A Case of Fecal Incontinence: Medical and Interventional Treatment Options
HPI

• JP is a 69 year-old F with a 12-month history of FI. Her symptoms began after a colonoscopy

• She has been experiencing passive “accidents” 3-4x/week consisting of the loss of 1.5 teaspoons -1/4 cup of pasty Bristol 5 stool

• She denies urge, stress, and overflow components. She is passing 1 Bristol 4 BM daily
HPI

• Obstetric History;
  – 2 vaginal deliveries
  – (+) episiotomies with each delivery
  – No acute episodes of FI

• Prior Diagnostics:
  – Colonoscopy x2 → Normal

• Prior Therapeutics:
  – PEG 3350 taken on an intermittent basis
- PMH: GERD, Hyperlipidemia
- PSH: Ventral hernia repair
- Meds: Zocor, Prilosec
- Allergies: Sulfa
- FHx: (-) GI disorders/malignancies
- SHx: Widowed, RN, (-) tobacco/ETOH
- ROS: 10/14 (-)
Physical Exam

• General Exam: No abnormalities

• External perianal exam: (-) EH; (-) fissures/fistulae; (-) excoriations/rashes; (+) anal wink; (+) appropriate descent; (-) prolapse identified

• DRE: (+) weakened resting tone and squeeze pressure, normal strain maneuver, no stool palpated
JP: Resting Pressure

Normal
Weak

Changes concerning for passive incontinence
JP: Maximum Squeeze Pressure

Normal

Changes concerning for urge incontinence

Weak
History Continued:

What treatment options are available for JP?
## Non-pharmacologic Management of Fecal Incontinence

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Mechanism of Action</th>
</tr>
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<tbody>
<tr>
<td>Incontinence pads/Cotton balls/Butterfly pad</td>
<td>Provides skin protection; prevents soiling; conduct moisture away from skin</td>
</tr>
<tr>
<td>Anal plugs</td>
<td>Provides a barrier to fecal incontinence; can be difficult to tolerate. Type can impact performance</td>
</tr>
<tr>
<td>Enemas</td>
<td>Voluntarily and selectively evacuates rectum</td>
</tr>
<tr>
<td>Anorectal biofeedback</td>
<td>Improves rectal sensation and compliance; coordinates external anal sphincter contraction; may increase anal sphincter tone</td>
</tr>
</tbody>
</table>

Long-term Results of Biofeedback for Solid Stool Fecal Incontinence

Assessed @ 1, 6, 36, 60 MONTHS

Group A: Continence fully recovered
Group B: >75% reduction in # of incontinence episodes
Group C: <75% reduction in # of incontinence episodes
Group D: No improvement or worse than before therapy

Pharmacologic Management of Fecal Incontinence

- Anti-diarrheals
- Tricyclic antidepressants
- Bile acid binding resins
- Topical phenylephrine gel

No pharmacologic treatments have been adequately evaluated in large, randomized, controlled studies in patients with fecal incontinence
History Continued:

• Based on ARM findings JP referred to the Rehabilitation Institute of Chicago for PFPT/BF

• She undergoes 6 sessions of PFPT/BF but decides to stop because she finds it ineffective

• What other options are available?
  – Injectable bulking agents
  – Sacral Nerve Stimulation (SNS)
Cochrane: Injectables for the Treatment of FI

5 trials:

- Silicone biomaterial
- Collagen
- Carbon-coated microbeads
- Dextranomer-hyaluronic acid

One large randomized controlled trial has shown that this form of treatment using dextranomer in stabilized hyaluronic acid (NASHADx) improves continence for a little over half of patients in the short term. However, the number of identified trials was limited and most had methodological weakness.

Injectable Bulking Agents for FI

• Biocompatible gel of dextranomer microspheres in hyaluronic acid (Solesta®)
• Administration
  – Done in physician office or hospital outpatient department w/o anesthesia
  – Four 1 cc injections through an anoscope into submucosal layer of the anal canal
  – Bulks and approximates anal mucosa closing anal canal or increasing pressure

• 2011:FDA-approved for the treatment of fecal incontinence in patients aged ≥18 years who have failed conservative therapy

