Updates on the Treatment of Fecal Incontinence

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ACG/VGS/ODSGNA Regional Postgraduate Course
September 6, 2014

No Financial Disclosures

Agenda

• **Overview of Fecal Incontinence (FI)**
  – Prevalence and Burden
  – Common causes of FI
  – Evaluation

• **Medical and Surgical Interventions**
  – Diet and Medications
  – Anal Sphinteroplasty
  – Sacral Nerve Modulation
  – Solesta
  – TOPAS
**Definition of Fecal Incontinence**

- **Fecal incontinence** is the involuntary loss of liquid or solid stool that is a social or hygienic problem (Norton 2010)
- **Anal incontinence** is the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem.
- **Accidental bowel leakage** (Brown 2012)- preferred term for patients; fecal incontinence is a symptom

**Types of FI**

- **Fecal Urgency**
  - Associated with external anal sphincter dysfunction

- **Passive FI**
  - Typically associated with internal anal dysfunction

- **Fecal seepage**
Prevalence of Fecal Incontinence

• Prevalence rates reflects:
  – The population being queried
  – The definition of the condition
  – Data-collection methods

• A systematic review of the literature addressing community dwelling adults noted FI prevalence rates of 0.4-18%

It is estimated that more than 18 million adults in the United States
– 1 in 12 suffer from fecal incontinence (FI)

FI is nearly as prevalent as many other chronic diseases and more prevalent than other illnesses well-known to impact many Americans.

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**FI Impacts Quality of Life**

Fecal Incontinence Quality of Life Scale (FIQL) Scores

* Higher scores translate to higher quality of life

**Maintenance of Continence**

Depends on complex interaction between:

- Anal Sphincter Function
- Puborectalis Muscle Activity
- Anorectal Sensibility
- Colorectal Motility
- Stool Consistency
- Rectal wall Properties
- Peripheral and Central Innervation
Sacral nerves modulate the evacuation reflex thru inhibition and stimulation

These nerves transmit information via afferent and efferent pathways

As rectal wall distends with feces, the parasympathetic (via afferents) stimulate bowel contractions, while sympathetics inhibit motility.
The evacuation reflex initiates EFFERENT action potentials that cause IAS to relax allowing movement of contents.

Causes of Fecal Incontinence Independent of Anorectal Physiology

• **Non-specific conditions**
  – Diarrhea (IBS, IBD, Celiac disease, carbohydrate malabsorption)
  – Fecal impaction
  – Medications
  – Irritable bowel syndrome
  – Dementia
### Anal Pathology

**General**
- Anal carcinoma
- Protruding internal hemorrhoids
- Rectal prolapse
- Fistula

**Injury Mediated**
- Colorectal Surgery (hemorroidectomy, fistulotomy)
- Obstetric Anal Sphincter Injuries *(OASIS)*

### Rectal

**General**
- Rectal carcinoma
- Rectal ischemia

**Proctitis**
- Inflammatory Bowel Disease
- Radiation induced infections

### Neurologic Conditions

**Central Nervous System**
- Stroke, dementia
- Toxic/metabolic
- Cord injury, tumors
- Multiple sclerosis, tabes dorsalis

**Peripheral Nervous System (Sensory Dysfunction)**
- Diabetic neuropathy
- Cauda equina lesions
- Idiopathic
- Iatrogenic (following CR/GYN surgery)
FI Evaluation: History

- **Onset:** #years, progression (sudden onset vs slow)
- **Type:** gas, liquid or solid stool loss, passive or associated with fecal urgency
- **Severity:** # pads/day, #episodes/week
- **Diet, fluid intake, and medications** affecting bowel functions
- **GI disorders**
- **Co-morbidities/complications**
  - urinary incontinence
  - pressure sores
  - sexual dysfunction
- **Neurological conditions**
  - functional level
- **Patient’s goals:** needs, restrictions and quality of life

Warning and Alarm Signs!

- Rectal bleeding
- Hemoccult positive stools
- Obstructive symptoms
- Recent onset of constipation/incontinence
- Weight loss
- Change in stool caliber
Evaluation: Physical Exam

**Neurologic Reflexes:**
(sensory and motor): anal wink, bulbocavernous

**Digital Rectal Exam:** (anal sphincter and PR): tone*, voluntary squeeze strength (strong, moderate, weak), and appropriate relaxation with valsalva; paradoxical contractions; rectal masses, fecal impaction

**Skin changes:** erythema, rash, scarring, ulcerations, fissures

**Anal exam:** perianal dimpling/dovetail sign
Evaluation: Physical Exam

**Vaginal exam** pelvic organ prolapse (especially rectocele), perineal descent

**Rectovaginal fistula**
Evaluation: Physical Exam

**Vaginal exam** pelvic organ prolapse (especially rectocele), perineal descent

**Rectovaginal fistula**

**Rectal prolapse/rectal mucosal prolapse**

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Bristol Scale and Bowel Diary

