



The Treatment Plateau: Recognizing When Incontinence Care Has Stalled

Fecal incontinence care rarely follows a straight line. Guidelines can help clinicians sequence evaluation and treatment, but patients bring preferences, mobility limitations, comorbidities, caregiver constraints, and personal definitions of success that do not always fit neatly into an algorithm.

Fecal incontinence affects approximately 8% of community-dwelling adults worldwide, with prevalence increasing among older populations.¹ Despite its frequency and impact, only an estimated 10% to 30% of affected individuals discuss their symptoms with a healthcare professional.²

The challenge is not always identifying a severe disease. Often, it is recognizing when a care plan has helped — but not enough.

In this article, earlier intervention does not mean bypassing assessment or escalating treatment prematurely. It means recognizing persistent symptom and lifestyle burden, reassessing modifiable contributors, and expanding conservative care before withdrawal, skin complications, or care demands deepen.

The following composite cases illustrate what that decision point may look like in practice.

~8% of community-dwelling adults affected¹

Only 10–30% discuss symptoms with a clinician²

Consider Reassessing the Plan When:

- ✓ Symptoms have improved but remain disruptive
- ✓ Containment is working better than the patient's confidence
- ✓ Participation in work, travel, or social activities is declining
- ✓ Skin or hygiene demands are increasing
- ✓ The patient is not ready or appropriate for procedural treatment

Recognizing When Conservative Care Has Plateaued

Early conservative management of fecal incontinence may include dietary modification and fiber supplementation, optimization of stool consistency and bowel habits, medication review, pelvic floor rehabilitation when accessible, and containment products such as pads or briefs.³

The American Society of Colon and Rectal Surgeons recommends dietary and medical management as first-line therapy. Approximately 22% to 54% of patients report symptom improvement after modifying diet, fluid intake, medications, or other daily factors.³

Improvement, however, is not the same as resolution.

A patient may have fewer episodes yet continue planning every outing around bathroom access. Containment may reduce visible leakage without restoring confidence. A scheduled toileting program may work at home but become impractical during travel.

The conversation may circle back to “continue the current plan” or “consider referral,” even when neither fully resolves the patient's ongoing symptoms.

What This Looks Like in Practice

The cases below are composite illustrations based on patterns reported in clinical research and practice. They do not describe specific patients, and the outcomes should not be interpreted as predictions or guarantees.

**Setting:**

- Primary care
- Community-dwelling

History:

- Chronic loose stools following prostate cancer treatment including pelvic radiation
- Well-controlled type 2 diabetes
- Mild-to-moderate FI

Lifestyle:

- Frequent work travel
- Client dinners
- Weekly golf

Primary concern:

- Unpredictable leakage affecting professional and social confidence

Case 1: Robert, 62, Active and Still Working

Background

Robert first noticed occasional leakage during work travel. At first, it happened once or twice a month and seemed manageable with dietary changes and careful planning.

Over time, episodes became less predictable. He stopped accepting overnight assignments, began skipping client dinners, and gradually disappeared from his weekly golf group. He told his wife he was tired, but privately he was worried about having an accident somewhere unfamiliar.

Bowel dysfunction, including diarrhea, urgency, and fecal incontinence, is a recognized potential late effect of pelvic radiotherapy for prostate cancer.⁵

Robert did not initially name the problem during primary care visits. He framed it indirectly: "I just need to know where the bathroom is."

Recent research suggests that men more often normalize symptoms, perceive limited impact, or doubt that a healthcare professional can help. They are also less likely than women to report being told that effective treatments exist.⁴

What Had Been Tried

- Fiber supplementation with partial improvement
- Trigger-food reduction
- Timed toileting, difficult during travel
- Pads, used reluctantly

The Clinical Decision Point

Robert's PCP reassessed his stool consistency, medication list, symptom pattern, and potential red flags. His underlying loose stools still required ongoing management, but first-line strategies had not restored the level of control he needed for daily life.

A specialist referral remained an option. Robert, however, preferred to try another conservative approach before considering a procedure.

The clinician introduced a prescription silicone anal insert, such as StaySure™, as a patient-managed option designed to help prevent accidental bowel leakage. They discussed realistic expectations, fit, tolerability, and how the device could be integrated with his broader bowel management plan.

Teaching Point

Lifestyle changes and indirect language may be the first signs that a patient is experiencing symptoms. Questions about travel, activity avoidance, spare clothing, and bathroom mapping can reveal burdens that a general question about "bowel problems" may miss.

What Changed

Over the following weeks, Robert's daily life began to open back up. His symptoms had not been cured, and procedural referral had not been eliminated; the immediate change was that he had another strategy available while his clinician continued to monitor his bowel pattern.

