

W9: Evidence and Case-Based Update on the Medical/Behavioural and Surgical Management of Faecal Incontinence

Workshop Chair: Alayne D. Markland, United States
06 October 2015 14:00 - 15:30

Start	End	Topic	Speakers
14:00	14:05	Introduction and objectives	Alayne D. Markland
14:05	14:25	Epidemiology and pathophysiology of faecal incontinence	Patricia S. Goode
14:25	14:40	Evaluation and introduction to case studies	All
14:40	15:00	Pelvic floor training, medical management, and case studies	Alayne D. Markland
15:00	15:20	Surgical management and case studies	Holly E. Richter
15:20	15:30	Questions	All

Aims of course/workshop

Aims:

1. Understand the scope of the problem of faecal incontinence (FI)
2. Review the anatomy and physiology of normal defecation and maintenance of continence
3. Present an algorithmic approach for the evaluation of FI including case studies
4. Understand non-surgical management of FI including pelvic floor muscle training including biofeedback and electrical stimulation, bowel control strategies, diet and fibre, and medications
5. Discuss the role of surgery including perianal sphincter injection treatment, sphincter repair, and sacral neuromodulation in the treatment of FI

Learning Objectives

1. Understand the scope of the problem of faecal incontinence (FI) including the anatomy and physiology of the defecation process
2. Review an algorithmic approach for the evaluation of FI
3. Recognize the non-surgical and surgical management of FI

Workshop Description:

Epidemiology

FI can be a devastating and socially isolating illness. Rates vary from 3-24% (Bharucha, 2005; Macmillan, 2004; Nelson, 1995; Varma, 2006; Melville, 2005; Goode, 2005; Whitehead, 2009). Age has been established as a risk factor for FI in many population-based studies (Macmillan, 2004; Melville, 2005; Goode, 2005; Whitehead, 2009). Other factors that have been associated with increased rates of FI included: female gender, co-existence of UI, poor general health, physical limitations, cognitive impairment, and high body mass index (Bharucha, 2005; Macmillan, 2004; Nelson, 1995; Varma, 2006; Melville, 2005; Goode, 2005; Whitehead, 2009). Factors related to FI among women include: hysterectomy, post-menopausal status, obstetrical history (parity and type of delivery), and pelvic organ prolapse. Prior surgical procedures such as internal anal sphincterotomy and hemorrhoidectomy may also lead to FI (Nelson, 2004; Pernikoff, 1994). Many other conditions are associated with FI and included: chronic diarrhea, diabetes, irritable bowel syndrome, inflammatory bowel disease, and neurological diseases, such as cerebrovascular disease (Wald, 1995; Harari, 2003; Bytzer, 2001; Johanson, 1997). The association between fecal incontinence and diarrhea is most robust in nursing home studies (Johanson, 1997) and in community-dwelling older adults (odds ratio = 6.4) for FI (Goode, 2005; Whitehead, 2009). As supported by the epidemiologic data, the etiology of fecal incontinence remains multifactorial and treatment depends on the underlying mechanisms.

Pathophysiology

Functional, sensory, and anatomical factors work together to produce a bowel movement and maintain continence (Whitehead, 2001) Multiple factors influence the ability to have a “normal” bowel movement. One important factor is the transit time through the colon (which affects stool consistency). Another is the ability to retain stool in the rectum (involving compliance and sensation), in order to delay defecation with the appropriate sphincter function until defecation can occur in a socially appropriate setting. Both the external anal sphincter and the puborectalis muscles, striated muscles innervated by the pudendal and pelvic nerves, are critical to voluntarily postponing defecation. Injury to the sphincter muscles can lead to FI, but even without anatomical damage, stool consistency plays an important role in maintaining continence.

Evaluation

Basic - History and Physical Exam; Severity determination – Bowel diary with Bristol Stool Form Scale, validated assessment tools (Fecal Incontinence Severity Index, Vaizey/St. Mark’s Score, ICIQ-B); Impact on quality of life – FI-QOL, Modified Manchester Health Questionnaire, ICIQ-B. Additional diagnostic evaluation – Anorectal manometry, Endoanal ultrasound, Defecography, Functional MRI.

