Sacral Neuromodulation for Fecal Incontinence and Constipation

Toyia James-Stevenson, MD

January 6, 2015

Indiana University Health

SCHOOL OF MEDICINE

INDIANA UNIVERSITY

Focus of Talk

- Discuss work-up of patients prior to SNS
- Literature review of pts with FI and Constipation
- Discuss details of SNS placement

SACRAL NEUROMODULATION IN FECAL INCONTINENCE

Definition

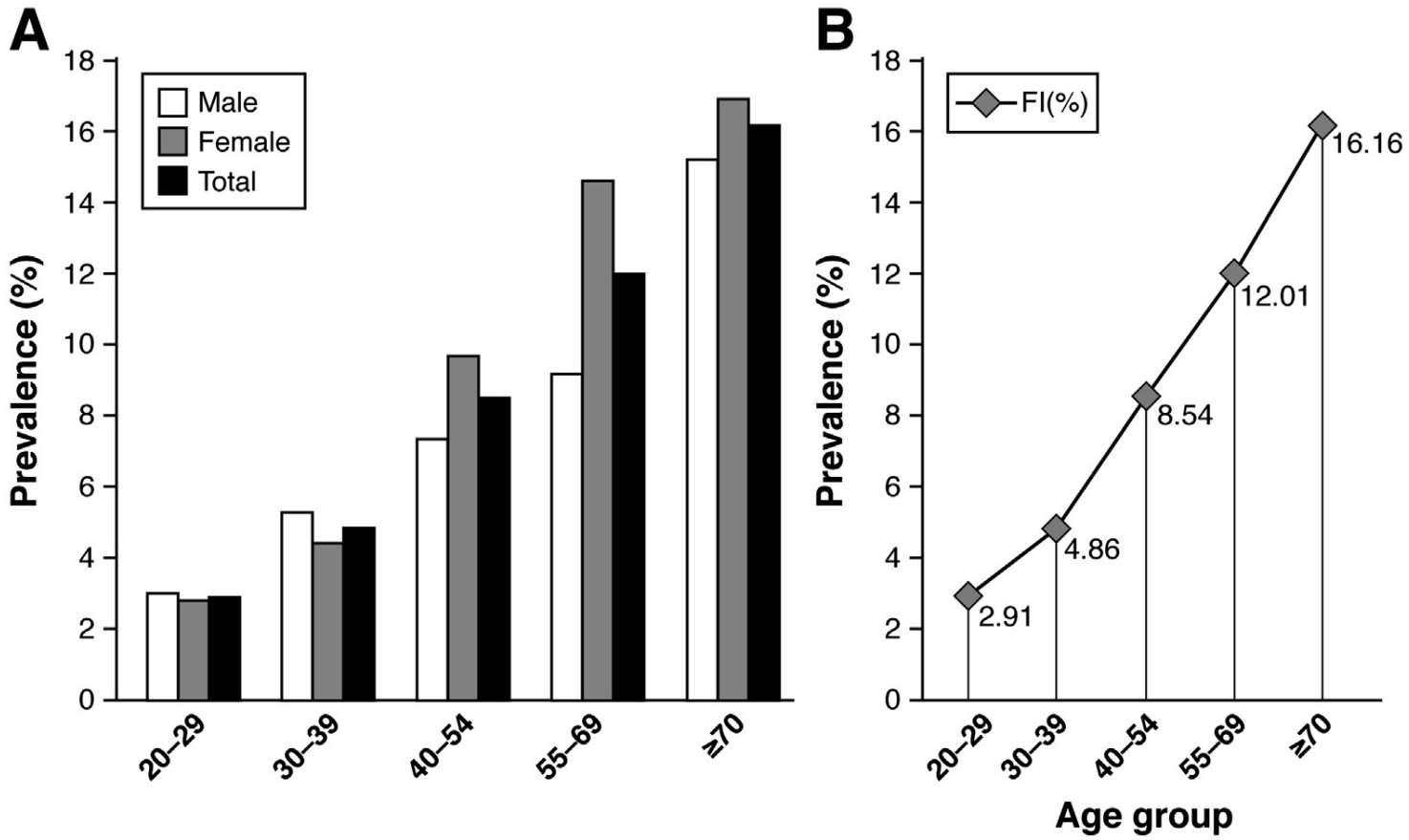
- Fecal Incontinence - Unintentional loss of solid or liquid stool
- Anal Incontinence - Includes leakage of gas and/or fecal incontinence

