Current and Novel Treatments for Fecal Incontinence

Peter L. Rosenblatt, M.D.
Director of Urogynecology and Pelvic Reconstructive Surgery
Mount Auburn Hospital, Cambridge
Assistant Professor, Harvard Medical School

Learning Objectives

• Understand the prevalence and impact of fecal incontinence
• Identify the various etiologies of fecal incontinence
• Describe the medical and surgical treatments for fecal incontinence, including new and investigational options.

Disclosures

I disclose the following financial relationships with commercial entities that produce healthcare-related products or services relevant to the content I am planning, developing or presenting:

– American Medical Systems
Why should we care about FI?

- Devastating medical condition for individual
- Effect on self-confidence and personal image
- Leads to isolation / depression
- Second leading cause of admission to nursing homes
- Patients are often reluctant to discuss with health care professionals.

Incidence of Fecal Incontinence After Childbirth

- 8,774 women responded (40%) at 3 – 6 months
  - 2,569 (29%) reported FI
    - 46% stool incontinence
    - 38% flatal incontinence only
- FI associated with
  - Higher BMI
  - Forceps delivery
  - Longer 2nd stage
  - 3rd / 4th degree episiotomy
  - Smoking


Fecal Incontinence in U.S. Women

- Population-based postal survey in WA state
  - 6,000 women
    - Age 30 – 90
- Fecal Incontinence at least once a month
- Prevalence of FI = 7.3%
  - 3.6% of 30 – 39 year olds
  - 15.2% of 80 – 90 year olds

Fecal Incontinence

*recurrent, uncontrolled passage of fecal material over a period of at least one month, in an individual with a developmental age of at least 4 years*

Minor Fecal Incontinence

*inadvertent escape of flatus or partial soiling of undergarments with liquid stool*
**Major Fecal Incontinence**

*involuntary excretion of solid feces*

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**Continence Factors**

- Stool volume and consistency
- Mental function
- Colon transit
- Rectal distensibility
- Anorectal reflexes
- Anorectal sensation
- **Anatomic factors**

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**Internal Anal Sphincter (IAS)**

- Responsible for 80% resting tone
- Continuation of circular smooth mm of rectum
- Innervated by parasympathetics (S2 – S4)
- Rectoanal Inhibitory Reflex
  - 20 – 40 cc
  - “Sampling” rectal contents
External Anal Sphincter (EAS)

- Striated muscle under voluntary “squeeze” control
- Innervated by pudendal nerve (S₂-₄)
- Commonly injured during vaginal delivery

Pelvic floor muscles

- Puborectalis / pubococcygeus
- Innervated by levator ani nerve
- Responsible for anorectal angle
- Maintains stool in rectum
- Relaxes for defecation

Nichols, Vaginal Surgery, 3rd ed
Obstetrical Risk Factors for FI

• Multiparity
• Instrumental delivery
• Large birth weight
• Prolonged second stage

Anal Disruption During Vaginal Delivery

• Prospective study of 150 women before and after delivery with anal U/S
• Results
  - Primiparous
    • No sphincter defects before delivery
    • 35% had defects after delivery
      - only 3% apparent at time of delivery
  - Multiparous
    • 40% had sphincter defects before delivery
    • 44% had defects after delivery

Sultan AH et al. NEJM 1993;329:1905-11
Evaluation of Fecal Incontinence

- History and Physical
- Digital Rectal Exam (DRE)
- Imaging studies
  - Endoanal Ultrasound
  - Defecography
  - Pelvic Floor MRI*
- Functional studies
  - Anorectal Manometry
  - Pudendal Nerve Terminal Motor Latency*

Traditional Treatment of Fecal Incontinence

- Non-surgical
  - Dietary modification
    • Bulking agents
  - Antidiarrheal medications
    • Loperamide (Imodium)
    • Diphenoxylate-atropine (Lomotil)
  - Biofeedback
- Surgical
  - Anal sphincteroplasty
  - Artificial anal sphincter

Long-Term Results of Overlapping Sphincter Repair

<table>
<thead>
<tr>
<th>Place / Year</th>
<th># Pt</th>
<th>Follow-up Average (months)</th>
<th>Totally Incontinent (%)</th>
<th>Incontinent of Flatus Only (%)</th>
<th>Totally Continent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>St. Marks, 2000</td>
<td>38</td>
<td>77</td>
<td>89</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>France, 2000</td>
<td>74</td>
<td>40</td>
<td>49</td>
<td>23</td>
<td>28</td>
</tr>
<tr>
<td>Cleveland Clinic, 2002</td>
<td>49</td>
<td>69</td>
<td>54</td>
<td>32</td>
<td>14</td>
</tr>
<tr>
<td>University of Minnesota, 2004</td>
<td>104</td>
<td>120</td>
<td>77</td>
<td>17</td>
<td>6</td>
</tr>
</tbody>
</table>
Anal sphincter defects in incontinent and continent women

- Endoanal US in 468 patients
  - 65% sphincter defects in incontinent Pts (n=335)
  - 43% sphincter defect in continent Pts (n=115)
- “Caution should be used in attributing incontinence to anal sphincter defects alone”


Artificial Anal Sphincter

- Multicenter, prospective, nonrandomized study of 112 patients (86 women)
  - Mean age 49 (18-81)
- Surgical revision in 51 patients (46%)
- Removal in 41 patients (37%)
- 53% successful outcome (intent-to-treat).