Medical/Behavioral Therapy

Biofeedback and other Behavioral Interventions for FI

Initial treatments for FI includes conservative measures (pelvic floor muscle training with or without biofeedback and electrical stimulation), dietary modifications, and medical treatments (constipating agents, stool bulking agents, laxatives, and/or evacuation aids). In treatment algorithms, the first step in the management of FI is conservative and medical therapy (Bharucha, 2014; Wald, 2014; Whitehead, 2014). Conservative therapy may improve FI rates up to 50-75% depending on the type of modality used (Norton, 2012; Omar 2013). A randomized control trial for FI compared advice alone, advice with exercises, and biofeedback, and showed that pelvic floor muscle exercises and biofeedback were no better than advice alone in improving FI frequency (Norton, 2003). However, 53% of all patients in this study had decreased FI frequency, better quality of life, and improved anorectal manometry pressures. In those patients who improved, it was maintained one year after the study. Others have also had similar long-term improvement from biofeedback with anorectal manometry (Ozturk, 2004). In a randomized, controlled trial of anal electrical stimulation for FI in 90 patients, there was not a statistical difference in incontinence frequency after 8 weeks between the sham treatment group (1 Hz) and intervention group (35 Hz) (Norton, 2006). However, 63% of those who completed the study (70 patients) reported improved continence irrespective of the treatment group. A trial of biofeedback compared with pelvic floor muscle exercises alone in 108 women who were not adequately treated with medication, education, and behavioral strategies showed significantly greater reductions on the Fecal Incontinence Severity Index ($p=0.01$), fewer days with incontinence ($p=0.08$), and more patients reporting adequate relief (76% vs. 41%) in the biofeedback group at 3 months (Heyman, 2009). Improvement persisted to 12 months.

Medications for FI

In the 2013 Cochrane review of drug treatment for FI, only three randomized crossover trials with adequate methodology for inclusion evaluated pharmacologic treatment of diarrhea-predominant FI in adults (Omar, 2013). All trials compared drug versus placebo (one used diphenoxylate [n = 15], one used loperamide [n = 26], and one compared loperamide with codeine to diphenoxylate plus atropine [n = 30]) (Harford, 1980; Palmer, 1980; Read, 1982). All had decreases in frequency of FI episodes, volume, and improved consistency. More people on drug reported adverse events that included constipation, abdominal pain, diarrhea, headache, and nausea. In a recent RCT of 189 adults, comparing 3 types of fiber (psyllium, gum-arabic, or carboxymethylcellulose) to placebo, only psyllium improved rates of incontinent stools (45% decrease in proportion of incontinent stools) compared to placebo in individuals with liquid/loose stool consistency FI (Bliss, 2014). In another RCT comparing psyllium to loperamide, both treatments were effective at improving FI episodes with no differences between them (Markland, 2015). Most drug studies are limited by short treatment durations.

Surgical Approaches

Surgical therapies are usually considered after credible behavioral or medication attempts have been made and may include repair of anal sphincter tears usually sustained at the time of vaginal delivery. Short-term continence rates have been reasonably good with up to 75% of patients becoming continent to liquid/solid stool. However, longer-term results suggest that these results are not robust (Malouf, 2000; Tan, 2007; Halvorson, 2002). Other surgical modalities include the artificial bowel sphincter and colostomy, however the use of artificial bowel sphincter has significant associated morbidity and colostomy is essentially used as a salvage procedure (Wexner, 2010). Neuromodulation (Interstim™) has been approved in Europe since 1994 (Medtronic, 2007) for refractory FI and several prospective reports describe efficacy for the treatment of refractory FI with or without sphincter defects (Wexner, 2010; Matzel, 2004; Jarrett, 2004; Hetzer, 2007; Govaert, 2009; Melenhorst, 2007; Uludag, 2004; Ganio, 2001; Brouwer, 2010; Fraser, 2004). A minimally invasive surgical approach utilizing a perianal injection of dextranomer microspheres and hyaluronic acid demonstrated 1 year outcomes superior to placebo (Graf, 2011) and one RCT (n = 126) showed no differences in efficacy compared to biofeedback (Delhi, 2013)

Epidemiology and Pathophysiology of Fecal Incontinence

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Learning Objectives:

1. To outline the prevalence and incidence data for fecal incontinence from the epidemiologic literature
2. To recall the anatomy and physiology of defecation
3. To recognize clinical tests for the evaluation of bowel incontinence in adults

Fecal Incontinence Defined

- Defining FI: Accidental Bowel Leakage
- Importance of incorporating 'bother'
- Terminology
 - Patient-oriented
 - 'Accidental Bowel Leakage' preferred