Clinical Sub-types of FI

- Passive – stool leakage with little or no forewarning (often have low resting pressure)
- Urge – occurs despite active efforts to retain stool
  - May have abnl squeeze pressure and duration
  - May have reduced rectal capacity with rectal hypersensitivity
- Seepage – Leakage after BM

– Incomplete evacuation or impaired sensation

Prevalence of FI by Sex and Age



I. Ditah, P. Devaki, H.N. Luma, et al. Prevalence, trends, and risk factors for fecal incontinence in United States adults, 2005-2010; Clin Gastroenterol Hepatol, 12 (2013), pp. 636–643.

Risk Factors

- ***Chronic Diarrhea***
- ***Rectal Urgency***
- ***Burden of Chronic Illness (Comorbid count, DM)***
- Urinary Incontinence
- Pelvic Surgery
- Caucasian Race
- Smoking (also RF for external sphincter atrophy on MRI)
- Obesity
- Instrumented Vaginal Delivery
- Decreased physical activity
- Advanced Age

Bharucha AE, et al;Am J Gastro. 2015 Jan;110(1):127-36

Management

OPTIONS FOR MANAGEMENT OF FECAL INCONTINENCE
Conservative Management (Meds, Dietary Advice, Kegels)
Pelvic Floor Therapy/Biofeedback
Continence Products
Anal Plugs
Sphincter Repair (Overlapping Sphincteroplasty)
Sacral Nerve Stimulation
Posterial Tibial Nerve Stimulation (not FDA-approved)
Injectable Bulking Agent (Sodium Hyaluronate Dextranomer Microspheres)
Temperature-Controlled Radiofrequency Energy to Internal Anal Sphincter
Diversion with Colostomy
Artificial Bowel Sphincter/Magnetic Anal Sphincter

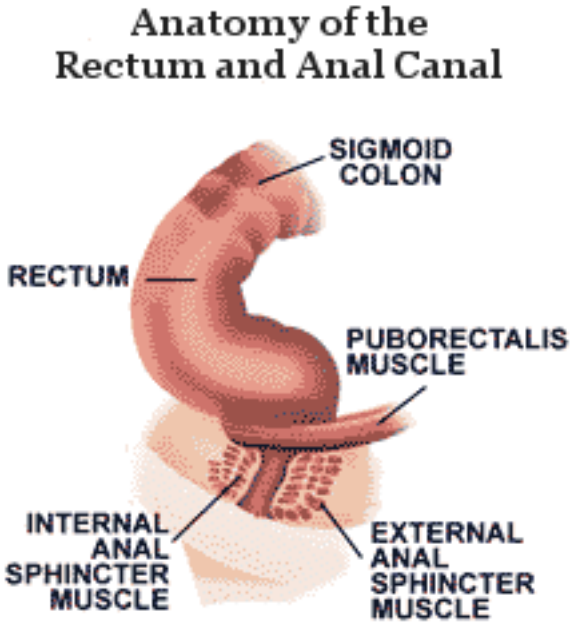
Womens Health (Lond Engl). 2015 March ; 11(2): 225–238.

Why Is This Important?

- Can have devastating impact on quality of life
- Loss of dignity, modesty, confidence
- Many do not share with closest relatives and friends
- Fewer than 30% discuss their FI with physicians
- Caregiver burden >>urinary incontinence
- Common cause of nursing home admission

Normal Anorectal Function

- IAS- smooth muscle, 70-85% of resting tone
- Stool causes rectal distention
  - Rectal contraction
  - Urgency sensation
  - Relaxation of IAS (RAIR)
- EAS, PR and levator ani can be voluntarily contracted to maintain continence (85% of squeeze tone)



