Fecal Incontinence: Practical Evaluation and Management

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Learning Objectives

- To appreciate that fecal incontinence (FI)/Accidental Bowel Leakage (ABL) is a reasonably prevalent pelvic floor disorder (PFD) significantly impacting quality of life
- To understand that the evaluation of FI may involve specialized tools
- First-line treatment options involve a behavioral approach
- To appreciate that the optimal treatment regimen for fecal incontinence (FI) may be a complex combination of various non-surgical and surgical approaches
- · Surgery is a credible option for the treatment of FI

Definition

- Fecal incontinence, (also known as accidental bowel leakage ABL) is the involuntary loss of liquid or solid stool that is a social or hygienic problem¹
- Anal incontinence is the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem¹
- Accidental Bowel Leakage² (leakage in past year)
- · Fecal incontinence is a symptom
- Types of FI: urgency, passive and fecal seepage³

1. Norton, 2010; 2. Brown, 2012; 3. Shah, 2011

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

Prevalence Rates of Pelvic Floor Disorders in Women from the National Health and Nutrition Examination Survey (NHANES) 2005-06



Anatomy and Physiology

 <u>Fecal Continence</u> depends on the integrated function of the IAS, EAS, PR, neurosensory pathway (pudendal n), volume (consistency of stool), rectal compliance, anorectal sensation and anal sphincter resting tone.





Fecal continence depends on:

- Normal mental function
- · Volume and stool consistency
- Colonic transit time
- Anorectal sensation and reflexes
 recto-anal inhibitory reflex (RAIR)
- Rectal distensibility
- Anal sphincter function



FI Evaluation: History

- Onset and duration of symptoms
- Severity, frequency
- · Impact on quality of life
- Precipitating events
- *Medical History (diabetes/neurologic disease), Surgical History (anorectal surgery),Obstetric History
- Prior treatments
- Bowel habits/Stool consistency
- Dietary intake
- · Adaptive Behaviors
- Medications

Patient Reported Symptoms

- Bowel Diary
- Fecal incontinence Severity*
 - FISI (Grade C)
 - Vaizey/St. Mark's Score (Grade C)
 - ICIQ-B (Grade B)
- Impact on Quality of Life
 - Fecal Incontinence QOL (FIQOL)
 - Modified Manchester Health Questionnaire
 - ICIQ-B

Norton C et al, ICI, 2016

	 Stool co 	nsister	NCY (Br	istol Stool Scale-Lewis and Heaton, 1997)		
K		Stool Form	Correlate	s to Intestinal Transit Time			
		1	The Bristol	Stool Form Scale			
	Slow Transit	Type 1	•	Separate hard lumps, like nuts			
		Type 2		Sausage-like but lumpy			
		Type 3		Like a sausage but with cracks in the surface			
		Type 4		Like a sausage or snake, smooth and soft			
		Type 5	ర్య ం	Soft blobs with clear-cut edges			
N.	-	Type 6	100	Fluffy pieces with ragged edges, a mushy stool			
	Fast Transit	Type 7		Watery, no solid pieces			

Evaluating Fecal Incontinence



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

Choose treatments based on:

- Severity of FI
- Structural integrity of sphincter
- Conservative
 - Mild cases of FI
 - Biofeedback can be used for any cause
 - Painless and risk-free
- Treat underlying medical and surgical causes: - Cancer, IBS, rectal prolapse, impactions
- · Start with simplest and least invasive FIRSTmainstay of treatment for FI is behavioral therapy



- Malabsorbtion syndromes
 - Lactose
 - Gluten
- Sorbitol
- Natural laxatives
- Spicy foods
- Dietary fiber intake
- Soluble and insoluble

An Evidence-Based Look at **Dietary and Medication** Treatments for Fecal Incontinence

Supplemental Fiber Intake

•	Stool	bulking	vs sid	le-effects
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Trade name	Active Ingredient	Form	Natural or	Amount of fiber/dose	Bulks
			Synthetic		stool
Metamucil	Psyllium husk	Powder	Natural	3.4 gm/tsp.	Yes
Metamucil capsules	Psyllium husk	Capsules	Natural	0.525 gm/capsule	Yes
Citrucel	Methylcellulose	Powder	Semi- synthetic	2 gm/tsp.	Yes
Citrucel caplets	Methylcellulose	Caplets	Semi- synthetic	0.5 gm/caplet	Yes
Konsyl	Psyllium husk	Powder	Natural	6 gm/tsp.	Yes
Benefiber	Wheat dextrin	Powder	Natural	3 gm/tsp	No
Fibersure*	Inulin	Powder	Natural	5 gm/tsp	No
Fibercon caplets	Calcium polycarbophil	Caplet	Synthetic	0.5gm/caplet	Yes
Fiberchoice	Inulin	Capsule	Natural	2 gm/tablet	No