Overall FI Prevalence Rates

- 1% to 25% in community-dwelling adults
 - 9-30% among older adults
 - Between 1 in 5 and 1 in 6 women
 - Between 1 in 6 and 1 in 7 men
- 18-33% in acute care settings
- 30% or higher among care-seeking populations
- 38% among those receiving home services
- 50% or more in long term care settings
- Prevalence of FI in US Adults: National Health and Nutritional Survey

Incidence Rates of FI

- Community-based incidence of FI
 - 6-17% overall
 - 4-year = 6% (95% CI 5% - 9%) – monthly FI
 - 4-year = 17% (95% CI 14% - 20%) – any FI
 - 9-year = 6% (95% CI 4.5% - 8.6%)
- Post-partum FI incidence rates from a multicenter 12-year prospective cohort study
 - 3 mo – 8.2% (n=307/3763)
 - 6 yrs – 9.7% (n=287/2944)
 - 12 yrs – 12.9% (n=487/3763)
 - Total – 19.9% (n=747/3763)

Risk Factors: Conceptual Framework

- Physical Status
 - Age, Gender, Race/ethnicity
 - Obesity
 - Activity/Mobility
- Genetic
- Neurological/Psychiatric
 - Stroke
 - Depression
- Trauma
 - Surgical
 - Obstetrical
- Disease Burden

- Medical conditions/co-morbid diseases
- Bowel Symptoms
 - Diarrhea, Urgency, Constipation

Bowel Symptoms

- Stool consistency
 - Diarrhea/loose stool
 - Constipation/hard stool
 - Increased stool frequency
- Urgency
- Irritable bowel syndrome
 - Younger age groups
- Inflammatory bowel disease

Concomitant Pelvic Floor Disorders and FI

- Urinary incontinence
 - Consistently increased odds in adjusted models
 - Women – OR 2.0-5.0
 - Men – OR 2.3- 2.6
- OAB
- Pelvic organ prolapse
 - Rectocele
- Constipation
- Anorectal Mechanisms

Fecal Incontinence: Assessment

- Patient Reported Outcomes
- Bowel Diary
 - Stool consistency
- Fecal incontinence Severity
 - FIS (Grade C)
 - Vaizey/St. Mark's Score (Grade C)
 - ICIQ-B (Grade B)
- Impact on Quality of Life
 - Fecal Incontinence QOL
 - Modified Manchester Health Questionnaire
 - ICIQ-B

Anorectal Manometry: Examples of New Types of Technology

- Additional Diagnostic Evaluation
- Dependent on initial findings
 - Treatment non-response
- Types of evaluations
 - Endoanal ultrasound
 - Defecography
 - Functional MRI

Case Studies

Cases will be presented that highlight 6 community-dwelling adults with FI whose treatment options are based on the etiology of their symptoms as well as response to initial therapy.