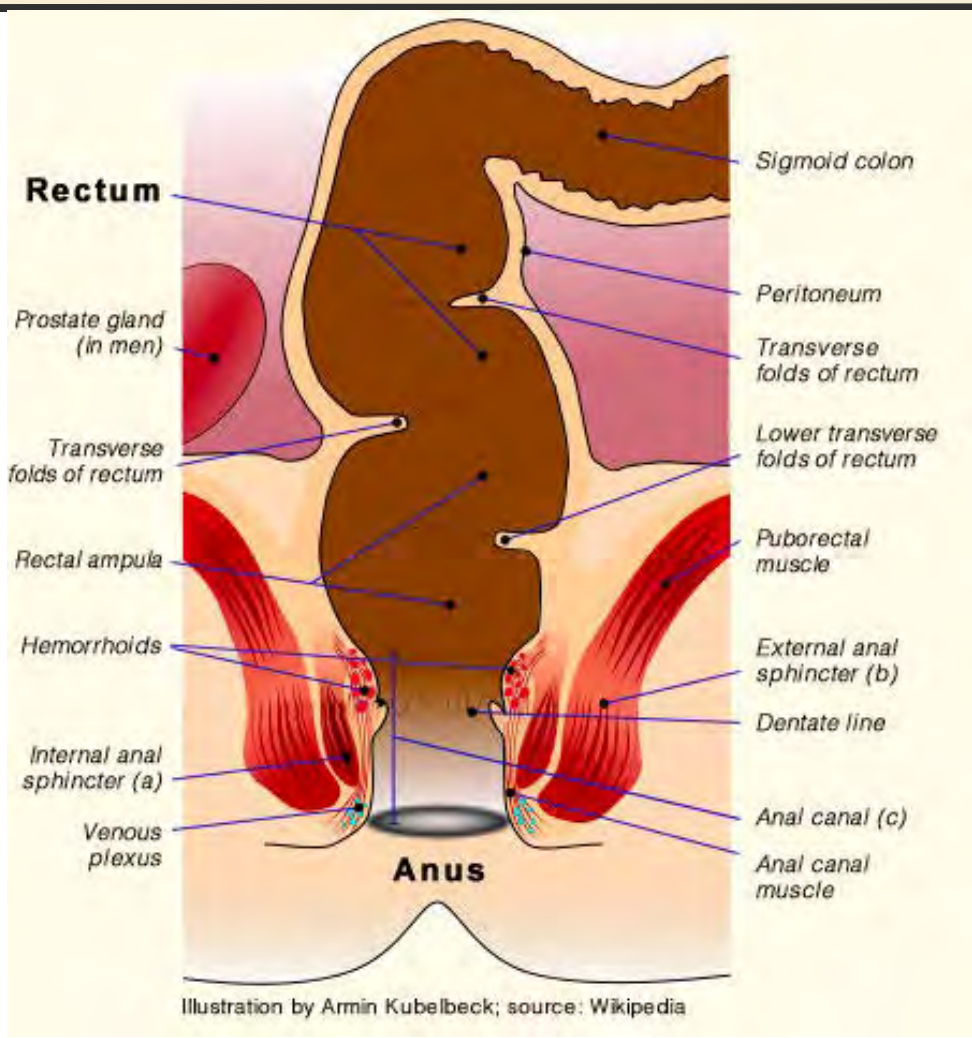
Changes in Anorectum with Age

- Lower resting and squeeze pressures (decrease by 30-40% in pts >70 yo
- Denervation of anal sphincter
- Decreased rectal compliance (stiffer rectum)
- Decreased rectal sensation
- Perineal laxity