Robert's Journey

1

Withdrawing from work & golf

2

Conservative option introduced

3

Re-engaging with travel & social life

What Changed for Robert:

- ✓ Resumed selected work and social activities
- ✓ Relied less on avoidance and containment
- ✓ Continued medical management of loose stools
- ✓ Deferred, but did not rule out, procedural evaluation
- ✓ Reported greater confidence and control

**Setting:**

- Assisted living

History:

- Chronic constipation with episodes of overflow leakage
- Osteoarthritis
- Mild cognitive changes

Lifestyle:

- Previously active in music programs
- Group meals
- Family outings

Primary concern:

- Social withdrawal
- Skin irritation
- Growing care demands

Case 2: Dorothy, 78, Care-Supported and Withdrawing

Background

Dorothy had always been socially engaged. She attended music programs, played bingo on Fridays, and went to lunch with her daughter each week.

After hospitalization for a fall, her mobility declined and her medication regimen changed. Her bowel symptoms became more difficult to manage. She started declining activities, attributing it to fatigue.

Staff assumed she was slowing down. Her daughter suspected embarrassment. Nursing staff noticed more frequent clothing changes and early perineal irritation.

Dorothy was not simply tired. She was worried about having an accident in front of people she knew.

What Had Been Tried

- Review and adjustment of the bowel regimen
- Fiber and stool-consistency management
- Scheduled toileting
- Absorbent briefs
- Barrier cream and routine skin checks

Teaching Point

In care-supported older adults, reduced participation may be attributed to aging, fatigue, mood, or cognitive change. Targeted questions about stool consistency, leakage, toileting access, and fear of accidents may reveal a more specific — and potentially manageable — barrier.

The Clinical Decision Point

The care team first addressed the suspected overflow pattern. They reassessed Dorothy's bowel regimen, medication effects, toileting schedule, mobility, and potential fecal impaction. A device was not considered a replacement for treating constipation or resolving active impaction.

Once her bowel routine was more stable, the team discussed whether an additional conservative option could support planned activity periods. Procedural treatment was not aligned with Dorothy's clinical profile or preferences.

After reviewing the Instructions for Use and confirming she could use it safely with caregiver support, Dorothy agreed to trial a prescription anal insert during selected activities.

What Changed

Within a few weeks, Dorothy started returning to the parts of daily life she had stepped away from. Staff continued monitoring stool patterns, fit, tolerance, skin integrity, and caregiver workload, and the insert remained one component of an individualized plan.

What Changed for Dorothy:

- ✓ Resumed selected social activities
- ✓ Experienced fewer unscheduled care interruptions on some activity days
- ✓ Continued constipation management and skin protection
- ✓ Gave family and staff a concrete option to evaluate
- ✓ Maintained ongoing clinical monitoring and shared decision-making

Dorothy's Journey

1

Withdrawing from activities

2

Bowel routine stabilized, option added

3

Back to music program & outings

What These Cases Have in Common

Robert and Dorothy appear very different on paper. One is a working adult managing travel and professional expectations. The other is an older adult receiving daily support.

Yet they reached a similar clinical crossroads:

- Initial conservative measures helped but did not adequately address daily burden
- Symptoms were affecting participation before either case appeared “catastrophic”
- Procedural care was not the preferred or appropriate immediate next step
- Success was defined by function and participation, not cure alone

“Improvement is not the same as resolution.”

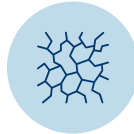
Why Timing Matters

Clinical literature supports the broader pattern reflected in these cases.



Quality of Life

FI is associated with embarrassment, anxiety, social isolation, and limitations in work and daily activities. Patients often prioritize a return to normal activities over complete symptom elimination.⁶



Skin Integrity

Repeated exposure to liquid stool and moisture can contribute to incontinence-associated dermatitis, including erythema, erosion, and secondary complications.⁷



Caregiver Burden

In a 2024 survey of family caregivers assisting older adults with toileting, **88% reported at least one form of burden.**

Contributing factors included odor, leakage from products, nighttime assistance, and disposal costs.⁸

Healthcare Utilization

In one primary care cohort, severe FI was associated with:

55%

higher total
healthcare costs

77%

higher
GI-related costs

Only 2.7% of patients reporting FI symptoms had a corresponding diagnosis documented.⁹ Downstream costs may also include skin-related care, increased caregiver support, and, in some cases, escalation to procedural intervention — though these vary by patient and setting.

These findings establish the burden associated with FI. They do not prove that earlier use of any one therapy will prevent future procedures, institutional care, or healthcare costs.

Earlier recognition does, however, give clinicians an opportunity to address modifiable causes, protect skin, support caregivers, and preserve function before reactive care is the only option left.