Case 1: 70 yr old overweight man with fecal smearing, fecal urgency and FI

Case 2: 75 yr old woman with urgency FI for one year that is worse with diarrhea

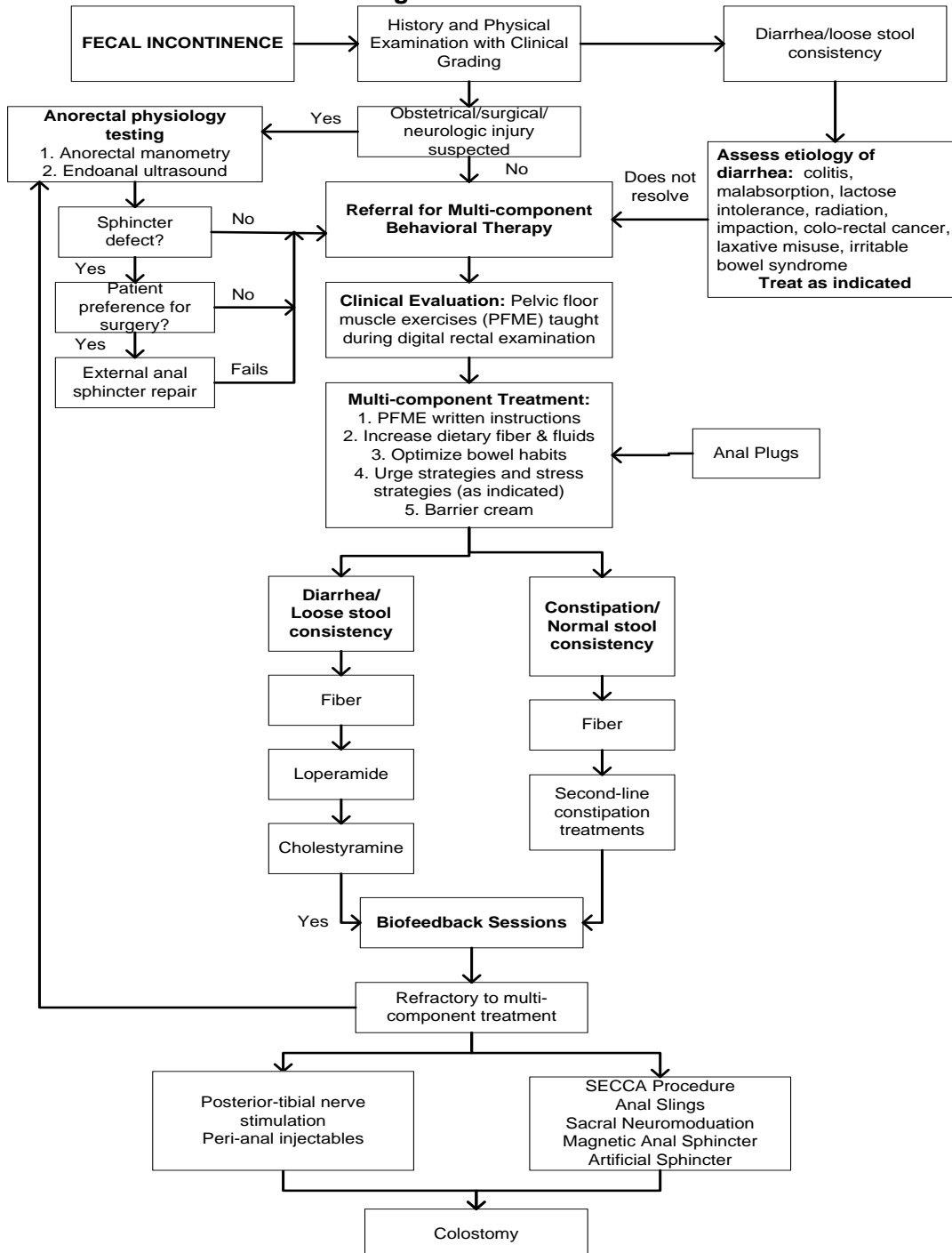
Case 3: 75 yr old woman with dementia, constipation, and fecal incontinence

Case 4: 55 yr old women who failed behavioral treatments and medications with urgency & passive FI

Case 5: 26 yo old women, 3 months postpartum who had a fourth degree OASI

Case 6: 58 yr old women who had a failed sphincter repair and has passive FI

Fecal Incontinence Treatment Algorithm for Adults:



Treatment of Fecal Incontinence: Pelvic Floor Training, Medical Management, and Case Studies

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Disclosures: None

Learning Objectives

Conservative Treatments

- Goals of treatment - patient preferences
- Life Style Changes
 - Diet and fluids
 - Weight loss
 - Smoking Cessation
- Behavioral treatments
 - Pelvic floor muscle exercises
 - Bowel control strategies
 - Biofeedback (and electrical stimulation)
- Medications

Life Style Changes

- Weight loss
- Smoking
- **Diet and Fluids**

Weight Loss and Fecal Incontinence (FI)

- 99 morbidly obese women - body mass index ≥ 40 kg/m²
- 12 months after laparoscopic Roux-En-Y weight loss surgery
- BMI decreased from 49 to 35 kg/m²
- **Fecal Incontinence decreased from 19.4% to 8.6% (p=.02)**

Impact of Tobacco Usage on FI

- Tobacco Usage
 - Nicotine is thought to speed recto-sigmoid transit
 - Nicotine may exacerbate fecal urgency
 - Anecdotal evidence of reduction in fecal urgency with smoking cessation
 - No formal studies
- Alcohol Usage
 - Unclear effect, more studies needed

Conservative Treatments

- Behavioral treatments
 - Pelvic floor muscle exercises
 - Bowel control strategies
 - Biofeedback (and electrical stimulation)

Behavioral Treatments for Incontinence

- Improve bowel control through systematic changes in patient behavior and teaching skills for preventing fecal (and flatal) loss
- Often multi-component
 - Reduce incontinence severity and frequency

- Avoid side-effects of drug therapy and surgery

Behavioral Treatment: Multi-component Program

- **Pelvic floor muscle training**
- **Home practice of exercises**
 - **Increase duration of contraction over time**
 - **15 in a row, 3 times a day, vary position**
- **Bowel Control Techniques**
 - **Urge suppression strategy, “walk don’t run”**
 - **Hypervigilance to bowel sensations**
- **Self-Monitoring with bowel diaries**