**Bristol Stool Chart**

*Described in 1997*
Food and Bowel Diary

- # of BM’s/ day
- Stool consistency
- # of FI episodes/ week
- Dietary associations

Anorectal Diagnostic Testing

- Because of the complex interactions involved in defecation, evaluation of defecation function generally requires a combination of two or more assessment techniques.
- **There is no single objective study that can definitively assess all aspects of anorectal function.**
Anorectal Physiology Testing*

**Definitely needed**
- Endoscopic evaluation (anoscopy, proctoscopy): visualization of the rectal cavity to rule out tumors, inflammatory causes, or impaction.

**Probably helpful (especially if failed initial therapy)**
- Anal manometry and compliance testing

**Possibly needed**
- Defecography – Ultrasound
- Electromyography – MRI
- Pudendal nerve terminal latency

**Treatment of FI**
Case 1 – 58 yo man with 7 yr h/o FI (diarrhea)

- S/p fistulotomy following complications of an infected hemorrhoidectomy 7 yrs ago
- Reported bowel leakage 0-2X/ week especially following meals (landscaping)
- Fecal seepage after BM’s.
- PE: scarring at 7 o’clock with small defect of posterior EAS, normal tone, loose stool
- Bowel diary: consistently Bristol 6-7 BM’s

Optimal Medical Therapy

Conservative treatments include:

- **Dietary changes**
- **Anti-diarrheal medications (e.g. loperamide)**
- Biofeedback
Fiber Treatment for FI

• N= 189, RCT, 32 days, dose adjusted
• Placebo or fiber supplement, 16 gm/day
  – Gum arabic
  – Psyllium
  – Carboxymethylcellulose
• Overall low symptoms among the types of fibers
  – Psyllium greater sense of fullness
  – All groups had 1.2-2.0x more bloating, flatus, belching, fullness than at baseline


Pharmacologic Treatment of FI

• 16 trials, 558 participants
• 11 trials included treatment for liquid stools
• Loperamide* - 3 placebo-controlled trials
  – Loperamide superior to placebo in all studies
  – Side effects greater than placebo
  – Less side-effects noted on loperamide compared to Lomotil®

Omar and Alexander Cochrane Database Syst Rev. 2013
Surgical Management for Fecal Incontinence- Cochrane Review 2013

• Surprising lack of high quality randomized controlled trials on fecal incontinence surgery that have been carried out in the last 10 years.

• Small number of relevant trials identified, small sample sizes and other methodological weaknesses limit the usefulness of this review for guiding practice

• Can not identify or refute clinically important differences between the alternative surgical procedures

• Larger rigorous trials are still needed.

• **Optimal treatment regime may be a complex combination of various surgical and non-surgical therapies**

Case 2: 26 yo woman, 18 months postpartum with fecal incontinence

• 2-3x/ week-solid & liquid stool, flatus, and soiling
• Precipitous delivery, infant weighed 4600 g
• Laceration repaired in the “operating room” (op note-4th degree OASI)

• Physical Exam: thin membrane between vagina and rectum

• Endoanal US: External anal sphincter anterior defect; Internal anal intact
Anal sphinteroplasty (AS)

Safe, minimally invasive, low morbidity procedure, with “good” short-term outcomes. What is the evidence?
Systematic Review of FI studies 1991-2010
16 studies selected with 900 patients

<table>
<thead>
<tr>
<th>Year</th>
<th>Authors</th>
<th>Study design</th>
<th>Modified NOS</th>
<th>Initial N</th>
<th>Follow-up N (%)</th>
<th>Length of follow-up (mo)</th>
<th>Apex surgery (%)</th>
<th>Female (%)</th>
<th>Cause (%)</th>
<th>Repeat repair (%)</th>
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<td>48 (26-70)</td>
<td>100</td>
<td>Obstetric 71.4</td>
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</table>

Long-term Outcome of AS

![Graph showing long-term outcome of AS with patients with 'good' outcome (%) over months](image-url)
Anal Sphincteroplasty - Summary

• About 2/3 of patients report improvement
  – Based on patient recall, little prospective data
  – Defined by "good", no standardized outcomes used until recently
  – No factor significantly associated with a worse outcome
    • age
    • Severity
    • Duration
    • previous repair
    • pudendal nerve delay implicated
    • diagnostic tests

• Still an appropriate first line therapy for women with major sphincter defects
  – Restore sphincter to circumferential configuration
  – Build up perineal body

