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# ADDRESSING THE CHALLENGES IN CHRONIC CONSTIPATION

Providing Optimal Care for Patients

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## ACTIVITY OVERVIEW

Chronic Idiopathic Constipation (CIC), which is also sometimes termed functional constipation, is a relatively common gastrointestinal disorder, with an estimated pooled prevalence of approximately 14% based on multiple studies throughout the world. Although CIC can affect all individuals, studies indicate that it disproportionately affects women, the elderly and those of lower socioeconomic status. Patients with CIC are also at higher risk of developing comorbidities. A meta-analysis of 35 different studies found an increased incidence of depression, diabetes, functional dyspepsia, and obesity associated with CIC. It is critical that PAs, who are often the initial point of contact for patients seeking care for their CIC symptoms, can effectively diagnose and manage patients with suspected CIC. To address these issues, a clinically focused monograph activity will be employed to generate an increase in knowledge and practice behavior change.

**AAPA TAKES RESPONSIBILITY FOR THE CONTENT, QUALITY, AND SCIENTIFIC INTEGRITY OF THIS CME ACTIVITY.**

## EDUCATIONAL OBJECTIVES

- Assess patients presenting with signs and symptoms of CIC including red flags to identify during a patient workup.
- Identify patient scenarios when referral to a specialist may be appropriate.
- Create integrated patient care plans to optimize patient outcomes in CIC.
- Implement and monitor disease specific pharmacologic therapy for patients with CIC based on individual patient characteristics.

## ACCREDITATION STATEMENT



This activity has been reviewed by the AAPA Review Panel and is compliant with AAPA CME Criteria. The activity is designated for .75 AAPA Category 1 CME credits. PAs should only claim credit commensurate with the extent of their participation. Approval is valid through January 31, 2024.

Estimated time to complete this activity: 45 minutes.

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## CASE CHALLENGE

**Rick Davis, PA-C:** Hello, and welcome to this program titled, "Addressing the Challenges in Chronic Constipation: Providing Optimal Care for Patients." I'm Rick Davis, a PA in gastroenterology in Gainesville, Florida. And joining me today is Gerald Simons, a PA with a special interest in the gut microbiome from Stony Brook School of Health in Southampton, New York.


My thanks to you for your involvement in this important continuing medical education activity, which consists of one video *eCase Challenge*. So, let's get started.

Our *eCase Challenge* is a patient we will call Vanessa. She's a 35-year-old IT professional and mother who presents to her primary care PA because of ongoing GI issues, particularly constipation.

She says that she was in her usual state of health until about a year ago, when she began to have a different bowel movement pattern. She previously reported having a bowel movement daily, and now reports typically having one bowel movement every 3 to 4 days or one to two times a week. She also relates no history of constipation after her two vaginal deliveries, both without complication, that occurred 3 and 5 years ago.

Currently, Vanessa describes having a feeling of incomplete evacuation associated with these bowel movements. Her stools are hard and pebble-like, a Bristol Stool Form Scale 1, and require excessive straining to pass. She hasn't noted any blood in her stool, nausea or vomiting, and she denies any abdominal pain or flank pain. She also denies weight loss and reports no fevers.

### Patient Case – Vanessa



- 35-year-old IT professional and mother
- Presents with ongoing constipation
  - Approximately one year in duration
- Reports having one bowel movement every 3-4 days
  - Previously experienced bowel movement daily
  - Feeling of incomplete evacuation, excessive straining
- Stool – describes as hard and pebble-like<sup>1</sup>
  - Bristol Stool Form Scale 1
- Denies hematochezia, N/V, abdominal or flank pain, weight loss

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<sup>1</sup> Lewis S, et al. *Scand J Gastroenterol*. 1997;32(9):920-924.

She says she eats a generally healthy diet with limited alcohol and tries to exercise two to three times per week, although this is tough with her busy schedule and family life, which leaves her tired at the end of the day.


Of note, her symptoms began about 6 months after a stressful life change, when her father passed away. She doesn't recall trying any new foods or medications around the time her symptoms started, and they have remained about the same since onset.

Her past medical history is pertinent for seasonal allergies, for which she takes cetirizine PRN, but other than that, she doesn't take any other medications except for an occasional multivitamin.

She denies any previous history of surgeries.

Regarding her family history, she has no family history of GI disorders or malignancies. Vanessa lives in her home with her husband and two children, and her vaccinations are up to date.

### Patient Case – Vanessa



- Social history
  - Generally healthy diet, exercises 2-3 times/week
  - Symptoms began 6 months after stressful life event
  - No new foods or medications around symptom onset
- Past medical history
  - Seasonal allergies
  - Takes cetirizine PRN and multivitamin
- Family history
  - No history of GI disorders or malignancies

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Now, let's pose our first clinical question.

**Which of the following components of Vanessa's presentation is more strongly associated with chronic idiopathic constipation, CIC, than irritable bowel syndrome with constipation, IBS-C?**


- A. Duration of symptoms
- B. Frequency of bowel movements
- C. Lack of abdominal or flank pain
- D. A feeling of incomplete evacuation

So, chronic idiopathic constipation and constipation-predominant IBS can have overlapping symptoms, but it's really important to differentiate the two. They can coexist in the same patient at times.

CIC is a functional bowel disorder characterized by patient-reported difficult, infrequent and/or incomplete defecation. CIC, also referred to as functional constipation, can be diagnosed using the Rome IV criteria.

This classifies patients with chronic constipation as having functional constipation, constipation-predominant irritable bowel syndrome, opioid-induced constipation, or functional defecation disorders.

### CIC and IBS-C




- Both can have overlapping symptoms<sup>1</sup>
  - Can co-exist in the same patient
- CIC – characterized by difficult, infrequent and/or incomplete defecation<sup>1</sup>
  - Also referred to as functional constipation
- Diagnosis can be made using Rome IV Criteria<sup>2</sup>
  - Classifies patients with chronic constipation as having
    - Functional constipation
    - IBS-C
    - Opioid-induced constipation
    - Functional defecation disorder

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<sup>1</sup> Lacy BE. *Am J Manag Care*. 2019;25:S55-S62.  
<sup>2</sup> Lacy BE, et al. *Gastroenterology*. 2016;150(6):1393-1407.

There are several criteria for functional constipation from the Rome criteria, and two or more must be present, including straining with over 25% of defecations, lumpy or hard stools with over 25%, a sensation of incomplete evacuation, or anorectal obstruction or blockage with over 25%, use of manual maneuvers with defecation, like digital evacuation or pelvic floor support, such as splinting, and fewer than three spontaneous defecations per week. You must have rare loose stools without laxative administration, and not have sufficient criteria for irritable bowel syndrome.

## Rome IV Criteria – Functional Constipation<sup>1</sup>




Onset of constipation symptoms must be at least 6 months before presentation. Criteria listed below must be present for the past 3 months.