FI: Pelvic Floor Muscle Training

Rectal Examination

- Resting tone
- Voluntary squeeze strength
- Relaxation

Urge Suppression Strategy

- **FREEZE AND SQUEEZE**
- Do NOT rush to the toilet
- Stop and stay still, sit if possible
- Squeeze pelvic floor muscles
- Relax rest of body
- Concentrate on suppressing urge
- Wait until the urge subsides
- Walk (don’t run) to bathroom at normal pace

Other Behavioral Strategies

- Stress Strategy
- Squeeze before you sneeze (or cough or lift)
- Squeeze as you get out of the chair, bed or car
- Hypervigilance to rectal sensations
- Don’t over wipe
- Squeeze as stand up, and wipe again after standing
- Don’t force out flatus

Prompted Voiding and FI

- N=165 nursing home residents (Veterans)
- Prompted voiding and QID fitness training
- Outcome - incontinence checks Q 2 hours x 3 days
- Results:
 - % of checks incontinent of stool - 8% to 0%
 - Number of continent bowel movements divided by the total bowel movements – 0% to 75%
- N=112 nursing home residents
- Q 2 hr prompted voiding, fitness training, extra fluids/snacks
- Outcome – incontinence checks Q 2 hrs x10 days
- Results: more **bowel movements, less constipation, more continent bowel movements, same FI**

Biofeedback is a teaching tool

- Small physiologic responses are amplified and converted to a display, usually visual
- Motor training
- Sensory training
- Sensory-Motor training

Biofeedback for Fecal Incontinence

- Motor training - external sphincter training to increase resting and squeeze pressures (outlet resistance)
- Sensory training –

- If decreased sensation, taught to sense progressively smaller rectal volumes
- If hypersensitive, taught to tolerate progressively larger rectal volumes.
- Coordination training - balloon and anal sensor to learn external anal sphincter contraction in response to increases in rectal pressure to counter the rectal-ano inhibitory reflex with involuntary internal anal sphincter relaxation
- Strength Training Example

Biofeedback for Fecal Incontinence: The Evidence

- Over 60 uncontrolled studies report improvement with biofeedback and/or PFME.¹
- Three randomized, controlled clinic trials exist for behavioral treatment or pelvic floor muscle exercises with or without biofeedback^{2,3,4}

Biofeedback for FI, Norton et al, 2005

- 4 randomization groups, n=171
 - 2 types of biofeedback (hospital-based ± home EMG unit)
 - Advice alone
 - Advice plus verbal instruction on sphincter exercises
- No significant difference between the 4 groups
 - 54% improvement in the biofeedback groups vs 53% improvement in the advice only
- Multi-component advice provided by a clinical nurse specialist is an effective treatment for FI

Biofeedback for FI, Heymen et al 2009

Stepped therapy

- 168 patients treated with medications to improve stool consistency
- 21% had adequate relief with medications/advice alone
- 108 patients then randomized to PFME alone or with EMG-assisted biofeedback for 6 weeks
- Primary outcome = FI severity score improvement
 - 77% in biofeedback group vs 41% in PFME group

PhysioFit Trial - Bols et al 2012

- N=80, mean age 59 years, 90% women
 - Multicenter RCT in the Netherlands
 - PFME with and without biofeedback including sensory and coordination training
 - Main outcome (Vaizey scores) – same improvement with or without biofeedback (sensory training)
 - Patient perceived improvement and Lifestyle subscale of the FIQL better with BF

Behavioral Therapy - Predictors

- 1979 - Little evidence that shows a relationship between pre-treatment anorectal function and outcomes
 - Rectal sensitivity >100ml before treatment associated with a poorer response
- 2012 – Secondary Analysis of Biofeedback RCT
 - Longer time with FI was unfavorable
 - Favorable factors include constipating medication usage, obstetrical factors, and more embarrassment
 - No physiologic variables predicted outcomes

Behavioral Therapy – Mechanisms

- Lack precise knowledge of the mechanisms responsible for improvement when biofeedback is used to treat FI
- Rectal sensitivity is the single physiological parameter that has been reported to most consistently improve with BF.
- Rectal sensation may be more important than sphincter strength.
- However not all patients who improve sensation improve FI
- Ability to sustain an EAS contraction may be more important than maximum squeeze pressure.