NASHA Dx

50% Decrease in FI episodes @ 6 months

52%

N=136

31%

N=70

p=0.0089
NNT=5

Secondary Endpoints: Decrease in FI Episodes After Solesta® Treatment

P<0.0001 @ 12 MONTHS

NASHA Dx: Improvement in Number of FI-Free Days

Almost 2-fold increase (4.4 to 7.8 days) of incontinence-free days

## NASHA Dx: Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Dextranomer Microspheres (n=136)</th>
<th>Sham (n=70)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proctalgia</td>
<td>19 (14%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Rectal hemorrhage</td>
<td>10 (7%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7 (5%)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Injection site bleeding</td>
<td>7 (5%)</td>
<td>12 (17%)</td>
</tr>
<tr>
<td>Rectal discharge</td>
<td>5 (4%)</td>
<td>—</td>
</tr>
<tr>
<td>Anal pruritis</td>
<td>2 (2%)</td>
<td>—</td>
</tr>
<tr>
<td>Proctitis</td>
<td>4 (3%)</td>
<td>—</td>
</tr>
<tr>
<td>Painful defecation</td>
<td>2 (2%)</td>
<td>—</td>
</tr>
<tr>
<td>Fever</td>
<td>11 (8%)</td>
<td>—</td>
</tr>
<tr>
<td>Rectal abscess*</td>
<td>1 (1%)</td>
<td>—</td>
</tr>
<tr>
<td>Prostate abscess*</td>
<td>1 (1%)</td>
<td>—</td>
</tr>
<tr>
<td>Others</td>
<td>22 (16%)</td>
<td>5 (7%)</td>
</tr>
</tbody>
</table>

*Serious adverse events

NASHA Dx: Long-Term Efficacy

Open-Label 12 & 24 Month Follow-UP

Responder defined as >50 % reduction in FI episodes

Sacral Nerve Stimulation (SNS) System

1. **Tined lead** is placed parallel to the sacral (S2, S3, or S4) nerve

2. **Neurostimulator** generates electrical pulses delivered through the leads

3. **Clinician and patients** set the parameters of the electrical pulses

4. FDA approved 2011

SNS Placement
Sacral Nerve Stimulation System: Bowel Control Study

Improvement in Weekly Incontinent Episodes

<table>
<thead>
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<th>Follow-up Interval</th>
<th>Percent of Patients</th>
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<tbody>
<tr>
<td>3 Months (n=113)</td>
<td>38.9</td>
</tr>
<tr>
<td>6 Months (n=107)</td>
<td>39.3</td>
</tr>
<tr>
<td>12 Months (n=106)</td>
<td>40.6</td>
</tr>
<tr>
<td>24 Months (n=67)</td>
<td>37.3</td>
</tr>
<tr>
<td>36 Months (n=30)</td>
<td>40</td>
</tr>
</tbody>
</table>

Sacral Nerve Stimulation System: Bowel Control Study

- Most common adverse events (≥5%) reported during the implant phase:

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant site pain</td>
<td>25.8%</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>12.5%</td>
</tr>
<tr>
<td>Implant site infection</td>
<td>10.8%</td>
</tr>
<tr>
<td>Change in sensation of stimulation</td>
<td>8.3%</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>6.7%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5.0%</td>
</tr>
</tbody>
</table>

26 SAEs: 13 (10.8%) experienced implant site infection. 5 infections treated with medication; 7 (5.8%) required surgical intervention (5 device explants and 2 device replacements)

The limited number of identified trials together with methodological weakness of many do not allow a definitive assessment of the role of anal sphincter exercises and biofeedback therapy in the management of people with faecal incontinence. We found some evidence that biofeedback and electrical stimulation may enhance the outcome of treatment compared to electrical stimulation alone or exercises alone. Exercises appear to be less effective than an implanted sacral nerve stimulator. While there is a suggestion that some elements of biofeedback therapy and sphincter exercise may have a therapeutic effect, this is not certain. Larger well-designed trials are needed to enable safe conclusions.
History Completed:

• Risks, benefits, and contraindications of interventional procedures discussed
• JP chooses Solesta® as initial intervention and this is injected without complications
• 3 months later she continues to experience significant improvement
  – Mild leakage 1-2x/week
  – 1 cc of liquid stool in her undergarment
• Barrier devices recommended PRN
Review: Treatment Options for Fecal Incontinence

Least Invasive

Decision based on balance between risk & likelihood of positive outcome

Most Invasive

Pharmacology/Non-pharmacological Interventions

Dextranomer Microsphere Injections

SNS

Other Surgical Interventions

Decision based on balance between risk & likelihood of positive outcome.