
• Done by colorectal surgery, urology, urogynecology

Primary adverse effects are pain and infection
Bowel Diary and Incontinence Score

• Useful and baseline and in short term for assessment of symptoms

• Incontinence score useful to monitor outcomes compared with baseline values

• Long-term QOL assessment is also important
Predictors of Good Outcomes in SNS for FI

- No correlation between:
  - Age
  - BMI
  - Duration
  - Urge vs Passive Incontinence
  - Preoperative manometry (small study suggests negative correlation of response in pts with higher squeeze pressures)

- More significant the reduction in FI episodes during temporary SNS trial

Preprocedural Counseling

• Reprogramming or Revisional Surgery may be required for permanent stimulator including removal

• 75% of patients will have improvement but not abolishment of fecal incontinence
SNS Special Consideration

• Limited Data in Pediatrics

• Pregnancy
  – SNS should not be implanted during pregnancy
  – No detrimental effects seen in pts who become pregnant
  – Typical recommendations are to switch off device as soon as pregnancy noted

• Elderly good candidates as long as deemed fit

Maeda et al, Colorectal Dis. 2015 Apr;17(4):O74-87
Special Considerations

- Concomitant urinary symptoms (urgency, incontinence, retention) common and these patients may benefit and should be discussed with urologist/urogyn

- Case reports Benefits seen in pts with incomplete spinal cord injuries, spina bifida, cauda equina, disc prolapse
Contraindications

• Patients requiring regular MRIs of abdomen or thorax

• Technical success rates lower and risk of complications should be explained:
  – Sacral Deformity
  – Skin condition at site of implant
  – Bleeding diathesis
Sacral Neuromodulation Long-term

- Data from 67/120 pts available at 5-8yrs
- FI episodes per week ↓ from a mean of 9.1 at baseline to 1.7 at 5 years,
- 89% (n = 64/72) had ≥50% improvement (p < 0.0001)
- 36% (n = 26/72) had complete continence
- 27/76 (35.5%) pts required a device revision, replacement, or explant.

Tjandra, Disease of Colon and Rectum, Feb 2013
Permanent SNS

- Meta-analysis from 2000-2008 shows complication rate of 15% with removal in 2.7%

- Newer device smaller but expensive ($40K) and associated with fewer complications
Sacral Neuromodulation Long-term

Tjandra, Disease of Colon and Rectum, Feb 2013
Economic Impact of FI

• Lack of US data on economic impact
• No prospective studies comparing cost effectiveness of conservative therapy versus SNS or bulking agents
• In UK, each increment in quality-adjusted life year gained with SNS for FI costs $35,000
• Largest impact likely from indirect costs
  – Potential for NH admission
  – Maintenance of productivity
SNS for Constipation

• Not FDA-approved
• Slow-transit and/or dyssynergic defecation refractory to medications and pelvic floor biofeedback

• Baseline evaluation:
  – ARM with compliance and sensation
  – Balloon Expulsion Test
  – Colon transit study
  – Defecography
SNS and the Colon

- 5 studies looking at segmental and total colon transit effects in those with FI showed no change

- One FI study looking at colon scintigraphy showed ↑ in retrograde movements during defecation (10/13 pts)

- One study of 11 pts with FI using colon manometry showed ↑ in distal retrograde propagating contractile sequences

Constipation and Colon Manometry with SNS

• 1 study of 8 pts undergoing 24-hr manometry:
  – doubling of anterograde pressure sequence frequency throughout colon
  – frequency of high amplitude pressure sequences
  – pressure sequences propagating more than 30 cm along the bowel
  – Sx improvement and ↓laxative use in 6/8

• Newer studies have not shown as great a benefit in constipation as seen in FI

Dinning et al, Colorectal Dis 2007; 9: 123–32
Summary

• Sacral Neuromodulation is a safe and effective therapy for treatment of FI when more conservative management fails and patients respond to temporary trials

• More data is needed on patient selection and effectiveness in patients with refractory constipation