- Two or more criteria must be present:
  - Straining with >25% of defecations
  - Lumpy or hard stools with >25% of defecations (Bristol stool form types 1 and 2)
  - Sensation of incomplete evacuation with >25% of defecations
  - Sensation or anorectal obstruction/blockage with >25% of defecations
  - Manual maneuvers required with >25% of defecations (e.g., digital evacuation, pelvic floor support)
  - Fewer than 3 spontaneous defecations per week
- Rare loose stools without laxative administration
- Insufficient criteria for irritable bowel syndrome

1. Lacy BE, et al. *Gastroenterology*. 2016;150(6):1393-1407. © American Academy of PAs and Medical Logix, LLC. All rights reserved.

Now, the AGA, the American Gastroenterological Association, criteria classifies patients with constipation into one of three groups, either normal-transit constipation, slow-transit constipation, or pelvic floor dysfunction or defecatory disorders.

## American Gastroenterological Association Classification<sup>1</sup>




- American Gastroenterological Association (AGA) criteria classifies patients with constipation into 1 of 3 groups
  - Normal-transit constipation (NTC)
  - Slow-transit constipation (STC)
  - Pelvic floor dysfunction or defecatory disorders (DD)

1. Bharucha AE, et al. *Gastroenterology*. 2013;144(1):218-238. © American Academy of PAs and Medical Logix, LLC. All rights reserved.

Now, it's important to establish a differential diagnosis when you're seeing your patient with complaints of constipation. Could this actually be IBS-C? Could it be medication-induced? Could there be a mechanical obstruction? Metabolic disorders? Eating disorders? Dietary changes? Immobility? Or possibly even paraneoplastic syndromes?

## Differential Diagnosis<sup>1</sup>




- CIC differential diagnosis
  - IBS-C
  - Medication-induced constipation
  - Mechanical obstruction
  - Metabolic disorders
  - Eating disorders
  - Dietary changes
  - Immobility
  - Paraneoplastic syndromes

1. Lacy BE. *Am J Manag Care*. 2019;25:S55-S62. © American Academy of PAs and Medical Logix, LLC. All rights reserved.

And then there are red-flag symptoms to consider, as well, which would require more urgent and further evaluation, such as colonoscopy. So, any patient with sudden weight loss, rectal bleeding, anemia or nocturnal symptoms should undergo further evaluation.

## Red Flag Symptoms<sup>1</sup>



- Consider referral for further evaluation/colonoscopy if any of the following symptoms are present
  - Sudden weight loss
  - Rectal bleeding
  - Anemia
  - Nocturnal symptoms

1. Lacy BE. *Am J Manag Care*. 2019;25:S55-S62. © American Academy of PAs and Medical Logix, LLC. All rights reserved.

However, generally we can begin with a comprehensive review of the patient's history, such as their surgical history, dietary history, medical, psychological, and then a thorough physical exam. And this includes a digital rectal exam, which may identify pelvic floor dyssynergia or an occult malignancy.


We should also evaluate for secondary causes of chronic constipation and potential red flags, assess the stool frequency, a colonic transit and anorectal function.

The Bristol Stool Form Scale can be used as a surrogate for colonic transit, such as hard, lumpy stools, the stool has been in the colon for a longer period of time; looser, watery stools, usually not so much.

And there are also labs to consider, too, if necessary, but looking at inflammatory markers, like a CRP, a CBC, a complete metabolic profile and thyroid functions. And Gerry, I wanted to ask you, too, on your practice, I believe you also will use an IgA?

**Gerald Simons, PA-C:** Correct. So I'm a big fan of immunoglobulin A for really looking at that gut mucosal health, looking at the health of the gut microbiome. Many people here are saying, "IgA? That's for celiac." We can actually order a freestanding immunoglobulin A level kind of as an initial assessment for gut microbiome health, the quality of that mucosal lining. And I learned this as a surgical PA, where this was used with surgical nutrition assessment to help us figure out how much glutamine patients should be getting, which directly enhances the level of IgA in the system. So, for me, I'm a big fan of IgA and C-reactive protein early on in these patients.

## Making the Diagnosis of CIC<sup>1</sup>



- Comprehensive patient history
  - Surgical, dietary, medical, psychological
- Thorough physical examination
  - Including digital rectal exam
- Assess stool frequency, colonic transit, anorectal function
  - Bristol stool form scale
- Labs to consider – CRP, CBC, LFT, CMP, TFT, IgA
- Evaluate for secondary causes of chronic constipation, potential red flags

1. Lacy BE. *Am J Manag Care*. 2019;25:S55-S62. © American Academy of PAs and Medical Logix, LLC. All rights reserved.

**Rick Davis:** Okay, interesting. Thank you.

**Gerald Simons:** Great. Rick, thanks for that great introduction, and I think a lot of people listening to this case are finding it very familiar, something that we all see every day.

So, let's think about the question that was just posed, which asked, which of the following elements of our patient Vanessa's history is

more strongly associated with CIC than IBS-C? Now, the correct answer is (C) Lack of abdominal pain, lack of flank pain. So it's an important question to ask, if patients are having abdominal pain with their constipation.

So, when we are reviewing Vanessa's history, that'll help us figure out which elements are consistent with CIC and/or IBS-C. So, we think about the duration of her symptoms, the frequency of her bowel movements, as well as her feeling of incomplete evacuation.

Now, all of these could fit with either disease, but her reporting a lack of abdominal pain, a lack of flank pain is more consistent with CIC, as the presence of constipation and pain is more consistent with IBS-C.

The remainder of her medical, family and social history did not really help differentiate between CIC and IBS-C. Although, take note, if a family history of colon cancer was present, that would indicate a need for a more aggressive workup.

Now, in today's case, Vanessa's case, based on her detailed history, her physical exam, including that digital rectal exam and a negative evaluation for secondary causes and those red flags Rick mentioned a few minutes ago, a diagnosis of CIC was made.

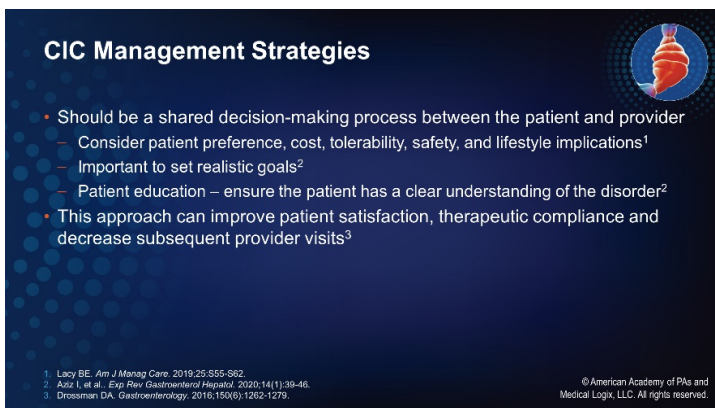
Now, before we give you more of Vanessa's case, we have another question for you.