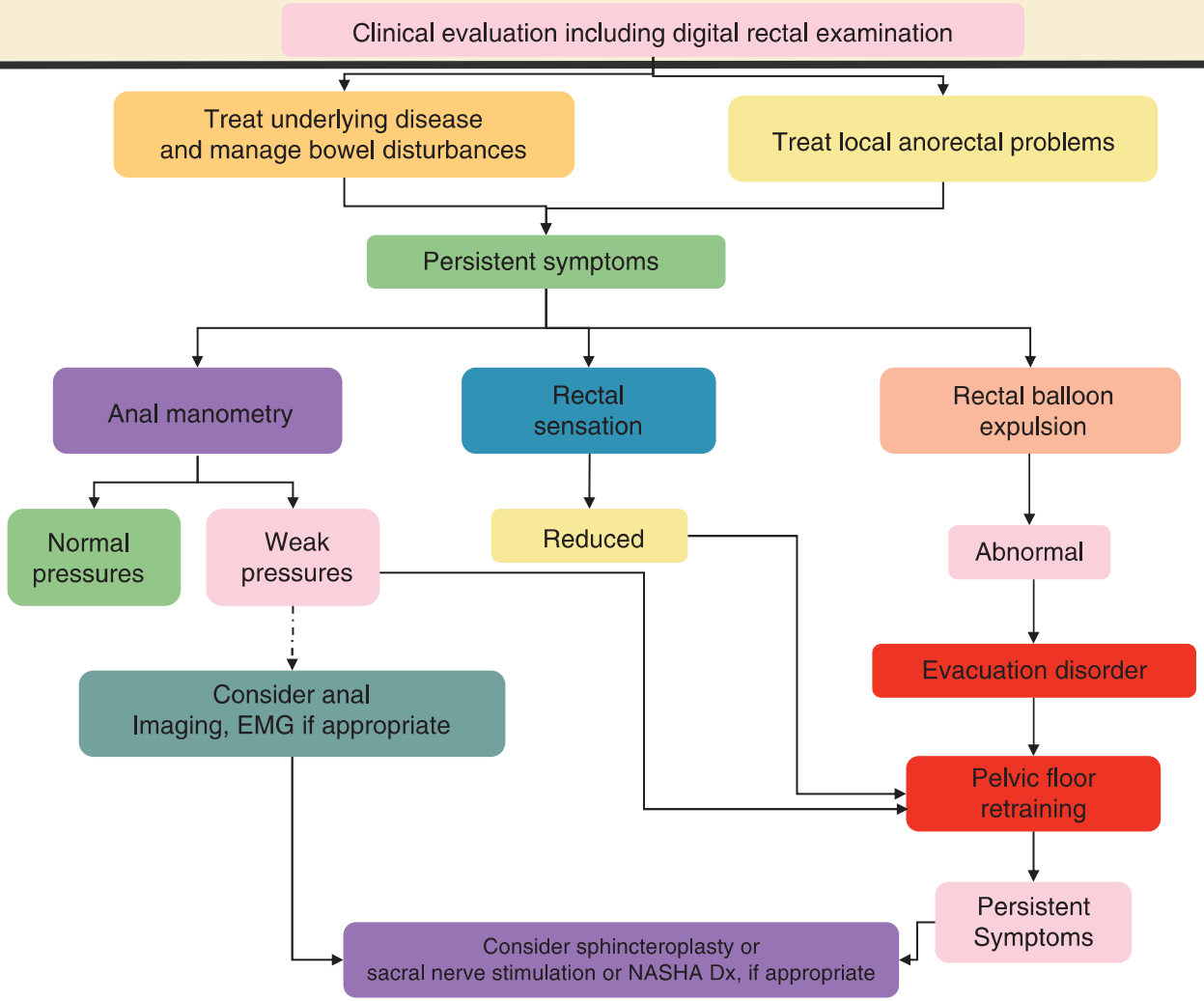
Fox et al, Dis Colon and Rectum, Nov 2006

At Least 8 Factors Affect Continence

1. Sphincter function
2. Anorectal sensation
3. Puborectalis function
4. Rectal compliance
5. Colorectal motility
6. Stool consistency
7. Peripheral/central innervation
8. Cognition



Suggested algorithm for evaluation and management of fecal incontinence.



Wald A, et al. Am J Gastroenterol 2014; 109:1141–1157

Biofeedback

- A few small single-center studies have shown benefit of biofeedback over pelvic floor exercises
- Benefit may be highest in those with urge incontinence and predominantly EAS weakness