Pelvic Floor Electrical Stimulation

- Stimulates pudendal nerves
 - Increases outlet pressure

- Decreases urgency
- Teaching tool for pelvic floor muscle contraction (often combined with biofeedback)
- Biofeedback & Electrical Stimulation
- Multi-site RCT in Germany, N =158, mean age 62
- Randomized to
 - Home BID Electrical Stimulation therapy and EMG biofeedback
 - Home EMG biofeedback alone
- Allowed stool consistency treatment in both groups (psyllium, loperamide, teas)
- Outcome measure: Cleveland Clinic Incontinence Score (0=continent to 24=completely incontinent)
- Results: median change from baseline was 8 in BF/ES group and 5 in BF group (p=.002)

Behavioral Therapy Outcomes

- **Reported improvement ranges from 0% to 100%, with the majority being in the range of 50-80%**

Conservative Treatments

- Dietary Changes
- Fiber Supplementation
- Medications
 - To improve stool consistency and reduce urgency
- Stool Consistency Goal

Dietary Considerations

- Malabsorption
 - Lactose intolerance – highly prevalent, especially in Asians and African Americans
 - Fructose intolerance in Irritable Bowel Syndrome
 - Gluten enteropathy
- Bile acid salt
- Spicy foods
- Fatty Foods
- Dietary fiber
- Fiber Supplements

Evidence for Fiber Treatment

- Fiber Supplementation - 1 RCT for FI¹
 - ♦ Well-powered, single site RCT, n=189
 - ♦ 4 groups: psyllium, gum arabic, methylcellulose and placebo
 - ♦ Significant improvement in incontinence stools on a 7-day diary for psyllium and guar gum compared to placebo
 - ♦ Worsening with methylcellulose

Diarrhea Prevention

- Avoid inappropriate antibiotic usage
- Probiotics with antibiotics (prevent C difficile)
- Avoid sorbitol
 - Sugar-free gum and candy
 - Liquid medications (e.g. commonly used with tube feeding)

Pharmacologic Treatment of FI

- 16 trials, 558 participants
- 11 trials included treatment for liquid stools
- Loperamide - 3 placebo-controlled trials¹
 - Loperamide superior to placebo in all studies
 - Side effects greater than placebo
 - Less side-effects noted on loperamide compared to Lomotil®
 - Very small study, n=19, for loperamide increased resting tone
 - Combination Therapy
- Loperamide ± Fiber - 1 placebo-controlled trial¹
 - No additional improvement in FI severity by adding fiber
- Cholestyramine – case series reported²

- Improved FI episodes and number of bowel movements when added to biofeedback-assisted behavioral therapy
- Loperamide vs Fiber – 1 placebo-controlled RCT³
 - Crossover design
 - Both improved FI episodes with no between group differences
 - Fiber better tolerated

Emerging Treatments

- Alpha 1 – adrenoreceptor agonist suppository¹
 - Libertas/NRL001 - a multicentre, Phase II, double-blind, randomized, placebo-controlled, parallel group study
- Anal Plugs – Containment/Management²
 - Improved designs – silicon, disposable
 - Tolerability

Controlling Anal Incontinence by Performing Anal Exercises with Biofeedback or Loperamide (CAPABLE)

- NIH-Funded Multicenter Network Trial, NCT02008565
- CAPABLE RCT, n=289, 7 clinical sites
 - Loperamide only
 - Biofeedback training for pelvic floor exercises only
 - Loperamide and biofeedback training together
 - Usual care / placebo pill
 - Treatment for 6 months. Primary outcome = change in FI severity
 - Recruitment began March 2014, results 2017

Constipation and Fecal Incontinence

- Liquid stool overflows around an impaction
 - Particularly common in homebound, hospitalized or nursing home patients
 - Digital exam
 - +/- plain abdominal x-ray
 - Interpretation as diarrhea, worsens the impaction, due to treatments administered
- Constipation and Fecal Incontinence
- Laxative-induced diarrhea
 - Improve Constipation Management
 - Regular pattern of defecation following a meal (gastro-colic reflex). Use foot stool, particularly with raised toilet seats.
 - Fruit, vegetables, and fluids
 - Osmotic laxative in daily dose (adjust as needed) – e.g. polyethylene glycol
 - Regular stimulant laxative (e.g. senna)
 - As needed glycerin suppository (or bisacodyl suppository or phosphate enema) vs. stimulant laxatives

Patient Case 1

- 70 year old
- Recently myocardial infarction; trying to eat healthy- fiber cereal with skim milk for breakfast x 3 months; sugar-free candy
- 30 pounds overweight – weight stable
- Bowel movements are soft formed or mushy. Fecal smearing many days; occasional small amount of stool loss on the way to the bathroom with urgency.
- Treatment options?