**Given Vanessa's history, which of the following may be an appropriate initial step to address her constipation?**

- A. Initiation of linaclotide therapy
- B. Increasing dietary fiber intake
- C. Initiating a stimulant laxative
- D. Initiation of plenicantide therapy

So, when we think of this question, naturally, everyone has their own protocol, but you really want to think of a management strategy that is going to work for the patient. So, this is really shared decision-making. You have to look at patient preferences. What are their dietary preferences? What about cost? Not everybody can get food that's all organic and super-healthy. What is a patient willing to tolerate? Safety and what fits in with their lifestyle.

Our patient, Vanessa, was pretty busy with work and family life, still recovering from the death of her father.



**CIC Management Strategies**

- Should be a shared decision-making process between the patient and provider
  - Consider patient preference, cost, tolerability, safety, and lifestyle implications<sup>1</sup>
  - Important to set realistic goals<sup>2</sup>
  - Patient education – ensure the patient has a clear understanding of the disorder<sup>2</sup>
- This approach can improve patient satisfaction, therapeutic compliance and decrease subsequent provider visits<sup>3</sup>

1. Lacy BE. *Am J Manag Care*. 2019;25:S55-S62.  
2. Aziz I, et al. *Exp Rev Gastroenterol Hepatol*. 2020;14(1):39-46.  
3. Schuster BG, et al. *Can Fam Physician*. 2015;61(2):152-156.  
4. Lacy BE, et al. *Gastroenterology*. 2016;150(3):1393-1407.

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So, the second part is making sure that we have some realistic goals and that the patient really understands what the disorder is. And really, when you see this patient on your next shift, you really want to think that this concept of shared decision-making, what works for your patient, and setting realistic goals, is going to not only make your patient more satisfied, but hopefully improve the

therapeutic compliance, helping them to feel better so they don't have as many office visits, less visits later on.

So that initial treatment begins with patient education. Almost all of our EMRs have a patient ed form on constipation. And of course, a medication review and lifestyle modifications.

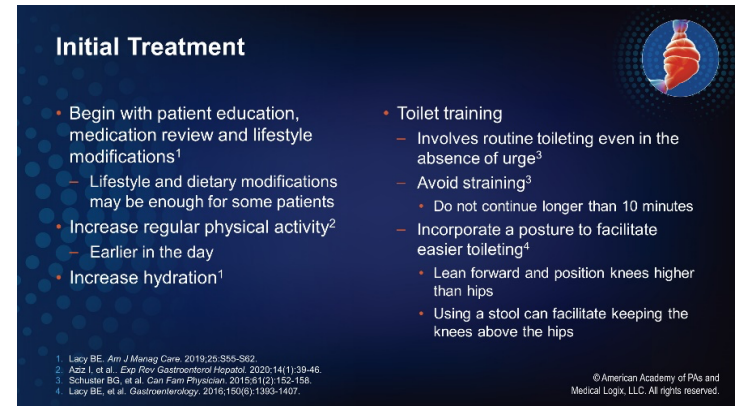
Now, for many patients, just lifestyle and dietary modification may provide sufficient relief in some patients. Increasing physical activity daily, and especially earlier in the day. There was a great research article back in 2020 showing early exercise seems to help with bowel mobility basically than later in the day.

Of course, everybody tells patients to drink more water. But in these patients, you really want to emphasize making sure they drink more water, maybe even writing them a prescription to drink more water.

Toilet training. It's strange. This is an adult woman, but we'd still talk a little bit about toilet training, trying to create a bathroom or toilet routine where they have a standard routine, morning or evening, even without having an urge. Very important to have these patients understand they should not strain.

There's a famous 10-minute rule, where I tell patients, "If you're on the toilet more than 10 minutes and nothing's happening, probably nothing is going to happen, and you're just straining all of those muscles." Relaxation techniques are also important during this time.

And we know more about the function of those pelvic floor muscles and the importance of good posture during these toileting sessions, having patients lean forward with the feet supported on short stool so that the knees are higher than the hips. If you look at pictures of cavemen or cavewomen when they were having a bowel movement, that's kind of that classic squatting position that we were kind of designed for.



**Initial Treatment**

- Begin with patient education, medication review and lifestyle modifications<sup>1</sup>
  - Lifestyle and dietary modifications may be enough for some patients
- Increase regular physical activity<sup>2</sup>
  - Earlier in the day
- Increase hydration<sup>1</sup>
- Toilet training
  - Involves routine toileting even in the absence of urge<sup>3</sup>
  - Avoid straining<sup>3</sup>
    - Do not continue longer than 10 minutes
  - Incorporate a posture to facilitate easier toileting<sup>4</sup>
    - Lean forward and position knees higher than hips
    - Using a stool can facilitate keeping the knees above the hips

1. Lacy BE. *Am J Manag Care*. 2019;25:S55-S62.  
2. Aziz I, et al. *Exp Rev Gastroenterol Hepatol*. 2020;14(1):39-46.  
3. Schuster BG, et al. *Can Fam Physician*. 2015;61(2):152-156.  
4. Lacy BE, et al. *Gastroenterology*. 2016;150(3):1393-1407.

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Encourage patients to eat more fiber-rich and bulk foods that directly address constipation. Prunes and bran, figs, flaxseed. And Rick, don't forget that kiwi is actually a really good food for constipation.

And of course, increasing the amount of dietary fiber. Hopefully you all remember that we have a fiber crisis in America. Most Americans do not get nearly the amount of fiber that they should. And if you're not encouraging fiber and hydration early on, any of the additional therapies probably aren't going to work that well. So, if you're taking notes, write down, "More fiber is key."

**Rick Davis:** When you're talking to your patients about adding more fiber, do you distinguish between insoluble and soluble fiber, or just try to get that number up in total?

**Gerald Simons:** I just try to get the number up. You know, my idea of whatever works for the patient, if they'll eat more foods with high fiber, maybe they'll add on a favorite fiber powder, maybe

even a fiber capsule. So, I've found that if I'm too specific, soluble, insoluble, label reading, how to cook your food, it goes way over their heads. But they can remember the message of, "You need more fiber."

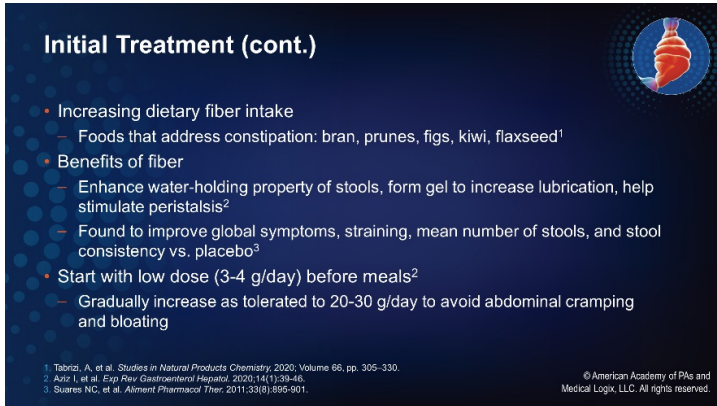
**Rick Davis:** Okay.