Evidence for Fiber Treatment

- Fiber: placebo-controlled pilot study¹
- Pilot study, n=27
 - Comparing psyllium, guar gum, and placebo
 - Significant improvement in the proportion of incontinence stools on a 7-day diary for both types of fiber compared to placebo

Fiber, cont

- · Dietary supplements used to manage FI
- Little known regarding fiber type where effectiveness appears to be related to fermentability of the fiber resulting in increased bulking, waterholding and gelling
- Single-blind RCT* to compare effects of carboxymethylcellulose (CMC), gum arabic (GA) and psyllium to placebo in community dwelling individuals with loose stools and FI
- 1°outcome: FI frequency; 2°outcomes: FI amt and consistency, supplement tolerance and QOL

*Bliss et al, Res Nurs Health, 2014

Results

- 14 day baseline diary
- N=189 subjects consumed placebo or 16 g total fiber/d for 32 days
- Baseline: approx 6.2 FIE/w in placebo, 4.7 CMC, 5.3 GA, 5.0 psyllium
- Post supplementation ITT: 5.5 FIW/w placebo, 6.2 CMC, 4.3 GA and 2.5 psyllium (51% decrease)
- · Consistency and amt of FI-no difference

QOL

 No significant differences in FIQoL, including lifestyle, coping, depression and embarrassment scores baseline or post supplementation (ITT or PP)

Pharmacologic Treatment of FI

- 16 trials, 558 participants
- 11 trials included treatment for liquid stools
- Loperamide* (synthetic opioid inhibiting peristalsis and increases anal sphincter tone) - 3 placebo-controlled trials¹
 - Loperamide superior to placebo in all studies
 - Side effects greater than placebo
 - Less CNS side-effects noted on loperamide compared to lomotil®

¹Omar and Alexander Cochrane Database Svst Re

^{1.}Bliss. Nurs Res, 2001

Other Pharmacologic Treatments

- Loperamide ± Fiber¹: placebo-controlled trial
- No additional improvement in FI severity by adding fiber
- Loperamide vs Psyllium Fiber²: RCT, double-blind, placebocontrolled cross-over trial comparing loperamide (followed by psyllium) to psyllium (followed by loperamide)
- N=80, at least 1 FIE/7-day bowel diary; 1°outcome FIE/7-day bowel diary
- Participants received either daily loperamide+placebo psyllium or psyllium+loperamide placebo for 4 weeks; 2-week washout, participants crossed over to alternative treatment
- Mean age 60.7±10.1 years, 68% men; combined analyses showed no differences between loperamide and psyllium groups for reducing FIE: loperamide:7.9 to 4.2, p=0.001, psyllium: 7.3 to 4.8, p=0.008; no difference in symptom severity or QoL;, all p>0.05
- Constipation 29% loperamide, 10% psyllium
 ¹Lauti et al, Dis Colon Rectum 2008; ²Markland et al, Dis Colon Rectum, 2015;

Other Pharmacologic Treatments

- Cholestyramine : case series reported²
- Improved FI episodes and number of bowel movements in addition to biofeedback
- Diphenoxylate HCI (Lomotil)
- Hyocyamine (helps in postprandial leakage)
- Amitriptyline- small uncontrolled study
 Anticholinergic effect decreasing motor
- complexes
- *Low-dose clonidine (α adrenergic agent): reduces rectal sensation and urgency^2
- Phenylephrine gel-increases IAS tone³
 - ¹Remes-Troches, 2008; 2. Costilla, 2013, 3. Omar, 2013

Cochrane Review 2013 Surgery for Fecal Incontinence

The review is striking for the lack of high quality randomized controlled trials with any fecal incontinence surgeries that have been carried out in the last 10 years....

