# Complete Summary

## GUIDELINE TITLE

Practice parameters for the treatment of fecal incontinence.

## BIBLIOGRAPHIC SOURCE(S)

Tjandra JJ, Dykes SL, Kumar RR, Ellis CN, Gregorcyk SG, Hyman NH, Buie WD, Standards Practice Task Force of The American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of fecal incontinence. Dis Colon Rectum 2007 Oct;50(10):1497-507. [132 references] PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Fecal incontinence (including incontinence of flatus)

### GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

### CLINICAL SPECIALTY

Colon and Rectal Surgery
Family Practice
Gastroenterology
Geriatrics
Internal Medicine

## INTENDED USERS

Health Care Providers
Patients
Physicians

## GUIDELINE OBJECTIVE(S)

To provide practice parameters for the treatment of fecal incontinence

## TARGET POPULATION

Adults with fecal incontinence

## INTERVENTIONS AND PRACTICES CONSIDERED

### Evaluation

Severity (type, frequency, and amount of incontinence) and impact (quality of life) assessments using reliable and validated grading and summary scales

### Diagnosis

1. History and physical examination (including inspection of perianal skin, Valsalva maneuver, digital examination, anoscopy, flexible sigmoidoscopy)
2. Endoanal ultrasound
3. Anorectal physiology studies (anal manometry)

### Treatment

*Nonoperative*

1. Increased fiber intake
2. Antidiarrheal agents (adsorbents, opium derivatives)
3. Enemas, laxatives, and suppositories
4. Biofeedback
5. Anal plug

*Surgical Options*

1. Sphincter repair (overlapping, direct, and repeat)
2. Internal anal sphincter (IAS) repair alone (considered but not generally recommended)
3. Injectable therapy (silicone biomaterial, carbon-coated beads)

4. Sacral nerve stimulation (SNS) (not approved for fecal incontinence by the US Food and Drug Administration [FDA])
5. Post anal repair or total pelvic floor repair
6. Dynamic graciloplasty (not approved by the FDA)
7. Artificial bowel sphincter
8. Delivery of temperature-controlled radiofrequency energy to the anal canal (SECCA procedure)
9. Stoma (colostomy or ileostomy)

### MAJOR OUTCOMES CONSIDERED

- Response rate to treatment
- Duration of response
- Quality of life
- Recurrence rate of symptoms of fecal incontinence following treatment
- Wound healing and complications rates from surgery
- Sensitivity and specificity of diagnostic tools

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A MEDLINE search was performed, from 1966 to February 2006, using the key words "fecal incontinence," "anus," "implants," "bowel sphincter," "graciloplasty," and "artificial sphincter." Selected embedded references also were reviewed. The Cochrane Database of Systematic Reviews was queried.

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

#### Levels of Evidence

I. Meta-analysis of multiple well-designed, controlled studies, randomized trials with low false-positive and low false-negative errors (high power)
II. At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low power)

III. Well-designed, quasi-experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
IV. Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
V. Case reports and clinical examples

Adapted from Cook DJ, Guyatt GH, Laupacis A, Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 1992;102(4 Suppl):305S–11S. Sacker DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 1989;92(2 Suppl):2S–4S.

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

### Grades of Recommendations

A. Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
B. Evidence of Type II, III, or IV and generally consistent findings
C. Evidence of Type II, III, or IV but inconsistent findings
D. Little or no systematic empirical evidence

Adapted from Cook DJ, Guyatt GH, Laupacis A, Sackett DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 1992;102(4 Suppl):305S–11S. Sacker DL. Rules of evidence and clinical recommendations on the use of antithrombotic agents. Chest 1989;92(2 Suppl):2S–4S.

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

# RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

The levels of evidence (**I-V**) and the grades of recommendations (**A-D**) are defined at the end of the "Major Recommendations" field.

**Assessment**

1. Evaluation of fecal incontinence should include consideration of severity and impact. **Level of Evidence: Class II; Grade of Recommendation: B**

   Severity instruments assess type, frequency, and amount of incontinence. Impact questionnaires address quality of life and attempt to evaluate the effect of incontinence on emotional, occupational, physical, and social function. Both should evaluate these relatively subjective factors with reliability and validity.

**Diagnosis**

1. A problem-specific history and physical examination should be performed. **Level of Evidence: Class V; Grade of Recommendation: D.**

   A detailed medical history may help to elicit contributing or exacerbating factors, such as gastrointestinal or neurologic disorders. An obstetric account or history of previous anorectal surgery or perineal trauma can direct/prompt a more focused examination.