**Gerald Simons:** Right. Now, we all remember that fiber enhances that water-holding property of the stool. It kind of helps to form that gel to increase stool lubrication, serves as a stool bulking agent, helps to stimulate peristalsis. So, fiber's doing all of these great things.

Now, we do know that, to Rick's question, that the benefit appears to be exclusive to soluble fiber, like psyllium, and not so much insoluble fiber, such as bran. But if I can get a patient to increase the amount of bran and maybe have less meat, that's going to enhance that soluble fiber effect.

Now, even though everybody's getting excited about fiber, it's important to not push it too hard early on, typically starting with 3 or 4 g/day, and increasing it to two or three times a day before a meal. And our goal is to get to 20 to 30 g/day.

If you move too fast, patients are not going to be happy. They're going to have gas and bloating, GI discomfort. So start with 3 or 4 g/day and work your way into it.



**Initial Treatment (cont.)**

- Increasing dietary fiber intake
  - Foods that address constipation: bran, prunes, figs, kiwi, flaxseed<sup>1</sup>
- Benefits of fiber
  - Enhance water-holding property of stools, form gel to increase lubrication, help stimulate peristalsis<sup>2</sup>
  - Found to improve global symptoms, straining, mean number of stools, and stool consistency vs. placebo<sup>3</sup>
- Start with low dose (3-4 g/day) before meals<sup>2</sup>
  - Gradually increase as tolerated to 20-30 g/day to avoid abdominal cramping and bloating

1. Tabrizi, A. et al. *Studies in Natural Products Chemistry*, 2020; Volume 66, pp. 305-330.  
2. Aziz, I. et al. *Exp Rev Gastroenterol Hepatol*, 2020; 14(1):33-46.  
3. Scafero NC, et al. *Aliment Pharmacol Ther*, 2011;23(8):895-901.

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And psyllium does not necessarily have to be that gradually increased, but the overall idea is, get fiber going, start low and work your way up.

A couple of good reviews have shown that soluble fiber did improve global symptoms, did reduce straining, did increase the mean number of stools per week and helped with even stool consistency. So, again, if you're writing things down, remember, just start with fiber.

**Rick Davis:** Good points, Gerry. So, let's review that last question, which asked, "Given Vanessa's history, which of the following may be an appropriate initial step to address her constipation?"

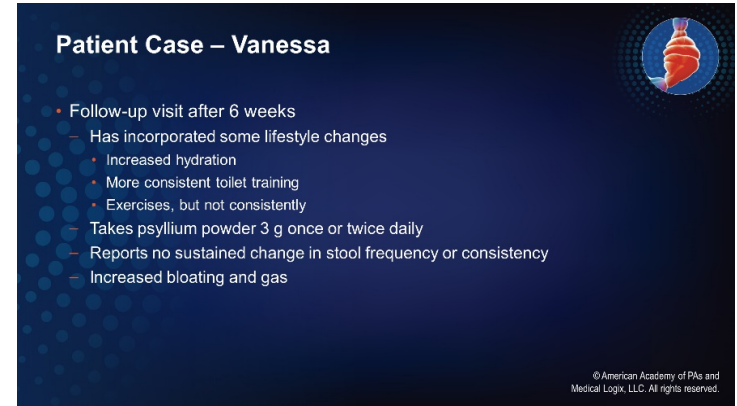
The correct answer is (B) Increasing dietary fiber intake, which is one of the initial lifestyle modifications in patients with CIC that Gerry just discussed.

In addition, Vanessa is counseled regarding other lifestyle modifications, including the importance of more regular exercise, hydration, and the toilet training that you just discussed. During her visit, she is receptive to the lifestyle counseling and increasing dietary fiber and to initiating psyllium, a soluble fiber, but starting at a lower dose and increasing gradually.

Now, for the next steps in our case.

At Vanessa's follow-up visit 6 weeks later, she states that she has incorporated some of the lifestyle changes. She is focused on increasing her hydration and more consistent toilet training. She admits that she has still not been able to exercise regularly, but is taking psyllium powder 3 g once or twice a day.

She reports no sustained change in the frequency or consistency of her stool, but does report having increased bloating and gas, which is why she did not continue to increase the psyllium dose.



**Patient Case – Vanessa**

- Follow-up visit after 6 weeks
  - Has incorporated some lifestyle changes
    - Increased hydration
    - More consistent toilet training
    - Exercises, but not consistently
  - Takes psyllium powder 3 g once or twice daily
  - Reports no sustained change in stool frequency or consistency
  - Increased bloating and gas

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This brings us to our next clinical question.

**Given Vanessa's lack of response to initial lifestyle modifications, what would be the most appropriate next step?**

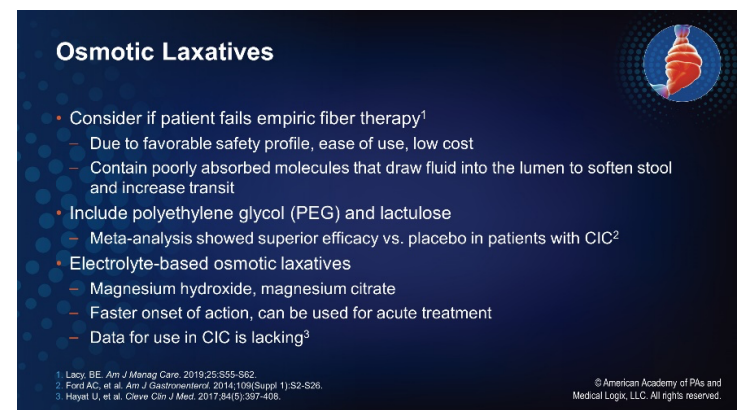
- A. Adding an osmotic laxative
- B. Increasing psyllium intake
- C. Initiation of linaclotide therapy
- D. Initiation of prucalopride therapy

So, if a patient fails or does not receive sufficient benefit from empiric fiber therapy, osmotic laxatives are typically the next agent of choice. They have a favorable safety profile, ease of use and low cost.

Osmotic laxatives contain poorly absorbed molecules and remain in the intestinal lumen, where they draw fluid into the lumen to soften stool and increase intestinal transit. PEG, or polyethylene glycol, and lactulose are both effective osmotic laxatives.

In a meta-analysis of randomized controlled trials, the efficacy of osmotic laxatives were actually found to be superior than placebo for the treatment of chronic idiopathic constipation.

Electrolyte-based osmotic laxatives include magnesium-based products, such as magnesium hydroxide or magnesium citrate. These have a faster onset of action and can be used for acute treatment, although data for specific use in CIC is lacking.