What the Evidence Says About Silicone Anal Inserts

The composite cases above illustrate clinical decision-making; they are not evidence of product efficacy. The evidence base for StaySure™ and related liquid-filled silicone anal inserts includes U.S. clinical data submitted for FDA 510(k) clearance and a European randomized trial of the Navina anal insert, the European-market brand identified in the trial registration.

Taken together, the evidence supports a selective, trial-based approach rather than a one-size-fits-all promise. Some patients may experience meaningful episode reduction, but fit, retention, tolerability, functional goals, and expectations should all be reassessed.

Evidence in Context

- StaySure™ is FDA-cleared for management of accidental bowel leakage due to bowel incontinence
- The device is designed for self-insertion to seal and help prevent involuntary stool leakage
- U.S. clinical evidence submitted for FDA clearance showed meaningful episode reduction in a single-arm study
- A 2026 European randomized trial of the Navina anal insert adds randomized evidence for liquid-filled silicone anal inserts, with fewer weekly episodes and improved quality-of-life subdomains, though it did not meet its primary severity endpoint
- Not every patient responds to or tolerates an insert in the same way
- Use should follow the current Instructions for Use and an individualized care plan

Recognizing the Moment

The appropriate time to broaden conservative management may be more subtle than clinicians expect.

It May Look Like:

- A patient declining invitations they previously accepted
- A traveler planning life around restroom access
- A caregiver saying, “This is becoming harder to manage”
- Recurrent skin irritation or frequent clothing changes
- A follow-up visit where symptoms are stable, but function is shrinking
- A patient asking, “Isn’t there something else we can try?”

These signals should prompt reassessment — not automatic progression to a device or procedure, but a closer look at whether the current plan still meets the patient’s needs.

Practical Takeaways for Clinicians

1. Ask Directly and Use Clear Language

Most patients will not volunteer FI symptoms. Consider:

- “Have you had any accidental bowel leakage, even small amounts?”
- “Do bowel symptoms ever keep you from traveling, working, or attending activities?”
- “Do you carry spare clothing or plan outings around bathroom access?”

In one survey, only 35% of primary care clinicians reported screening for FI, despite recognizing its importance.¹²

U.S. Study Supporting StaySure™ FDA Clearance¹⁰

- ✓ Prospective, open-label, single-arm
- ✓ Enrolled adults inadequately helped by conservative therapy and biofeedback
- ✓ 44 of 58 evaluable participants (**75.9%**) achieved **≥50%** reduction in ABL episodes vs. baseline
- ✓ No device-related serious adverse events

European Randomized Trial — Navina Anal Insert¹¹

- ✓ First RCT of a liquid-filled silicone anal insert
- ✓ Significantly fewer weekly FI episodes than usual care; more achieved **≥50%** episode reduction
- ✓ Coping and depression QoL subdomains improved
- ✓ Did not meet primary endpoint (≥3-point reduction in St. Mark’s score), though episode-level and quality-of-life benefits were observed
- ✓ Device-related adverse events generally mild

2. Reassess Before Adding Another Intervention

Review:

- Stool consistency and bowel frequency
- Constipation, overflow, diarrhea, and urgency
- Medications and supplements
- Mobility, cognition, and toileting access
- New bleeding, pain, weight loss, or other red flags
- The need for specialist evaluation or diagnostic testing

3. Define Success With the Patient

A clinically meaningful goal may be completing a work trip, returning to church or a community program, reducing unscheduled clothing changes, sitting through a meal without anxiety, or lessening the planning required to leave home.

Episode counts matter, but so does whether the patient can resume daily life.

4. Consider Device-Based Conservative Care Selectively

A prescription anal insert may be worth discussing when:

- First-line measures have produced only partial control
- The patient remains dissatisfied with containment alone
- A non-surgical, patient-managed approach is preferred
- The patient can insert and remove the device safely or has appropriate caregiver support
- The current Instructions for Use do not identify a contraindication or precaution that precludes use

5. Reassess After the Trial

Monitor:

- Leakage frequency
- Fit and retention
- Comfort and adverse effects
- Skin condition
- Activity participation
- Caregiver workload
- Whether the device remains aligned with the patient's goals

A trial should generate information about whether the approach fits, not signal that the care plan is finished.

The Next Step Begins With Three Questions:

1. What remains uncontrolled?
2. What is the patient no longer doing?
3. Is there another appropriate option we have not yet discussed?

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Earlier Options Can Keep the Conversation Moving

Fecal incontinence care is not always about choosing between maintaining the current plan and escalating to a procedure.

Sometimes, the most important step is recognizing when a patient's world has begun to narrow despite partial symptom improvement.

For patients like Robert and Dorothy, the turning point was not a cure or a dramatic intervention. It was a clinician recognizing persistent burden, reassessing the cause, and offering an additional option within conservative care.

Earlier intervention cannot guarantee that a patient will avoid future procedures or higher care needs. It can ensure that quality of life, function, and patient preference are addressed before the condition narrows the patient's daily life further.