Haymen, S, Dis Colon Rectum 2009

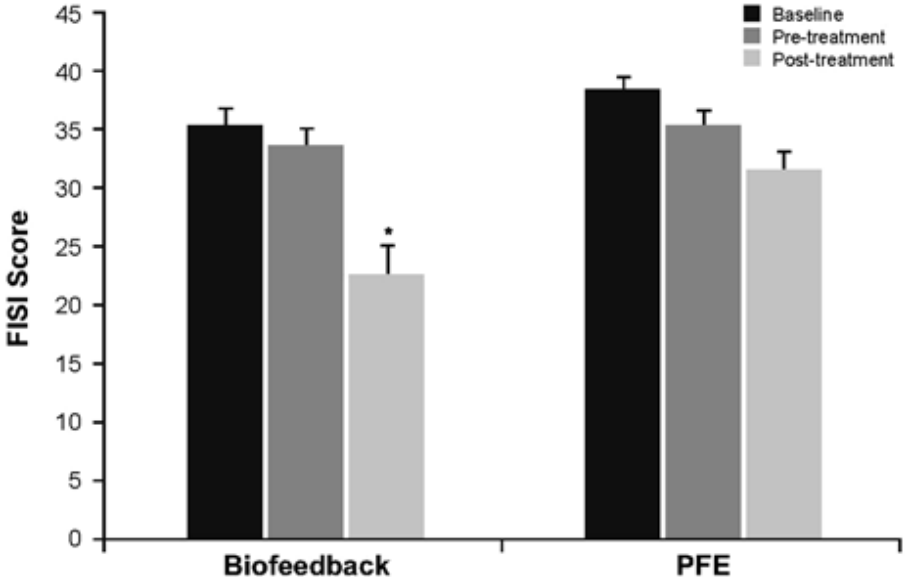


FIGURE 1. Fecal Incontinence Severity Index (FISI) scores at baseline, pretreatment (end of run-in), and at 3 months post-treatment in patients treated with biofeedback versus pelvic floor exercise (PFE). At the 3-month follow-up, patients in the biofeedback group had greater reductions in FISI scores versus patients in the PFE group ($P = 0.01$, ANOVA). *$P = 0.01$, biofeedback versus PFE. Adapted from Heymen et al.[40]

Overlapping Sphincteroplasty

- EAS muscles overlapped in the anterior midline
- Better outcome than end-to-end repair
- Long-term data shows suboptimal improvement
-

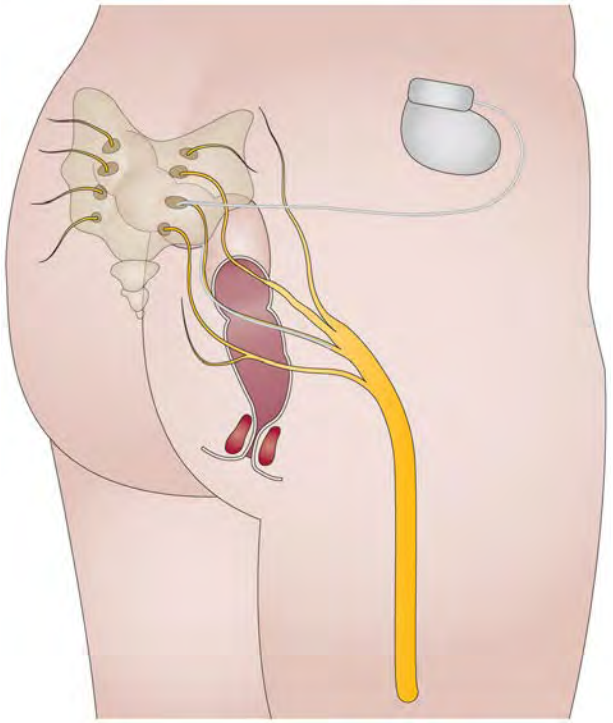
Year	Author	*N*	Months follow-up	Results
2000	Karoui et al.[84]	74	40	45% Continent to solid and liquid
2002	Halverson and Hull[85]	49	69	4 Stomas 46% Continent to solid and liquid
2006	Barisic et al.[86]	65	60	48% "Good or excellent"
2009	Oom et al.[87]	120	69	37% "Good or excellent"

SNS Indication in FI

- Most appropriate in those who have failed conservative management and NOT having diarrhea:
  - Medications (Fiber, Imodium, Laxatives)
  - Dietary Advice (Low FODMAPs, lactose free)
  - Biofeedback

Proposed Mechanism of Action

- Stimulation of the anterior ramus of the sacral spinal nerves S3 or S4
- Why do patients improve?
  - Pelvic afferent and/or central level
  - Peripheral motor stimulation is not primary mechanism of action