Stimulated Dynamic Graciloplasty

- 52 patients underwent surgical repair*
  - 73% continent after median 2 years
- 128 patients (multicenter trial)**
  - 66% success (>70% improvement)
  - 39% major wound complications

Future Treatments of Fecal Incontinence

- Sacral Nerve Stimulation
- Injectable agents*
- Magnetic Anal Sphincter*
- Trans-Obturator Post Anal Sling (TOPAS)*

*Not FDA approved for fecal incontinence

Sacral Nerve Stimulation

- Electrical stimulation of sacral nerve roots
- Initially used for urologic indications
- First reported for FI in 1995*
- Received FDA approval for FI March, 2011

*Smatz, KE. Lancet 1995; 346:1124

SNS for fecal & urinary incontinence long-term follow-up

- 24 women with FI and UI
- Mean follow-up 28 months
- Results
  - 31.8% with improvement in FI / UI
  - 54.5% without any improvement in FI
  - 4 patients with colostomy
  - 4 patients had IPG explanted
    - infection or poor clinical response

El Gazzaz. Int J Colorectal Dis 2009;24(12)1377-81
Sacral Nerve Stimulation for Fecal Incontinence: Results of a 120-Patient Prospective Multicenter Study

- 133 patients underwent test stimulation
  - 120 (90%) patients received implant (110 women)
  - 12 month results
    - 83% success (>50% reduction in FI episodes)
    - 41% total continence
    - Incontinent episodes per week: 9.4 to 1.9
  - Adverse events
    - 25.8% implant site pain
    - 12.5% paresthesia
    - 10.8% implant site infection


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InterStim Therapy for Bowel Control

Clinical Efficacy: Reduction in Episodes

![Graph showing reduction in bowel incontinence episodes over time]


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Clinical Efficacy: Complete Continence

![Graph showing percentage of patients with complete continence]

Injectable Agents for FI*

- Contigen®
  - cross-linked collagen
- Permacol®
  - porcine dermal collagen
- Silicone
  - PTP, Bioplastique®
- Bulkmam®
  - hydrogel cross-linked with polyacrylamide
- Durasphere®
  - pyrolytic carbon coated beads

*not FDA approved for FI

Intra-anal collagen injections for fecal incontinence

- 73 patients (59 women), median age 63
- Total 5 ml Contigen® injected
- 63% improved CCFIS at 12 months
  - Median pre-treatment score 10
  - Median post-treatment score 6
  - 5% completely continent
- No change in mean resting pressure


Magnetic Anal Sphincter

- 14 Pt with > 2 FI episodes/week, mean age 62
- No intraoperative complications
- Adverse events in 7 patients
- 2 devices removed and 1 passed spontaneously
- 5 patients at 6 months had significant decrease in FI
  - 7.2 to 0.7 per week
- Wexner Score 17.2 to 7.8

Methods

- Retrospective analysis of initial experience with Transobturator Posterior Pelvic Sling
- Pre-operative evaluation
  - Bowel diary
  - POP-Q, digital rectal exam
  - Pelvic floor MRI
  - Anorectal manometry / PNTML
  - FIQOL, Wexner scale
- Post-operative evaluation
  - Bowel diary
  - POP-Q, digital rectal exam
  - FIQOL, Wexner scale

Pre-operative Evaluation

<table>
<thead>
<tr>
<th>MRI (n=12)</th>
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<tbody>
<tr>
<td>EAS intact</td>
<td>9/12</td>
</tr>
<tr>
<td>IAS intact</td>
<td>9/12</td>
</tr>
<tr>
<td>Anorectal Angle (rest)</td>
<td>121.5° (99-160°)</td>
</tr>
<tr>
<td>Anorectal Angle (strain)</td>
<td>129.9° (100-160°)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Anorectal Manometry (n=12)</th>
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<tbody>
<tr>
<td>Max resting pressure (mean)</td>
<td>46.2 mm Hg</td>
</tr>
<tr>
<td>Max squeeze pressure (mean)</td>
<td>72.6 mm Hg</td>
</tr>
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Fecal Incontinence: Summary

- Fecal incontinence is a common, underreported disorder in women
- Etiology is often multifactorial
- Medical management & dietary changes may significantly improve FI
- Renewed interest with evolving minimally-invasive surgery