*Larger rigorous RCTs (including the use of sham treatments) are needed, however, it should be recognized that the optimal treatment regime may be a complex combination of various surgical and nonsurgical therapies"

Brown et al 2013



Case 1

- 55 yo female P3013 with 5 year history of FI and anorectal urgency
- FI of liquid/solid stool and gas despite a credible attempt at management with behavioral therapy
- Spontaneous vaginal delivery (SVD) X 3 with largest infant weighing 3700 g
- · Forceps delivery and a lot of "stitches" with first SVD
- Alternating constipation & diarrhea
- · PMH: obesity
- PSH: cholecystectomy

Physical Examination and Diagnostic Testing

- Examination: decreased anal tone, intact reflexes, dove tail appearance, 1.5 cm thickness
- Surface Electrode EMG: reasonable isolation with decreased squeeze pressure activity, good relaxation, no evidence of dysynergia
- Anal Manometry: anal resting tone of 25 mm Hg, squeeze to 55 mmHg, normal sensation, compliance 200 cc, normal RAIR
- Endoanal Ultrasound:



Fecal Incontinence with Abnormal Sphincter

- Trauma
 - Direct sphincter injury Obstetric (majority)
 - Surgical (anal or rectal)
 - Congenital anomalies

Sphincteroplasty

- The term sphincteroplasty is used to describe secondary or delayed reconstruction of the anal sphincter musculature, injury to which has either not been recognized or the outcome of the repair unsatisfactory
- Among women who had a sphincter tear repaired at the time of delivery, 35% continued to have IAS gaps and of those women, the majority had concomitant EAS disruptions at 6 and 12-months*

*Bradley, Richter, Gutman et al. Am J Obstet Gynecol, 2007



















Sphincteroplasty-Summary

- Approximately 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 and pudendal nerve delay implicated)
- Still an appropriate first line therapy for women with major sphincter defects
 - Restore sphincter to circumferential configuration-although MRI data may dispute this
 - Build up perineal body

Most common complication: wound infection (2.2-35%)

Case 2

- · 67 yo female with a 7-year history of FI
- FI of liquid/solid stool, 3-times per week necessitating constant pad use and scared to leave her home
- Has had a sphincter repair, tried behavioral therapy including pelvic muscle exercises, other PT strategies, attention to diet, and use of medications with some improvement, but still room for improvement
- Recent 2 week diary revealed nearly daily bowel movements with leakage 2 times the first week and 3 times week 2
- PMH: hypertension
- PSH: hysterectomy

Physical Examination & Diagnostic Testing

- Examination: decreased rectal tone, intact reflexes
- Surface Electrode EMG: reasonable isolation with good subjective squeeze pressure activity, good relaxation, no evidence of dysynergia
- Anal Manometry: anal resting tone of 40 mm Hg, squeeze to 70 mmHg, normal sensation, compliance 100 cc, normal RAIR
- Endoanal Ultrasound: intact external and internal anal sphincters She is considering colostomy
 - what surgical options are available?



How Does It Work?

- Many potential neurologic targets
 - Voluntary somatic
 - · Afferent sensory
 - Efferent autonomic
- Rectal blood flow increased with stimulation as measured by doppler flowmetry-effect was reversible $^{\rm 1}$
- Decreased episodes of spontaneous sphincter relaxation²
- Electrical stimulation of the sacral nerves causes:
- Modulation of neural reflexes
 - · Interrupts constant sensory input from rectum

¹Kenefick, Br J Surg 2003; ²Vaizey, Gut 1999







SNS Data Summary Short, Medium, Long-term

 When reviewing short (<12 months), medium (12-36 months) and long-term (>36 months) success (success defined as a 50% reduction in FI episodes):

-ITT median (range) rates of 63% (33-66%), 58% (52-81%), 54% (50-58%), respectively

-Per protocol median (range) rates of 79% (69-83%), 80% (65-88%) and 84% (75-100%), respectively

Matzel et al, 2009

SNS Adverse Events

- Most AEs occur within 1st year of implantation
- Common events include: device pain (28%) and paresthesia (15%)
- Meta-analysis reported lower rate of implant site pain (6%)*
- With advancements in lead design and techniques, explantation rarely necessary (3-4%)*
- Infection rate 3-11%**

*Tan et al 2011; **Wexner et al,2010; Mellgren et al, 2011





70			1	-	
Results of Artificial Bowel Sphincter					
No. of Patients	Follow-Up (mo)	Preoperative Score	Postoperative Score	P Value	
28	19	14.9	2.6	< 0.001	
53	26.5	17	4	0.001	
13	30	17	4.5	< 0.00	
14	6	19	4.8	0.002	
22	28	18	4	< 0.00	
6	10	19.5	4.5	0.00	
28	19	98.5	5.5	< 0.00	
10	29	99.9	28.4	< 0.00	
8	10.5	95	19.4	<0.004	
24	20	106	25	<0.00	
16	25	105	23	<0.05	
112	12	106	48	-0.00	
	14	100	-10	40.00	
17	60	5	2.5	<0.00	
	00	•	LIU	10100	
35	24	103	24	<0.00	
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	ABS C	omplicati	ons	
	Complications	of Artificial Bowel Sph	incter	
Study	Explants (%)	Revision (%)	Erosion (%)	Infection (%
Altomare et al. 120	18	25	11	18
Casal et al.126	30	10	10	60
Christiansen et al. 131	41	35	6	18
Devesa et al.121	23	30	21	21
Dodi et al.127	25	Not stated	25	25
Lehur et al.122	31	62	8	7
Lehur et al.28	33	38	13	4
Lehur et al. ¹²⁹	31	13	6	Not state
O'Brien et al. ¹²³	23	31	8	23
Ortiz et al. ¹²⁴	41	27	23	9
Parker et al. ¹³²	40	64	11	31
Vaizey et al. ¹²⁵	17	17	17	33
Manna at at 130	37	65	25	38