Carrington et al, Neurogastroenterol Motil. 2014 Sep;26(9):1222-37

Pretreatment Evaluation

- Anorectal Manometry with Compliance and Sensation
  - Can help identify patients with dyssynergic defecation
  - Can identify patients with rectal hyposensitivity, which can improve with SNS
- Endoanal ultrasound
- Neither test has been shown to predict who will have best outcomes
- Plain Xray identified skeletal abnormalities
  - Imperforate anus
  - Spina bifida (MRI first as potential skeletal deformity)
  - Meylomeningocele
  - Previous Spinal surgery

Evaluating FI When Conservative Measures Fail

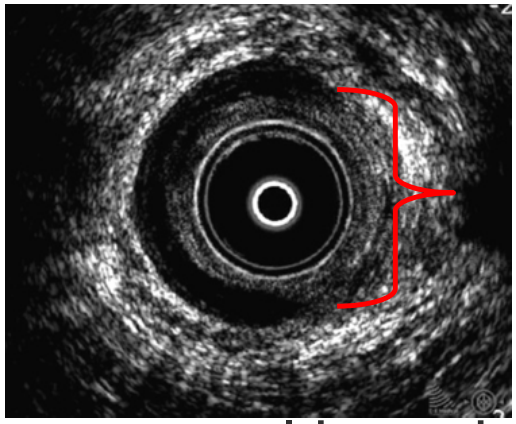
Tests for Fecal Incontinence	Benefits
Anorectal Manometry with Sensation and Compliance (ARM)	Evaluates for: a) Weakness of IAS/EAS b) hyper- and hyposensiviity c) stiff or overly lax rectum d) paradoxical sphincter contraction, which can lead to overflow incontinence/fecal seepage e) intact reflexes
Balloon Expulsion Test (BET)	Prolonged times indicates obstructive defecation (most frequently due to dyssynergic defecation; can also be caused by anatomic issues like rectoceles)
Defecography (MR or Barium)	Evaluates anatomy of pelvis and sphincters
Endoanal Ultrasound	Evaluates for sphincter disruption or thinning
EMG	Assesses sphincter activity using surface electrode or concentric needle; may help distinguish neurogenic from myogenic inury

Why do ARM and Balloon Expulsion?

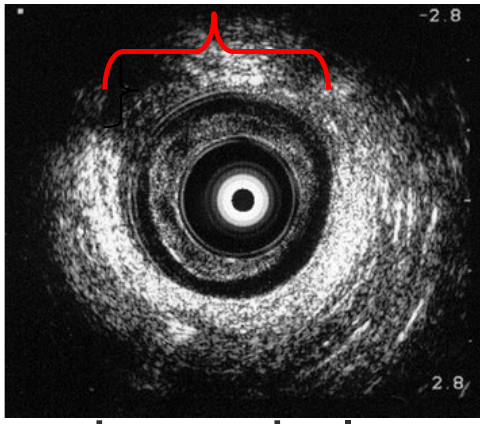
- In pts referred to IU Motility Lab for FI
  - 35 (18%) had obstructive defecation
  - 14 (10%) fulfilled criteria for dyssynergic defecation (abnl BET + paradoxical sphincter contraction/incomplete sphincter relaxation)
- Pts with fecal seepage may have abnl sphincter relaxation → ~70- 80% respond to biofeedback

Endoanal Ultrasound in FI

IAS Defect



EAS Defect



- Assesses structural integrity and morphology of anal sphincters
- Reliable for detecting IAS defects
- EAS assessment can be operator dependent (nl variation such as EAS gaps possible)
- Can have low specificity as degree of separation may not correlate with symptom severity

Vitton et al. Practical Imaging of FI. The Eyes of Science, 2014.