   Inspection of the perianal skin may reveal excoriation, surgical scars, or fistulas, and the anus may be noted to gape upon spreading the buttocks. Mucosal or full-thickness prolapse may be elicited with a Valsalva maneuver. Digital examination may provide a rough estimate of resting and squeeze pressures and is helpful to evaluate for a rectal mass or the presence of impacted stool, which would suggest overflow as a possible mechanism for incontinence. Anoscopy and flexible sigmoidoscopy may help to identify hemorrhoids, inflammatory bowel disease, or neoplasms.

2. Endoanal ultrasound is usually the procedure of choice to diagnose sphincter defects in patients with suspected sphincter injury. Anorectal physiology studies may be helpful in guiding management. **Level of Evidence: Class II; Grade of Recommendation: B.**

**Nonoperative Treatment**

1. A trial of increased fiber intake is recommended in milder forms of fecal incontinence to improve symptoms. **Level of Evidence: III; Grade of Recommendation: B.**

   Nonoperative therapy is usually the first maneuver to improve the symptoms of fecal incontinence. Most patients with mild fecal incontinence should usually receive an initial trial of nonoperative management.

   Gradual increase of fiber intake during a period of several days can reduce symptoms, such as abdominal bloating and discomfort that may be associated with increased fiber intake. Fiber supplements in the form of powder, granule,

or pill often facilitate this goal. Dairy products are problematic in patients with lactose intolerance.

2. Antidiarrheal agents, such as adsorbents or opium derivatives, may reduce fecal incontinence symptoms. **Level of Evidence: III; Grade of Recommendation: C.**

   Adsorbents, such as kaopectate (Pharmacia & Upjohn, Peapack, NJ), act by absorbing excess fluid in the stool. Commonly used opium derivatives are loperamide (Imodium, McNeil Consumer Healthcare, Fort Washington, PA), diphenoxylate hydrochloride plus atropine sulphate (Lomotil, Searle, Chicago, IL), codeine, and tincture of opium.

3. Enemas, laxatives, and suppositories may help to promote more complete bowel emptying in appropriate patients and minimize further postdefecation leakage. **Level of Evidence: V; Grade of Recommendation: D.**

   Evaluation and management of abnormal colonic transit also can be helpful.

4. Biofeedback is recommended as an initial treatment for motivated patients with incontinence with some voluntary sphincter contraction. **Level of Evidence: III; Grade of Recommendation: B.**

   Biofeedback may be considered a first-line option for many patients with fecal incontinence who have not responded to simple dietary modification or medication.

   Supportive counseling and practical advice regarding diet and skin care can improve the success of biofeedback. Biofeedback may be considered before attempting sphincter repair or for those who have persistent or recurrent symptoms after sphincter repair. It may have a role in the early postpartum period in females with symptomatic sphincter weakness. Biofeedback and a pelvic floor exercise program can produce improvement that lasts more than two years.

   Biofeedback home training is an alternative to ambulatory training programs, especially in the elderly.

5. An anal plug is effective in controlling fecal incontinence in a small minority of patients who can tolerate its use. **Level of Evidence: V; Grade of Recommendation: D**

**Surgical Options**

1. Sphincter repair is appropriately offered to highly symptomatic patients with a defined defect of the external anal sphincter. **Level of Evidence: II; Grade of Recommendation: A**.
2. Overlapping or direct sphincter repair yield similar results, as long as adequate mobilization of both ends of the sphincters are performed. **Level of Evidence: II; Grade of Recommendation: A.**

3. Repeat anal sphincter repair could be considered in patients who have recurrent symptoms and residual anterior sphincter defect after a previous sphincter repair. **Level of Evidence: III; Grade of Recommendation: B.**
4. Repair of the internal anal sphincter alone has a poor functional outcome and is not generally recommended. **Level of Evidence: III; Grade of Recommendation: B**.
5. When passive fecal incontinence caused by internal sphincter dysfunction is the predominant symptom, injectable therapy seems to be effective and safe, although its long-term efficacy has yet to be defined. **Level of Evidence: II; Grade of Recommendation: B.**
6. Sacral nerve stimulation (SNS) is a promising modality for fecal incontinence. **Level of Evidence: III; Grade of Recommendation: B.**
7. Postanal repair or total pelvic floor repair has a limited role in the treatment of neuropathic fecal incontinence. **Level of Evidence: III; Grade of Recommendation: B.**
8. Dynamic graciloplasty may have a role in the treatment of severe fecal incontinence when there is irreparable sphincter disruption. **Level of Evidence: III; Grade of Recommendation: B.**
9. The artificial bowel sphincter has a role in the treatment of severe fecal incontinence, especially in patients with significant sphincter disruption. **Level of Evidence: III; Grade of Recommendation: B.**
10. The SECCA (safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal) procedure may be useful for selected patients with moderate fecal incontinence. **Level of Evidence: IV; Grade of Recommendation: C.**

    The SECCA procedure consists of the delivery of temperature-controlled radiofrequency energy to the anal sphincters. It is believed that the heat generated causes collagen contraction, healing, and remodeling, leading to shorter and tighter muscle fibers.