**Osmotic Laxatives**

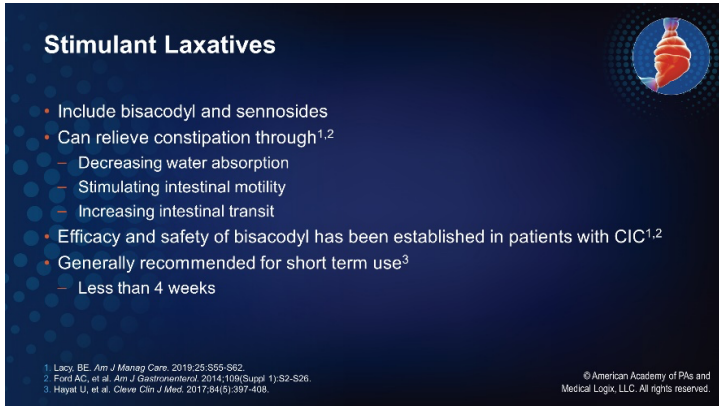
- Consider if patient fails empiric fiber therapy<sup>1</sup>
  - Due to favorable safety profile, ease of use, low cost
  - Contain poorly absorbed molecules that draw fluid into the lumen to soften stool and increase transit
- Include polyethylene glycol (PEG) and lactulose
  - Meta-analysis showed superior efficacy vs. placebo in patients with CIC<sup>2</sup>
- Electrolyte-based osmotic laxatives
  - Magnesium hydroxide, magnesium citrate
  - Faster onset of action, can be used for acute treatment
  - Data for use in CIC is lacking<sup>3</sup>

1. Lacy, BE. *Am J Manag Care*, 2019;25:555-562.  
2. Ford AC, et al. *Am J Gastroenterol*, 2014;109(Suppl 1):S2-S26.  
3. Heyet U, et al. *Croatica Med*, 2017;24(5):387-466.

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Stimulant laxatives, including bisacodyl and sennosides help relieve constipation by decreasing water absorption, directly stimulating intestinal motility and releasing prostaglandins that may increase intestinal transit.

Efficacy and safety of bisacodyl has been established in randomized controlled trials in patients with CIC. However, they're generally recommended for short-term use of less than 4 weeks and are less preferred for treating chronic constipation symptoms.



**Stimulant Laxatives**

- Include bisacodyl and sennosides
- Can relieve constipation through<sup>1,2</sup>
  - Decreasing water absorption
  - Stimulating intestinal motility
  - Increasing intestinal transit
- Efficacy and safety of bisacodyl has been established in patients with CIC<sup>1,2</sup>
- Generally recommended for short term use<sup>3</sup>
  - Less than 4 weeks

1. Lacy, BE. *Am J Manag Care*. 2019;25:S55-S62.  
2. Ford AC, et al. *Am J Gastroenterol*. 2014;109(Suppl 1):S2-S26.  
3. Hayat U, et al. *Cleve Clin J Med*. 2017;84(5):397-408.

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Gerry, in your practice, let's say your patient comes in, and the only thing that's working for them is a stimulant laxative. How do you have that discussion with them? They haven't tried an osmotic laxative yet.

**Gerald Simons:** Right. So basically, like everyone else, I go back to the beginning, diet, exercise, fiber intake, hydration. Sometimes, Rick, I'll actually find that their concept of hydration is drinking more coffee, which is just acting more as a diuretic, and they actually are losing more water when I thought they were actually drinking more. So, very often, it's going back to that baseline and kind of really assessing exactly where patients are.

Now, one of our advantages when we think of PEG, or the polyethylene glycols, is their availability and their ease of use. So, incorporating that in when a patient has failed some of these initial approaches, very often, I've found, can replace a fiber drink that they might be doing. And we very often have it fit easily into their program that way.

Once in a while, I'll actually have patients use a mag citrate in a low dose to kind of stimulate things to get everything going, and then switch to a PEG product after that. But again, this is always going back to the foundation if the patient's basic building blocks are in play.

**Rick Davis:** Right. And I've found that, too, in our practice, that if a patient hasn't had a bowel movement for, say, 4 or 5 days, sometimes the osmotic laxatives don't work as well.

**Gerald Simons:** Right.

**Rick Davis:** And so, they may need a little bit stronger, like a mag citrate kind of cleanout, and then start taking the osmotic laxative, and it seems to work much better for them.

**Gerald Simons:** Yes, right. Fantastic. Now, Rick, before we get into more of Vanessa's case, let's review the correct answer that you just gave to the clinical question. Now, based on the information that we've discussed, the correct answer is (A). The most logical step would be adding an osmotic laxative to her therapy. Again, everyone, this is an additive therapy. Diet modification and fiber should continue.

Now, due to the increased bloating and gas that Vanessa experienced with initiating psyllium and we warned people about this, if you rewind the tape a little bit, she was not interested in increasing the psyllium dose and, you know what, would probably not be compliant if that was our only recommendation anyway.

So the osmotic laxative is a logical choice to try to soften her stool and increase that intestinal transit, which is going to relieve her constipation, going back to that patient satisfaction idea we talked about in the beginning.

In addition, continuing patient education. So, another discussion around these lifestyle modifications, exercise, toilet training and hydration. And again, if she can tolerate it, at least getting 3 g twice a day of psyllium would be a good idea. But as I mentioned, some patients will have to take a psyllium dose out and replace it with the polyethylene glycol.

Now, going back to our case, it's another 6-week follow-up, and Vanessa's just even more frustrated with her symptoms. As we discussed her progress, she states she's been able to tolerate psyllium 3 g/day, but experiences that gas and bloating at higher doses, so she hasn't gone beyond that.

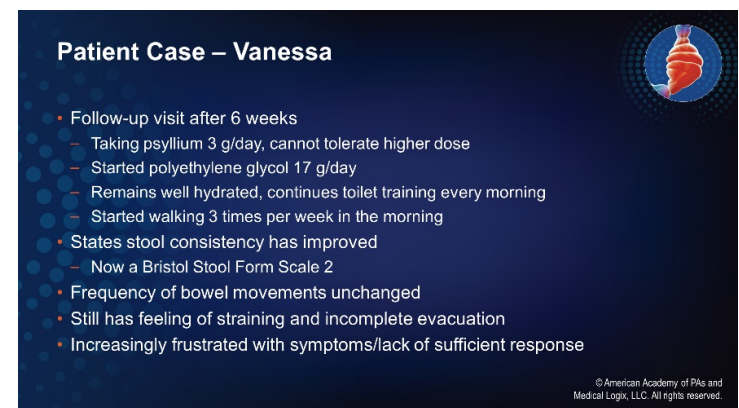
She's been taking polyethylene glycol 17 g daily, and while she feels her stool consistency has improved to a Bristol Stool Form Scale 2, the frequency of her bowel movements have not changed, and she still has that feeling of straining and incomplete evacuation.

Rick, I don't know about you, but I have a lot of patients that have the Bristol Stool Scale on their phone, and they actually have the pictures, and they are literally putting in their EMR message board, "Oh, I'm on a scale 1, 2 or 3." Do you get that a lot, ever, Rick?

**Rick Davis:** Not as many, but I do get it occasionally with some of our anxious students.

**Gerald Simons:** Got it. Exactly. Anyway, back to Vanessa. She states she's remained well hydrated, that's a good sign, is doing toilet training every morning. That's also good. And she's improved her walking to about 20 minutes three times a week early in the morning, just when we like it.

But she's increasingly frustrated that her efforts have resulted in a limited benefit in addressing her CIC and is now back to see if we could do something different.