Patient Case 2

- 75 year old woman who has fecal incontinence for 1 year
 - Continent with solid stool unless too far from the bathroom. Very little warning.
 - For the past year, if diarrhea, completely incontinent and stays home.
 - Sometimes diarrhea starts suddenly and not home. Very embarrassing. Again little warning.
- Treatment Options?

Patient Case 3

- 75 year old woman with mild dementia
- Constipated. Will go 3-4 days without a bowel movement then very hard and painful. Laxative (OTC stimulant pills) cause diarrhea and fecal incontinence
- Refuses to wear pads or pull-ups (diapers)
- Huge burden to caregiver

Evolving Surgical Treatments for Fecal Incontinence: An Evidence and Case-based Approach

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Disclosures:

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- Kimberly Clarke, consultant
- Up to Date
- NIDDK-research funding
- NICHD-research funding

Learning Objectives

1. To understand that conservative approaches to treatment of FI are considered first-line
2. To appreciate that the optimal treatment regimen may be a complex combination of various non-surgical and surgical approaches
3. Present evidence and case-based surgical treatment approaches for FI

Definition

- Fecal incontinence 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
- Fecal incontinence is a symptom
- Types of FI: urgency, passive and fecal seepage³

Cochrane Review 2013: Surgery for Fecal Incontinence

- The review is striking for the lack of high quality randomized controlled trials on fecal incontinence surgery that have been carried out in the last 10 years.....
- The continued small number of relevant trials identified together with their small sample sizes and other methodological weaknesses limit the usefulness of this review for guiding practice
- It was impossible to identify or refute clinically important differences between the alternative surgical procedures
- Larger rigorous trials are still needed, however, it should be recognized that the optimal treatment regime may be a complex combination of various surgical and non-surgical therapies

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
- General Limitations
 - Limited by lack of normative data
 - Lack of standardization of testing and reporting
 - Lack of robust data regarding negative and positive predictive value of test results for diagnosis or clinical outcomes of therapeutic interventions

Case 4

55 yo female P3013 with 5 year history of FI and rectal 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
- Examination: decreased anal tone, intact reflexes, ?dove tail appearance, 2 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 Ssphincter
 - Direct sphincter injury (majority)
 - Obstetric
 - Surgical
 - Trauma
 - Congenital anomalies
 - Prior anal or rectal surgery

Anal Sphincter Repair: Other evidence for efficacy?

- Systematic Review of FI studies 1991-2010
- 16 studies selected with 900 patients
- Quality of Data
- Long Term Data
- 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 and pudendal nerve delay implicated)
 - Still an appropriate first line therapy for women with major sphincter defects
 - Restore sphincter to circumferential configuration
 - Build up perineal body
 - Most common complication: wound infection (2.2-35%)
 - Sphincteroplasty
 - Long-term results are poor so we are looking elsewhere for treatment
 - Same treatment for defect or no defect
 - Combination treatment
 - Have we swung too far in the other direction?
 - Attempt at RCT of BF vs sphincteroplasty did not get off ground
 - RCT of sphincteroplasty and SNS?

Case 5

AH is a 26 yo P1, 3 months postpartum from an SVD presenting with fecal incontinence

- FI with solid & liquid stool, flatus, and soiling
- Precipitous delivery
- BW of infant 4600 g
- Laceration repaired in the “operating room” (review of op note-4th degree OASI)
- Exam: thin membrane between vagina and rectum
- Anal manometry: mean resting pressure at 2 cm 21 mmHg, mean squeeze pressure 36 mmHg
- EAUS: EAS, disrupted; IAS: intact

Obstetrical Anal Sphincter Injury (OASI)

- OASI occurs in 0.6-9% of deliveries¹

- Up to 11% of primiparous women may have occult injuries²

Overlapping vs. end-to-end sphincter repair

- Previous RCTs showed overlapping more favorable³
- Recent study found end-to-end more favorable⁴
- Most important: recognition of injury!
- Twice as likely to have postpartum FI⁵

Postpartum Care

- IV antibiotics at time of repair¹
- Sitz baths
- Avoid Constipation
- Pelvic Floor Exercises
- Monitor for Sx
- Endoanal US if persistent symptoms

Case 6

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 help
- 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 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