Important Safety Information

StaySure™ is a prescription-only medical device indicated for the management of accidental bowel leakage due to bowel incontinence. It is designed to help prevent involuntary leakage and is not a cure for underlying conditions. Individual results may vary.

The composite cases in this article are illustrative and do not represent specific individuals or guarantee outcomes. Please review the current Instructions for Use for complete indications, contraindications, warnings, precautions, and directions.

References

1. Mack, I., Hahn, H., Gödel, C., Enck, P., & Bharucha, A. E. (2023). Global Prevalence of Fecal Incontinence in Community-Dwelling Adults: A Systematic Review and Meta-analysis. *Clinical Gastroenterology and Hepatology: The Official Clinical Practice Journal of the American Gastroenterological Association*, 22(4): 712-731.e8. <https://doi.org/10.1016/j.cgh.2023.09.004>
2. Kunduru, L., Kim, S. M., Heymen, S., & Whitehead, W. E. (2015). Factors That Affect Consultation and Screening for Fecal Incontinence. *Clinical Gastroenterology and Hepatology*, 13(4), 709–716. <https://doi.org/10.1016/j.cgh.2014.08.015>
3. Bordeianou, L. G., Thorsen, A. J., Keller, D. S., Hawkins, A. T., Messick, C., Oliveira, L., Feingold, D. L., Lightner, A. L., & Paquette, I. M. (2023). The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Fecal Incontinence. *Diseases of the Colon & Rectum*, 66(5), 647–661. <https://doi.org/10.1097/dcr.0000000000002776>
4. Moureau, M. K., Jones, L. M., Schmuhl, N. B., & Brown, H. W. (2023). Men and women experience different barriers to care seeking for fecal incontinence. *Neurourology and Urodynamics*, 42(8), 1769–1776. <https://doi.org/10.1002/nau.25266>
5. Sargos, P., Faye, M. A., Bacci, M., Supiot, S., Latorzeff, I., Azria, D., Niazi, T., Vuong, T., Vendrely, V., & de Crevoisier, R. (2021). Late Gastrointestinal Tolerance After Prostate Radiotherapy: Is the Anal Canal the Culprit? A Narrative Critical Review. *Frontiers in Oncology*, 11, 145–153. <https://doi.org/10.3389/fonc.2021.666962>
6. Assmann, S. L., D Keszthelyi, Breukink, S. O., & Kimman, M. L. (2024). Living with faecal incontinence: a qualitative investigation of patient experiences and preferred outcomes through semi-structured interviews. *Quality of Life Research*, 33(11), 3121-3129. <https://doi.org/10.1007/s11136-024-03756-3>
7. Gray, M., Beeckman, D., Bliss, D. Z., Fader, M., Logan, S., Junkin, J., Selekof, J., Doughty, D., & Kurz, P. (2012). Incontinence-Associated Dermatitis. *Journal of Wound, Ostomy and Continence Nursing*, 39(1), 61–74. <https://doi.org/10.1097/won.0b013e31823fe246>
8. Shogenji, M., Yoshida, M., Kakuchi, T., & Hirako, K. (2024). Physical, emotional, and financial burdens of toileting assistance for family caregivers in home care settings and factors associated with each burden: A cross-sectional study. *Japan Journal of Nursing Science*, 21(4). <https://doi.org/10.1111/jjns.12615>
9. Dunivan, G. C., Heymen, S., Palsson, O. S., von Korff, M., Turner, M. J., Melville, J. L., & Whitehead, W. E. (2010). Fecal incontinence in primary care: prevalence, diagnosis, and health care utilization. *American Journal of Obstetrics and Gynecology*, 202(5), 493.e1–493.e6. <https://doi.org/10.1016/j.ajog.2010.01.018>
10. U.S. Food and Drug Administration. (2025, July 22). K243367: Minnesota Medical Technologies Fecal Incontinence Insert. https://www.accessdata.fda.gov/cdrh_docs/pdf24/K243367.pdf
11. Assmann, S. L., Winkens, B., Bours, A., Essers, B., Lam, T., Mujagić, Z., Breukink, S. O., & Keszthelyi, D. (2026). Controlling Fecal Incontinence With a Novel Anal Device. *JAMA Network Open*, 9(4), e269208. <https://doi.org/10.1001/jamanetworkopen.2026.9208>
12. Brown, H. W., Guan, W., Schmuhl, N. B., Smith, P. D., Whitehead, W. E., & Rogers, R. G. (2018). If We Don't Ask, They Won't Tell: Screening for Urinary and Fecal Incontinence by Primary Care Providers. *The Journal of the American Board of Family Medicine*, 31(5), 774–782. <https://doi.org/10.3122/jabfm.2018.05.180045>