Case 3- 65 yo woman with 5 year history of FI and fecal urgency

• Daily accidental bowel leakage of liquid and solid stool despite diet modifications, use of fiber, loperamide and biofeedback
• Three vaginal deliveries, largest weighing 8' 10"; forceps delivery
• PMH: Obese (BMI 32), Hypertension
• PSH: Laparoscopic Cholecystectomy
• Medications: HCTZ
• PE: intact EAS, decreased resting tone
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**Sacral Neuromodulation (SNM)**

- Focuses mild electrical pulses on the nerves that control the pelvic floor muscles, anal sphincters, and colon.¹

- Offers control of symptoms through direct modulation of the nerve activity.¹*


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**Electrical Stimulation (Estim) vs Interstim (Sacral Nerve Modulation)**

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InterStim® Therapy
Sacral Neuromodulation for Bowel Control

InterStim Therapy is a safe and effective treatment that is FDA approved for chronic fecal incontinence patients who have not benefited from conventional therapies.

- Has shown efficacy and safety in Europe since 1994, it is only recently approved in the US in 2011.

Mechanism of Action of SNM-
Poorly understood

- Sacral nerve root contains afferent and efferent autonomic nerves, as well as voluntary somatic fibers, all of which are thought to be involved.

- Studies have failed to show NO effect on intrarectal pressures or Pudendal Nerve Motor Latency.

- Endoanal US showed decreased diameter of IAS and EAS = contraction of pelvic floor.
**Neuromodulation Benefits**

- Effective treatment in properly screened patients
- Safe
- Reversible
- Does not preclude use of alternative treatments

**Other Neuromodulation Therapies**

- OCD¹
- Parkinson’s Disease
- Essential Tremor
- Dystonia¹
- Chronic Pain
- Severe Spasticity
- Gastroparesis¹

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¹: Additional therapies mentioned include OCD (OCD), Parkinson’s Disease, Essential Tremor, Dystonia, Chronic Pain, Severe Spasticity, and Gastroparesis.
Stage 1- SNM Trial Assessment

Outpatient minimally invasive procedure, a **tined lead** (thin wire) is placed near the sacral nerve (S3) with **fluoroscopy guidance** in prone position (45 minutes).

**No general anesthetic**, sedation (fentanyl, midazolam) and lidocaine injection; patient is awake.

- The lead is connected to an **external test stimulator** worn on the patient’s waistband for two weeks.
- If patient experiences success **> 50% improvement**, a neurostimulator may be implanted.
- If no improvement, the **lead is removed** and the patient will immediately be able to try other options.
Stage 2- Implant Procedure / IPG
(Internal Pulse Generator)
25 minutes procedure-(No fluoro)

• After successful test stimulation, the IPG/battery is implanted at previously made site.
• A pocket is typically created for the neurostimulator in the upper buttock
• Sedation and local analgesia.

Four Trials on SNM for FI

All different designs, similar results

1. Wexner (2010) InterStim Therapy for Bowel Control Prospective Therapy a prospective, non a prospective, non-randomized, randomized, multi-center study (n = 120)

2. Tjandra (2008) a prospective, randomized, single-center study (n = 113)

3. Leroi (2005) a prospective, randomized, double arm, blinded, single double arm, blinded, single--center study (n = 27)

4. Hetzer (2007) a prospective, non a prospective, non-randomized, randomized, single-center study (n = 30)

**Efficacy: Reduction in FI Episodes**

- **N=133**
- 90% implanted
- **N=120**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>12 Months</th>
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<tbody>
<tr>
<td>Mean Number of Weekly Incontinent Episodes</td>
<td>9.4</td>
<td>3.1</td>
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<tr>
<td><strong>Modified Worst Case (MWC)</strong> (n=120)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Per-protocol /Actual (n=106)</td>
<td>9.2</td>
<td>1.9</td>
</tr>
</tbody>
</table>

~80% reported therapeutic success


**Efficacy: Complete Continence at 12 months**

InterStim Therapy Bowel Control Study

- **MWC** (n=120)
- **Per-protocol** (n=106)
- **SNS group** (n=53)

<table>
<thead>
<tr>
<th></th>
<th>MWC</th>
<th>Per-protocol</th>
<th>SNS group</th>
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<tr>
<td>% Patients with complete continence</td>
<td>36%</td>
<td>41%</td>
<td>47%</td>
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~40% reported complete continence- cure

Efficacy: Quality of Life (FIQL)

Mean FIQOL Score (Completers Analysis)