**Patient Case – Vanessa**

- Follow-up visit after 6 weeks
  - Taking psyllium 3 g/day, cannot tolerate higher dose
  - Started polyethylene glycol 17 g/day
  - Remains well hydrated, continues toilet training every morning
  - Started walking 3 times per week in the morning
- States stool consistency has improved
  - Now a Bristol Stool Form Scale 2
- Frequency of bowel movements unchanged
- Still has feeling of straining and incomplete evacuation
- Increasingly frustrated with symptoms/lack of sufficient response

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Now, let's go to question 4.


At this time, which of the following evaluations is not necessary for monitoring and assessing Vanessa's CIC symptoms?

- A. Assessment of current Bristol Stool Form Type
- B. Obtaining additional bloodwork
- C. Evaluation of the Rome IV criteria
- D. Discussion of any adverse events identified which may be associated with therapy

So during these follow-ups, it's important to determine treatment efficacy, monitor the safety of all of these therapeutic interventions and identify circumstances where referral may be necessary. So maybe me, as more of a general surgery guy, may have to refer to Rick in his GI office.

Now, ongoing patient education regarding lifestyle modification and medication compliance is critical to achieve optimal outcomes. So always go back to that base and remind and reeducate patients.

### Follow-up Care



- During follow-up visits, evaluate patients for the following:
  - Treatment efficacy
  - Safety of therapeutic interventions
  - Patient tolerance of therapy
  - Circumstances where referral may be necessary for additional management
- Ongoing patient education regarding lifestyle modifications and medication compliance should also be completed at every visit

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Now, Rick, in your GI practice, do you get a lot of referrals for constipation-related issues, or do you find that that's more handled in the primary care office?

**Rick Davis:** Actually, we get quite a few. Usually, primary care has tried some things, but also have a direct open access to specialty care at our institution. So, patients frequently will get into the GI practice or the GI office in clinic a little bit sooner. So, yes, we see quite a few patients with chronic constipation.

**Gerald Simons:** Got it.

**Rick Davis:** Well, great. Those are all really good points. So, returning to our question, at this time it is not necessary to obtain routine bloodwork to assess Vanessa's response to therapy. Bloodwork may be necessary during the initial differential diagnosis, but unless there's a significant change in the disease course, and that's usually over time, routine levels are not required at follow-up visits.

However, these visits should include a discussion of the treatment efficacy, as you had mentioned, based on changes in their clinical symptoms, safety assessments as well as a discussion of how these align with the patient's treatment goals.

Now, Vanessa's complete picture should be documented in her record, including results of the full initial workup, disease activity and progress, lifestyle modifications initiated, OTC therapies she may be trying and prescription therapies along with their results. This is vital, because determination of her treatment course moving forward and her ultimate treatment success will depend on multiple factors.

So, this brings us to our last clinical question.

What is the best next step in Vanessa's management at this time?

- A. Increasing polyethylene glycol dose
- B. Continue current regimen for an additional 6 weeks
- C. Initiate prescription secretagogue therapy
- D. Begin a stimulant laxative such as bisacodyl


So nonprescription therapy alone may not be sufficient in refractory cases of chronic idiopathic constipation, and in these circumstances, patients may require combination therapy with both OTC and prescription treatment.

In one study, 50% of patients with CIC reported being dissatisfied with nonprescription laxatives due to their unpredictability, bloating side effects, poor symptom relief or the inability of therapy to improve their quality of life.

Secretagogues are typically considered first-line prescription therapies in patients with chronic idiopathic constipation.

Three prosecretory agents, or secretagogues, are currently FDA approved for the treatment of CIC: linaclotide, lubiprostone and plecanatide.

### Prescription Therapy for CIC



- Nonprescription therapy may not be sufficient for refractory cases
  - These patients may require both prescription and nonprescription therapy
  - One study found 50% of patients with CIC were dissatisfied with nonprescription laxative therapy<sup>1</sup>
- Secretagogues are typically considered first line prescription therapy in patients with CIC
- Include linaclotide, lubiprostone and plecanatide

<sup>1</sup> Johanson JF, et al. *Aliment Pharmacol Ther.* 2007;25(5):599-608.


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Linaclotide is a poorly absorbed amino acid that activates guanylate cyclase type C receptor and stimulates chloride secretion in the terminal ileum, leading to an increase in water secretion in the intestinal lumen and accelerating intestinal transit.

Approval for CIC was based on a couple of randomized trials which, the primary endpoint was increasing spontaneous bowel movements (SBM) per week with at least a minimum increase of one SBM per week. And this was achieved in 16 to 20% of patients in the two trials at one dose. The most common adverse effect leading to discontinuation was diarrhea in about 4%.

A lower dose of 72 mcg has also been approved in chronic idiopathic constipation.

### Linaclotide



- Poorly absorbed amino acid peptide that activates guanylate cyclase type C receptor<sup>1</sup>
  - Activation stimulates chloride secretion, leading to an increase in water secretion into the intestinal lumen and accelerating intestinal transit
- Approval for CIC based on 2 randomized phase 3 trials<sup>2</sup>
- 2 approved dosage strengths
  - 72 mcg and 145 mcg

<sup>1</sup> Andresen V, et al. *Gastroenterology.* 2007;133(3):761-768.

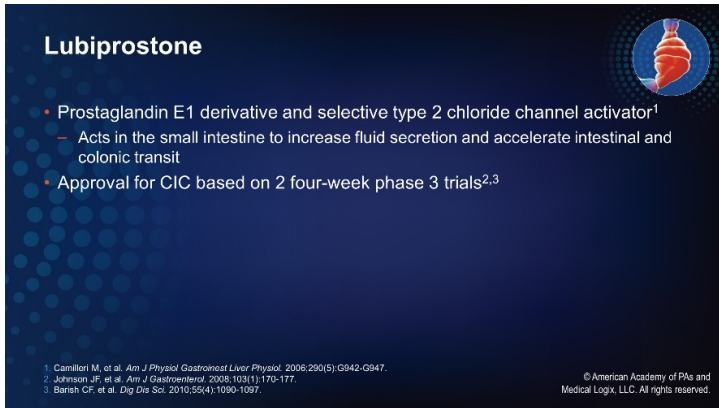
<sup>2</sup> Lembo AJ, et al. *N Engl J Med.* 2011;365(6):527-536.

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Lubiprostone also is a selective type 2 chloride channel activator that acts in the small intestine to increase fluid secretion and accelerates intestinal and colon transit. That approval was based on two 4-week phase 3 trials with the primary endpoint also being number of spontaneous bowel movements during the first week of treatment, which was significantly improved in patients taking lubiprostone versus placebo.

In a 48-week open-label safety trial, the most common adverse effect leading to discontinuation was nausea, but this actually was improved when taken with food.