Sphincter Defect in SNS

- NOT a contraindication
- Little data on whether pts with smaller defects do better
- Largest studies included only patients with defects of less than 120˚

Percutanous Nerve Evaluation (PNE)

- Temporary electrode or a tined (quadrupolar) lead which would be definitive in the event of > 50% improvement in symptoms
- Evaluation can last from 1-4 weeks (longer duration better in those not having daily symptoms)
- Patients with >50% symptom improvement can go on to have permanent stimulator placed
- Data suggests that those with greater improvement may do better long-term

Peripheral Nerve Evaluation

- Basic evaluation
  - Up to 7 days
  - Office or ASC
  - +/- fluoro or ultrasound
  - Local Anesthesia
  - Flexible thin wire
  - One electrode contact (typically switched to opposite side in 3 days)
  - Infection rare so no Abx
  - Positive result→ permanent device
  - Inconclusive result → ? Stage 1 device
- Stage I device
  - Up to 14 days
  - ASC or OR
  - + fluoroscopy
  - MAC or general anesthesia
  - Flexible lead with tines that anchor in place
  - Stays in place after positive evaluation
  - 4 electrodes
  - Abx prophylaxis
  - Positive result → permanent device
  - Inconclusive results → consider other therapies

Permanent Lead Placement

- Done under fluoroscopy
- 1.7X2.0 inches
- Weighs .77oz
- Implanted under the skin of the upper buttocks
- Done by cololrectal surgery, urology, urogynecology
- Primary adverse effects are pain and infection

Bowel Diary and Incontinence Score

- Useful and baseline and in short term for assessment of symptoms
- Incontinence score useful to monitor outcomes compared with baseline values
- Long-term QOL assessment is also important

Predictors of Good Outcomes in SNS for FI

- No correlation between:
  - Age
  - BMI
  - Duration
  - Urge vs Passive Incontinence
  - Preoperative manometry (small study suggests negative correlation of response in pts with higher squeeze pressures)
- More significant the reduction in FI episodes during temporary SNS trial

Maeda, et alBr J Surg 2010; 97: 1096–102.

Preprocedural Counseling

- Reprogramming or Revisional Surgery may be required for permanent stimulator including removal
- 75% of patients will have improvement but not abolishment of fecal incontinence

SNS Special Consideration

- Limited Data in Pediatrics
- Pregnancy
  - SNS should not be implanted during pregnancy
  - No detrimental effects seen in pts who become pregnant
  - Typical recommendations are to switch off device as soon as pregnancy noted
- Elderly good candidates as long as deemed fit

Maeda et al, Colorectal Dis. 2015 Apr;17(4):O74-87

Special Considerations

- Concomitant urinary symptoms (urgency, incontinence, retention) common and these patients may benefit and should be discussed with urologist/urogyn
- Case reportsBenefits seen in pts with incomplete spinal cord injuries, spina bifida, cauda equina, disc prolapse

Contraindications

- Patients requiring regular MRIs of abdomen or thorax
- Technical success rates lower and risk of complications should be explained:
  - Sacral Deformity
  - Skin condition at site of implant
  - Bleeding diathesis

Sacral Neuromodulation Long-term

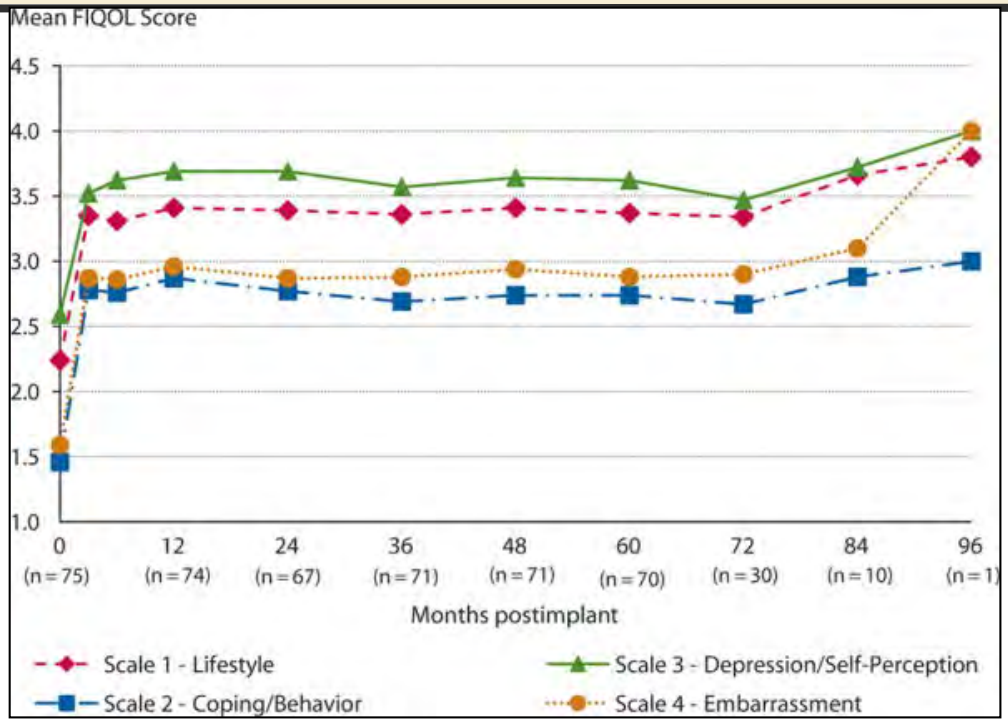
- Data from 67/ 120 pts available at 5-8yrs
- FI episodes per week ↓ from a mean of 9.1 at baseline to 1.7 at 5 years,
- 89% (n = 64/72) had ≥50% improvement ($p < 0.0001$)
- 36% (n = 26/72) had complete continence
- 27/76 (35.5%) pts required a device revision, replacement, or explant.