<table>
<thead>
<tr>
<th>Scale</th>
<th>Baseline (n=119)</th>
<th>3-Months (n=116)</th>
<th>6-Months (n=109)</th>
<th>12-Months (n=107)</th>
<th>24-Months (n=68)</th>
<th>36-Months (n=30)</th>
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<tr>
<td>Scale 1 - Lifestyle</td>
<td>2.31</td>
<td>3.22</td>
<td>3.26</td>
<td>3.36</td>
<td>3.32</td>
<td>3.52</td>
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<tr>
<td>Scale 2 - Coping/Behavior</td>
<td>1.49</td>
<td>2.64</td>
<td>2.69</td>
<td>2.77</td>
<td>2.69</td>
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<tr>
<td>Scale 3 - Depression/Self-Perception</td>
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<td>3.33</td>
<td>3.48</td>
<td>3.54</td>
<td>3.58</td>
<td>3.77</td>
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<tr>
<td>Scale 4 - Embarrassment</td>
<td>1.6</td>
<td>2.73</td>
<td>2.75</td>
<td>2.81</td>
<td>2.76</td>
<td>2.95</td>
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</table>


Adverse Events

The most common adverse events (≥5%) reported during the implant phase in clinical study included:

- Implant site pain
- Paresthesia
- Implant site infection
- Change in sensation of stimulation
- Urinary incontinence
- Diarrhea
**Sacral Neuromodulation Complications - 5 Studies**

<table>
<thead>
<tr>
<th>Author</th>
<th>Revision</th>
<th>Infection</th>
<th>Pain</th>
<th>Seroma/ Hematoma</th>
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<td>-</td>
<td>5.7%</td>
<td>1.9%</td>
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<td>-</td>
<td>1.5%</td>
<td>21.5%</td>
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<td>Hetzer (2007)</td>
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<td>-</td>
<td>12.7%</td>
<td>2.7%</td>
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<td>Michelsen (2010)</td>
<td>12.7%</td>
<td>1.6%</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Wexner (2010)</td>
<td>-</td>
<td>10.8%</td>
<td>5.8%</td>
<td>1.7</td>
</tr>
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**“Who should we refer?”**

- Dr. Traci Hedrick

- 2009 experts from 18 GI centers published a position paper on the use of SNM for FI.

**Consensus:**

- SNM reserved for those who have **at least one episode of FI per week on bowel diary**
- Significant changes in **quality of life**
- Should have **failed conservative management** with bowel regimen and biofeedback
- Should have FI to **liquid or solid stool** and not just flatal incontinence
What Can You Tell Your Patients?

• Refer to a **specialist** who will evaluate your condition further and determine if InterStim/SNM therapy might be a treatment option.

• The Interstim/ **SNM trial assessment** will give you a chance to find out after two weeks trial if long-term therapy may be a good option for you.

• SNM therapy is an **safe and effective treatment** that is FDA approved for chronic fecal incontinence patients who have not benefited from conventional therapies.

Not Ideal Candidates for SNM

**Not** appropriate for patients who:
- Have not demonstrated an appropriate compliance to the evaluation
- May require an MRI
- Are unable to operate the neuromodulation device
- Are not appropriate candidates for surgery (heavy smoker, obese, prior back trauma)

Safety and effectiveness of SNM have not been established for patients who:
- Are pregnant
- Are under age 16
- Have neurological disease origins such as multiple sclerosis or diabetes
- Require bilateral stimulation
Perianal Bulking: Hyaluronate Sodium (Solesta®)

Administered via anoscope to the proximal anal canal
- Out-patient setting
- No anesthesia
- Four 1ml blebs of Solesta

Hyaluronate Sodium: Clinical Review

Four trials reported in the literature
- 367 patients*
- Solesta demonstrated consistent efficacy for all types of FI
- Etiology (obstetrical, neuro, etc.)
- Demographics (male/female, age, etc.)
- No safety issues

Majority of AE’s were mild and self limited

Mostly recommended for fecal seepage.

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TOPAS System to Treat Fecal Incontinence (TRANSFORM)

Study ClinicalTrials.gov Identifier: NCT01090739

• **TOPAS (AMS) sling for FI**
  – Prospective, multi-center (12 sites)
  – Single-arm, open-label, two-stage, adaptive study with one planned interim analysis
  – Primary outcome 14-day bowel diary-50% reduction FI episodes
  – N=152
  – The mesh sling placed via the transobturator approach
  – Study completed, awaiting data accrual and analysis

Summary

• Fecal incontinence (FI) is a **common condition** that adversely impacts a person’s quality of life.

• **Medical Interventions** such as diet modifications and medications continue to improve ~50% of patients symptoms

• **Surgical Treatments** are safe and minimally invasive

  **Anal Sphincteroplasty**
  – 75-80% short-term cure rate
  – 25% long-term cure rate
Summary

- **Sacral Nerve Modulation** is a minimally invasive treatment for fecal incontinence, reserved for patients with > one episode of fecal incontinence/week with failed conservative management.
  - It is successful in > 80% of those tested
  - ~40% reporting cure

- Newer treatments **Hyaluronate Sodium injections** and **TOPAS (AMS) sling** are promising.