Anal Slings-investigational, TOPAS[®] System

- Self-affixing Type-I Polypropylene Sling
- Minimally invasive trans-obturator post-anal sling



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
 - N=152
 - The mesh sling placed via the transobturator approach

























SECCA® Efficacy Data

- Long-term* (5 year) study, mean Wexner incontinence score improved from 14 to 8, p<0.0003
- 80% subjects had 50% improvement
- N=19
- Other studies limited by short-term follow-up and small sample sizes (N=8-50)
- No comparative data
- Main AEs rectal bleeding and pain

*Takahashi-Monroy et al 2008



Posterior Tibial Nerve Stimulation

- Peripheral neuromodulation directed to L4-S3
 nerve roots
- Spleen 6 point in Chinese acupuncture
 - OAB, UUI, pelvic/bladder pain, impotence
- · RCT with sham effective for OAB/Urge UI



PTNS

- The largest prospective study including 115 patients with a median follow-up of 26 months (range, 12 42) reported 52% of patients achieving a \geq 50% reduction in FI episodes as well as improving QOL*
- First multi-center RCT (the CONtrol of Faecal Incontinence using Distal NeuromoulaTion [CONFIDeNT]) in the United Kingdom was recently published
- This trial included 227 patients to evaluate the efficacy and costeffectiveness of PTNS (n=115) comparing to sham electrical stimulation (n=112)
- Interestingly, the study reported no difference between the PTNS and sham groups in efficacy at 12 weeks: 38% in PTNS versus 31% in sham achieving a ≥50% reduction in the number of FI episodes per week, adjusted ratio 1.28 (95%CI 0.72-2.28; p=0.40) **

*Hoturas et al 2014; **Knowles 2015

Non-Animal Sodium Hyaluronate-NASHA Dx

Dextranomer microspheres and sodium hyaluronic acid – Identical to Deflux

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



Pivotal Trial

- Only large scale trial in the literature injectable bulking agent vs. sham
- 206 patients
 - 13 sites in U.S. and EU
- 80% female
- Three part primary endpoint
 - Superiority over sham at 6 months
- Threshold responder rate at 6 months
- · Durability of effect to 12 months

Graf et al, Lancet 2011



Most Common Related AEs - Solesta Patients Pivotal Study Through 18 Months

Preferred term	Events	% patients
Proctalgia	41	17.3
njection site hemorrhage		8.1
Rectal hemorrhage	15	7.6
Pyrexia	14	6.6
Injection site pain	10	5.1
Diarrhea	10	4.1
Anal hemorrhage	9	4.1
Anorectal discomfort	8	4.1
Rectal discharge	7	3.6
Proctitis	5	2.5
Majority of AE's we	re mild and self limit	ted



Fecal Diversion

- Considered "last resort"
- One case-control and two cohort studies
- · Results in improved QOL
- More cost effective at 5 years than artificial AS and dynamic graciloplasty
- Usually an end sigmoid colostomy without proctectomy (rectal stump)
- · Laparoscopic approach, safe and effective

Colquhoun et al 2006; Norton et al 2005; Ludwig et al 1996

New Paradigm: Vaginal Bowel Control (VBC) System

- A non-surgical treatment option consisting of a vaginal insert and pressure-regulated pump
- Designed to offer a low-risk and easily reversible treatment for FI
- <u>Dynamically</u> controls bowels under user control by reversibly deflecting the RVS and interrupt stool passage





Conclusions

- Cause of fecal incontinence (a lecture unto itself) is often multi-factorial
 - 1st line treatment is...
 - Education
 - Pelvic Floor Muscle Exercises
- Medications
 - Normalization Of Stool Consistency
- Bowel Habits
- Devices*
- Surgery helpful for many women
- Need to be able to discuss all options with patients and individualize care



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