**Lubiprostone**

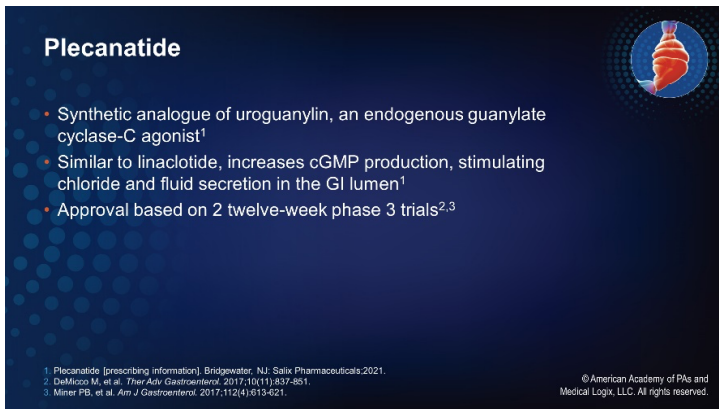
- Prostaglandin E1 derivative and selective type 2 chloride channel activator<sup>1</sup>
  - Acts in the small intestine to increase fluid secretion and accelerate intestinal and colonic transit
- Approval for CIC based on 2 four-week phase 3 trials<sup>2,3</sup>

1. Camilleri M, et al. *Am J Physiol Gastrointest Liver Physiol*. 2006;290(5):G942-G947.  
2. Johnson JF, et al. *Am J Gastroenterol*. 2008;103(1):170-177.  
3. Barish CF, et al. *Dig Dis Sci*. 2010;55(4):1090-1097.

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Plecanatide is a synthetic analogue of uroguanylin, also an endogenous guanylate cyclase C agonist similar to linaclotide. It stimulates chloride and fluid secretion in the GI lumen, especially in the terminal ileum.

It was approved based on two 12-week phase 3 trials, with the primary endpoint of increased overall spontaneous bowel movements of at least three within a week and an increase of at least one from baseline in the same week for at least 9 of the 12 weeks. And this was significantly better at 20% versus 12.8% when compared with placebo. Its most common adverse event was diarrhea also that occurred in 3.2 and 5.9% of patients.



**Plecanatide**

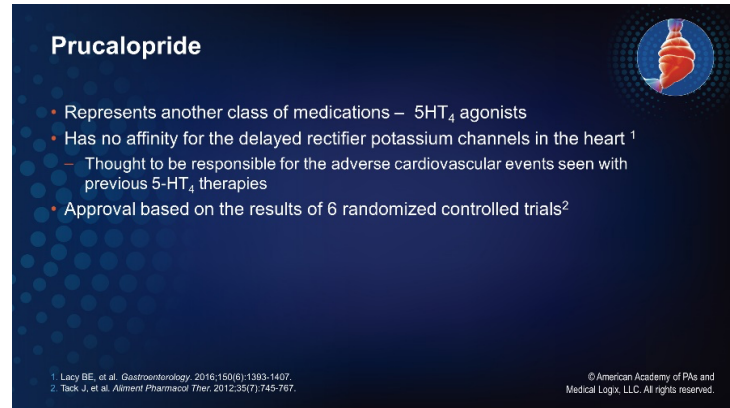
- Synthetic analogue of uroguanylin, an endogenous guanylate cyclase-C agonist<sup>1</sup>
- Similar to linaclotide, increases cGMP production, stimulating chloride and fluid secretion in the GI lumen<sup>1</sup>
- Approval based on 2 twelve-week phase 3 trials<sup>2,3</sup>

1. Plecanatide [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; 2021.  
2. DeMico M, et al. *Ther Adv Gastroenterol*. 2017;10(11):837-851.  
3. Miner PB, et al. *Am J Gastroenterol*. 2017;112(4):613-621.

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Prucalopride, a newer agent on the market, is a 5-HT<sub>4</sub> agonist and a promotility medication. It was approved by the FDA in 2018. Previous 5-HT<sub>4</sub> agonists had issues with potassium channels in the heart and adverse cardiovascular events, but this is not seen, there is no affinity for the delayed rectifier potassium channels in the heart with this agent.

There were six randomized controlled trials that demonstrated that significantly more patients taking prucalopride 2 mg daily for 12 weeks versus placebo had a mean of three or more spontaneous bowel movements per week of 27.8% versus 13%. The most common adverse events were nausea, diarrhea, abdominal pain, and headache.



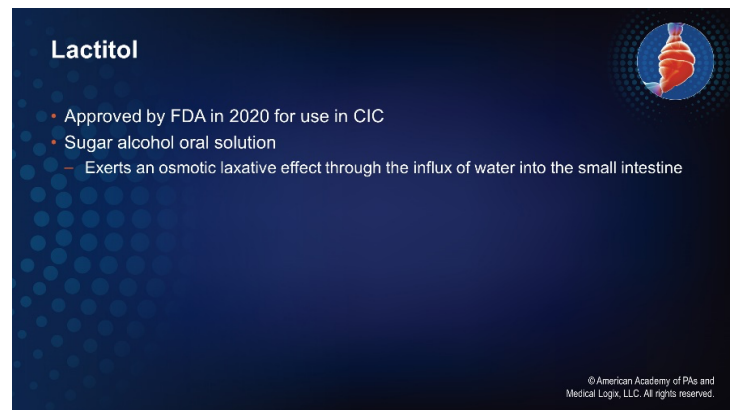
**Prucalopride**

- Represents another class of medications – 5HT<sub>4</sub> agonists
- Has no affinity for the delayed rectifier potassium channels in the heart<sup>1</sup>
  - Thought to be responsible for the adverse cardiovascular events seen with previous 5-HT<sub>4</sub> therapies
- Approval based on the results of 6 randomized controlled trials<sup>2</sup>

1. Lacy BE, et al. *Gastroenterology*. 2016;150(6):1393-1407.  
2. Tack J, et al. *Aliment Pharmacol Ther*. 2012;35(7):745-767.

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Now, lactitol was recently FDA approved in 2020 and has just recently been available in the U.S. commercially. And this is a sugar-alcohol oral solution that exerts an osmotic laxative effect, so not a true secretagogue, through the influx of water into the small intestine.



**Lactitol**

- Approved by FDA in 2020 for use in CIC
- Sugar alcohol oral solution
  - Exerts an osmotic laxative effect through the influx of water into the small intestine

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**Gerald Simons:** Great. Rick, that was a great overview of those medications, and it's interesting just how well the side effect profile really is. And I've definitely found that they are great agents to augment some of those foundational treatments we were talking about.

So we have that one last question. Let's review the correct answer to our last clinical question. What is the best next step in Vanessa's treatment? And as you probably can figure out, the correct answer is (C) Initiating a secretagogue therapy.

Now, as we talked about earlier, management of CIC has to involve discussion and input from both the patient and the provider. And if you've been tracking Vanessa's story, she's reached that stage of frustration that we all see in the clinic where she needs something else. We need initiation of another laxative, such as a stimulant laxative. But that's not necessarily an optimal long-term solution for her. It just is not going to work long term.

That's where we start doing our prescriptive therapy, which, again, augments everything else that we've been talking about during this session.