Tjandra, Disease of Colon and Rectum, Feb 2013

Permanent SNS

- Meta-analysis from 2000-2008 shows complication rate of 15% with removal in 2.7%
- Newer device smaller but expensive ($40K) and associated with fewer complications

Sacral Neuromodulation Long-term



FIQOL Scale	N	Baseline Mean	Baseline SD	5 Years Mean	5 Years SD	5 Years – baseline Mean	5 Years – baseline p*
Scale 1: lifestyle	67	2.26	0.79	3.36	0.68	1.10	<0.0001
Scale 2: coping/behavior	67	1.49	0.53	2.73	0.82	1.25	<0.0001
Scale 3: depression/self-perception	69	2.63	0.80	3.62	0.73	0.99	<0.0001
Scale 4: embarrassment	67	1.62	0.61	2.86	0.91	1.24	<0.0001†

*p values calculated by using paired *t* test except where noted.
†p value calculated by using Wilcoxon signed-rank test.

Tjandra, Disease of Colon and Rectum, Feb 2013

Economic Impact of FI

- Lack of US data on economic impact
- No prospective studies comparing cost effectiveness of conservative therapy versus SNS or bulking agents
- In UK, each increment in quality-adjusted life year gained with SNS for FI costs $35,000
- Largest impact likely from indirect costs
  - Potential for ↓ NH admission
  - Maintenance of productivity

SNS for Constipation

- Not FDA-approved
- Slow-transit and/or dyssynergic defecation refractory to medications and pelvic floor biofeedback
- Baseline evaluation:
  - ARM with compliance and sensation
  - Balloon Expulsion Test
  - Colon transit study
  - Defecography

SNS and the Colon

- 5 studies looking at segmental and total colon transit effects in those with FI showed no change
- One FI study looking at colon scintigraphy showed ↑in retrograde movements during defecation (10/13 pts)
- One study of 11 pts with FI using colon manometry showed ↑ in distal retrograde propagating contractice sequences

Michelsen et al, Br J Surg 2008; 95: 779–84.
Patton et all. Br J Surg 2013; 100: 959-68

Constipation and Colon Manometry with SNS

- 1 study of 8 pts undergoing 24-hr manometry:
  - doubling of anterograde pressure sequence frequency throughout colon
  - ↑ frequency of high amplitude pressure sequences
  - ↑ pressure sequences propagating more than 30 cm along the bowel
  - Sx improvement and ↓laxative use in 6/8
- Newer studies have not shown as great a benefit in constipation as seen in FI

Dinning et al, Colorectal Dis 2007; 9: 123–32
Dinning et al, Br J Surg 2012; 99: 1002–10

Summary

- Sacral Neuromodulation is a safe and effective therapy for treatment of FI when more conservative management fails and patients respond to temporary trials
- More data is needed on patient selection and effectiveness in patients with refractory constipation