11. A stoma (colostomy or ileostomy) is appropriate for patients with limiting fecal incontinence in which available treatments have failed, are inappropriate because of comorbidities, or when preferred by the patient. **Level of Evidence: III; Grade of Recommendation: B.**

**Definitions**:

**Levels of Evidence**

I. Meta-analysis of multiple well-designed, controlled studies, randomized trials with low false-positive and low false-negative errors (high power)
II. At least one well-designed experimental study; randomized trials with high false-positive or high false-negative errors or both (low power)
III. Well-designed, quasi-experimental studies, such as nonrandomized, controlled, single-group, preoperative-postoperative comparison, cohort, time, or matched case-control series
IV. Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies
V. Case reports and clinical examples

**Grades of Recommendations**

A. Evidence of Type I or consistent findings from multiple studies of Type II, III, or IV
B. Evidence of Type II, III, or IV and generally consistent findings
C. Evidence of Type II, III, or IV but inconsistent findings
D. Little or no systematic empirical evidence

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Improvement in symptoms of fecal incontinence
- Improved quality of life

### POTENTIAL HARMS

- Diphenoxylate can produce central nervous system (CNS) side effects and has greater potential for abuse.
- Tincture of opium is less commonly used because of the potential for CNS side effects and addiction.
- Most patients do not tolerate the anal plug because of discomfort.
- Severe denervation and pudendal nerve damage often are found in patients who remain incontinent after a sphincter repair. Dyspareunia might follow sphincteroplasty, although the true incidence has not been well documented.
- In one study, island anoplasty into an area of internal anal sphincter defect was associated with a high incidence of wound breakdown.
- Silicone biomaterial injected into the submucosa is more likely to be associated with infection, erosions of implants, or anal pain caused by the superficial location of the injected material compared to injection into the intersphincteric plane.
- The incidence of complications with sacral nerve stimulation (SNS) ranges from 5 to 26 percent in various studies.
- In one study, the explantation rate for artificial bowel sphincter was 20 to 37 percent. In a multicenter cohort study, a total of 384 device-related or potentially device-related adverse events were reported in 112 enrolled patients. Revisional surgery was required in 46 percent of patients. A lack of sensation for evacuation has been reported.
- Complications of temperature-controlled radiofrequency energy to the anal canal (the SECCA procedure) included mucosal ulcers and delayed bleeding.

- A stoma may be associated with significant psychosocial issues and stoma-related complications.

## CONTRAINDICATIONS

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Absolute contraindications for an artificial bowel sphincter include active perineal sepsis, Crohn's disease, radiation proctitis, severe scarring in the perineum, or anoreceptive intercourse.

## QUALIFYING STATEMENTS

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- These guidelines are inclusive, and not prescriptive. Their purpose is to provide information on which decisions can be made, rather than dictate a specific form of treatment.
- It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better
Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Tjandra JJ, Dykes SL, Kumar RR, Ellis CN, Gregorcyk SG, Hyman NH, Buie WD, Standards Practice Task Force of The American Society of Colon and Rectal

Surgeons. Practice parameters for the treatment of fecal incontinence. Dis Colon Rectum 2007 Oct;50(10):1497-507. [132 references] PubMed

## ADAPTATION

Not applicable: The guideline was not adapted from another source.

## DATE RELEASED

2007 Oct

## GUIDELINE DEVELOPER(S)

American Society of Colon and Rectal Surgeons - Medical Specialty Society

## SOURCE(S) OF FUNDING

American Society of Colon and Rectal Surgeons

## GUIDELINE COMMITTEE

Standards Practice Task Force of The American Society of Colon and Rectal Surgeons

## COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Colon and Rectal Surgeons Web site.

Print copies: Available from the ASCRS, 85 W. Algonquin Road, Suite 550, Arlington H eights, Illinois 60005.

## AVAILABILITY OF COMPANION DOCUMENTS

None available

## PATIENT RESOURCES

None available

## NGC STATUS

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