Sacral Nerve Stimulation

- 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 reversible¹
- Decreased episodes of spontaneous sphincter relaxation²
- Electrical stimulation of the sacral nerves causes:
 - Modulation of neural reflexes
 - Interrupts constant sensory input from rectum
- Indications
 - Most trials in patients with normal sphincter anatomy
 - Emerging studies in patients with disrupted sphincters
 - Low squeeze
 - Intact reflex activity
 - Usually reserved for those refractory to conservative therapy
 - Contraindications
 - Spina bifida
 - Skin disease at implantation site
 - Pacemaker or defibrillator

Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized controlled trial

- RCT, Pelvic Floor Clinic
- SNS vs optimal medical therapy for Severe FI (Wexner >12)
- N=120
- 12 month follow-up
- Measures: anorectal physiology, 2 week bowel diary, Wexner score, FI QOL index, SF-12
- Methods
- SNS group test stimulation positive in 90%
 - N = 53
- Medical therapy consisted of visits q month x 6 visits, then every 2 months x 3 visits
 - Pelvic Muscle Exercises, Bulking Agents, Dietary Manipulation.
 - N = 60
- SNS Group Results

Sacral Nerve Stimulation

- Touted by some as first line therapy
 - Is it appropriate for all severity and etiology (hammer looking for the nails?)
 - Is it appropriate for sphincter defects
- Does the test phase truly evaluate improvement in patients?
 - 10-14 day period, up to 1 month
 - Diary
 - Off study is anyone really checking this carefully?
- Cost
 - Should it be a first line therapy when its so costly?
 - Easier to get an insurance company to pay for SNS compared to biofeedback
 - Surgical/Other Procedural Treatments for Fecal Incontinence

Severe Refractory Fecal Incontinence

Artificial Bowel Sphincter (ABS)

- Efficacious
- High morbidity
- ABS Results
- ABS Complications

Anal Slings

- Similar to transvaginal tape or transobturator tape for UI
- Dacron, mersilene, polyester, and teflon mesh, fascia lata
- Wound infections, sinus tract, ulcer
- Treated with antibiotics or removal
- Used in conjunction with tx for rectal prolapse
- Small sized inadequate studies to date

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 Design

- Prospective, open label, FDA-regulated, single arm study
- Follow-up: 2 wks. and 3,6,12,24,48,60 months
- Sample Size:152 pts. using an Adaptive Model, p-value < .0087
- 14 US centers
 - 7 led by Urogynecologists
 - 8 led by Colorectal surgeons (one closed)

- Missing data analyzed as failures
- Comprehensive Safety Objective
- 2 Independent Oversight Committees
 - Adverse Events Adjudication Committee
 - Data Monitoring Committee

Primary Outcome

- 50% reduction in the number of FI episodes from baseline to 12 months post-operatively on a 14 day bowel diary.

Secondary Outcomes

- Decrease in Fecal Incontinent Days and Urge Episodes
- Symptom Severity: Cleveland Clinic Incontinence Scores
- Quality of Life: Fecal Incontinence Quality of Life (FIQOL)
- Mean surgical time = 33 minutes (range 11-71)
- Mean EBL = 13 cc (range 0-50)
- Mean hospital stay = 11 hours (2-57)
- NO visceral injuries or perforations

Other Procedural Treatments for Fecal Incontinence

SECCA

- SECCA Efficacy Data

Posterior Tibial Nerve Stimulation

- Peripheral neuromodulation directed to L4-S3 nerve roots
- Spleen 6 point in Chinese acupuncture
 - OAB, UUI, pelvic/bladder pain, FI, impotence
- RCT with sham effective for OAB/Urge UI
- RCTs pending for FI
 - 63-84% reported $\geq 50\%$ reduction of FI episodes/wk (bowel diary) in observational studies

Perianal Bulking: Hyaluronate Sodium

- Recent FDA Approval: 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
- 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
- Solesta Pivotal Trial: Results
- All 3 success criteria were met
 - Responder rates superior to sham at 6 months
 - Above the predetermined threshold
 - Durability of effect out to 12 months: 57.4% Responder₅₀
- Most Common Related AEs - Solesta Patients
Pivotal Study Through 18 Months

Magnetic Anal Sphincter

Final Consideration: Fecal Diversion

- 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)

Investigational Treatment Options

- Autologous myoblast injection

Conclusions

- Cause of fecal incontinence 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
- Conclusions
- Sphincteroplasty has excellent short-term but reduced long-term results
- Neuromodulation is promising therapy
- Other therapies needed
- Individualization of treatment
- Things could always be worse

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