So, Vanessa initiates her secretagogue therapy just as we prescribed. And now, at another 12-week follow-up, she notes that her symptoms are somewhat improved. She still has a feeling of straining, and she still has a feeling of incomplete evacuation. And the frequency of her bowel movements has improved to more consistently twice a week, but it's still not where she was at baseline of having a bowel movement every day about 18 months ago.

## Patient Case – Vanessa



- Follow-up visit after 12 weeks
  - Initiated secretagogue therapy
  - Psyllium 3 g/daily
  - Remains hydrated, consistent with toilet training
  - Walking for exercise 4-5 days per week
- States her symptoms have *somewhat* improved
  - Still has feeling of straining and incomplete evacuation
  - Frequency of bowel movements has improved to 2 times per week
    - Not back to baseline of daily bowel movement

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Now, back to those lifestyle modifications, Vanessa tells us that she's staying well hydrated. She's taking her 3 g of psyllium. She's got her toilet training and is walking four or five times a week.

So, again, where are we now? She's back again and still not getting the symptom relief that she needs. So, there are several options. Rick just went through them. Again, we could try a completely different type of therapy, like the newer 5-HT4 agonists. We could continue with current therapy, maybe increase some of those doses, remind her of those critical lifestyle modifications.

As we already discussed, we could refer to Rick and the GI practice for further management and really discussing with Vanessa about her progress and her individual goals. And for her, she's talking about when she was having a bowel movement every day about a year and a half ago.

**Rick Davis:** So, thanks, Gerry. You know, it's very interesting with Vanessa, too. Now she is a multiparas patient. She's had two vaginal deliveries, both without complication.

Her initial digital rectal exam did not suggest a dyssynergia, but that may be one of the things that the GI practice might further look into with either colonoscopy, flexible sigmoidoscopy for structural abnormalities, polyps, et cetera, large internal hemorrhoids after her pregnancy that may be interfering with outlet obstruction, but also whether she's developed dyssynergia, this failure of relaxation or tightening of the external sphincter in a response to trying to strain with a bowel movement.

So, there can be other options other than colonoscopy with referral to a specialist. But I think at this point, she's done a little bit better with the therapies, and it's probably a good idea to refer her on just to rule out some of these other things that may be contributing.

## Summary



- Identification and effective management of patients with CIC is critical in the primary care setting
  - Where patients will often initially present with symptoms
- Important to start with a thorough patient evaluation for the diagnosis of CIC, and identifying any red flags
- Patient education is critical for a successful outcome
- Some patients may achieve success with lifestyle changes and nonprescription therapies
  - Others will require the addition of prescription therapy

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So, as we bring our case to a close, we should remember that identification and effective management of patients with CIC is critical in the primary care setting, where patients typically present

with initial symptoms. Completing a thorough patient evaluation is important in the diagnosis of CIC, as well as identifying potential red flag symptoms and referring patients when appropriate.

Education regarding their condition, implementation of lifestyle changes, and inclusion of over-the-counter therapies may be enough for some patients to manage their disease symptoms. However, other patients will need additional prescription therapies to effectively manage their disease.

I would like to thank our expert, PA Gerry Simons, for your great insights and discussion, and I'd like to thank you, our audience, for participating in this program on addressing the challenges in chronic constipation.

**Gerald Simons:** Great. Thank you, Rick, for a great overview of the case and for helping me to participate. And just a general reminder, especially if you're taking notes, in your daily practice, everyone should screen for constipation. You know, ask patients about constipation. And again, all PAs should help address the lack of fiber in the American diet.

**Rick Davis:** On behalf of Gerry and myself, we hope that you enjoyed this program, and thanks for joining us.

## Clinical Pearl

Chronic idiopathic constipation, CIC, which is also termed functional constipation, is a relatively common gastrointestinal disorder. The diagnosis of CIC can be challenging, with a significant differential diagnosis to consider. CIC can be differentiated from IBS-C with the absence of abdominal pain.

CIC patients typically have fewer bowel movements, less than three per week, harder stools, and progressive bloating and discomfort without a bowel movement, while IBS-C patients must have abdominal pain which is associated with their bowel habits.

## Clinical Pearls



- Diagnosis of chronic idiopathic constipation (CIC) can be challenging
  - CIC can be differentiated from IBS-C with the absence of abdominal pain
  - CIC patients typically have fewer bowel movements (< 3/week), harder stools and progressive bloating/discomfort without a bowel movement
- Identification and effective management of patients with CIC is critical in the primary care setting, as well as know when referral would be appropriate
- Management decisions should be made by the provider and patient based on treatment goals, therapy-specific attributes and patient preferences
  - Patient education is key to achieve treatment success
- Some patients may achieve success with lifestyle changes and nonprescription therapies
  - Others will require addition of prescription therapy

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It is important for PAs to be aware and correctly identify signs and symptoms of chronic idiopathic constipation and to understand when referral to a specialist would be appropriate so that patients experience minimal time without proper and effective management that is individualized for their specific circumstances.

Several therapeutic options are available. Therefore, therapeutic management choices should be made by the provider and patient based on treatment goals, therapy-specific attributes and patient preferences.

So, education regarding their condition, implementation of lifestyle changes and inclusion of over-the-counter therapies may be enough for some patients to manage disease symptoms. However, other

patients will need additional prescription therapies to effectively manage their symptoms.

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**CME POST-TEST: Participants must: 1) read the educational objectives and faculty disclosures; 2) study the educational materials; 3) complete the post assessments in Learning Central. See page 2 for further information.**

**Question #1**

Which of the following would be considered a red flag symptom and would warrant further evaluation and potential colonoscopy in a patient with suspected chronic idiopathic constipation (CIC)

- A. Presence of symptoms > 6 months
- B. Sudden weight loss
- C. Symptom onset before age 50
- D. Straining with >25% of defecations

**Question #2**

Which of the following should be part of the routine work-up for patients with suspected CIC?

- A. Food allergy testing
- B. Stool culture
- C. Digital rectal exam
- D. Colonoscopy

**Question #3**

A 45-year-old woman presents with ongoing constipation (bowel movement 1-2 times per week). Which of the following additional pieces of information would support a diagnosis of CIC?

- A. The constipation symptoms began 2 months ago
- B. She also reports having abdominal pain
- C. She reports a sense of incomplete evacuation when having a bowel movement
- D. She notes that her stool is mixed with blood

**Question #4**

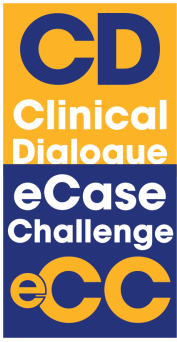
Which of the following would be an appropriate therapeutic option for a patient with CIC who has an insufficient response to lifestyle modifications and nonprescription therapy?

- A. Secretagogue therapy
- B. Tegaserod
- C. Cholestyramine
- D. Tenapanor

**Question #5**

Intake of which of the following foods is known to be helpful in directly addressing constipation?

- A. Fish
- B. Prunes
- C. Soy
- D. Wheat



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