Virginia B. Kalish, MD
Dewitt Army Community Hospital-National Capital Consortium Residency Program, Fort Belvoir, Va

Bridget Loven MLIS
Carolinas Healthcare System, Charlotte, NC

FAST TRACK

Inconsistent research findings cast doubt on the efficacy of fiber treatment for constipation

What is the best treatment for chronic constipation in the elderly?

Evidence-based answer

There is no one best evidence-based treatment for chronic constipation in the elderly. While the most common first-line treatments are dietary fiber and exercise, the evidence is insufficient to support this approach in the geriatric population (strength of recommendation [SOR]: for dietary fiber: **A**, based on a systematic review; for exercise: SOR: **B**, based on 1 good- and 1 fair-quality randomized controlled trial [RCT]).

Herbal supplements (such as aloe), alternative treatments (biofeedback), lubricants (mineral oil), and combination laxatives sold in the US have not been sufficiently studied in controlled trials to make a recommendation (SOR: **A**, based on systematic review).

An abdominal kneading device can be used to treat chronic constipation, but the evidence is limited (SOR: **B**, based on 1 cohort study.)

Polyethylene glycol has not been studied in the elderly. A newer agent, lubiprostone (Amitiza), appears to be effective for the treatment of chronic constipation for elderly patients (SOR: **B**, based on subgroup analysis of RCTs.)

Clinical commentary

Is the patient truly constipated?

Many older people feel that if they do not have a bowel movement every day they are constipated. However, constipation is defined as fewer than 3 bowel movements per week. So, the first thing we must do is to confirm that the patient is truly constipated.

Before I start my patients on any medicine, I suggest a trial of increased daily water and fiber intake along with exercise, followed by a trial of stool softeners and stimulant laxatives, if needed. If all of these methods fail, I consider trying polyethylene glycol, which can be titrated to effect. As with all medication use by the elderly, it is important to titrate cautiously ("start low and go slow") and add other medications only when necessary.

Mandi Sehgal, MD
Department of Family Medicine/Geriatrics, University of Cincinnati

Evidence summary

Few well-designed studies have focused on constipation treatment among the elderly. Our search located 1 systematic review of pharmacologic management, a systematic review of fiber management, 2 RCTs on the effect of exercise, and 1 before-after cohort study on abdominal massage. These studies were all conducted among geriatric patients with constipation. Two high-quality systematic reviews regarding chronic constipation manage-

ment for adults of all ages included management options not studied in exclusively geriatric populations, such as herbal supplements, biofeedback, tegaserod, and polyethylene glycol.

Laxatives, fiber, and exercise: Studies are inconclusive

Two good-quality systematic reviews looked at 10 RCTs comparing laxatives with placebo, and 10 RCTs comparing 1 laxative with another.[1,2] The studies generally had few participants, were of short duration, and were conducted in institutional settings. Most lacked power to make valid conclusions. These studies varied in the reported outcome measures, including stool frequency, stool consistency, straining, decrease in laxative use, and symptom scores. The reviews concluded that the best pharmacologic treatment for chronic constipation in the elderly has not been established.

Five of the higher-quality studies attained statistical significance. They showed a small but significant improvement in bowel movement frequency with a laxative when compared with placebo or another laxative (**TABLE**). The authors noted that multiple poor-quality studies have shown nonsignificant trends for improved constipation symptoms with laxatives compared with placebo.

Inconsistent findings on fiber. A good-quality systematic review[3] of dietary fiber in the treatment of constipation for older patients located 8 moderate- to high-quality studies (6 RCTs and 2 blinded before-after studies), with 269 study participants in institutional settings. Results among studies were inconsistent, casting doubt on the efficacy of fiber treatment for constipation in the institutionalized elder.

Two RCTs[4,5] investigating the effect of exercise on 246 institutionalized older patients showed no improvement in constipation. One study was of good quality, reporting adequate power and used an intention-to-treat analysis. The other was of fair quality.

TABLE

How well do these interventions work for older patients with chronic constipation?

INTERVENTION VS COMPARISON	STOOL FREQUENCY (STOOLS PER WEEK)	NNT‡
Agiolax* vs lactulose	4.5 vs 2.2	43
Agiolax* vs lactulose	5.6 vs 4.2	71
Lactitol† vs placebo	4.9 vs 3.6	77
Lactitol† vs lactulose	5.5 vs 4.9	160
Lactulose vs sorbitol†	7.0 vs 6.7	330
External abdominal kneading (before-after)	3.9 vs 1.4	40

* Agiolax is a combination bulk and stimulant laxative not readily found in the United States.

† Lactitol and sorbitol are sugar alcohols used as replacement sweeteners and approved by the FDA as food additives.

‡ Number needed to treat (NNT) for 1 person to have 1 more stool per week.

Alternative TXs not well studied

A high-quality systematic review[6] of constipation management among adults of all ages in North America found a lack of quality RCTs examining herbal supplement treatment. Biofeedback has been studied in adult populations, but no RCTs with placebo or sham-controls have been published.

One before-after cohort study[7] investigated an external kneading mechanical device (Free-Lax) that was applied to the abdomen for 20 minutes once daily in 30 randomly selected chronically constipated nursing home residents. Researchers found significant improvements in bowel movement frequency, stool consistency and volume, and colonic transit time without side effects (**TABLE**).

A look beyond geriatric patients

Polyethylene glycol, tegaserod, and lubiprostone have not been studied in trials of exclusively geriatric populations. Two high-quality systematic reviews,[6,8] including medium- to high-quality RCTs of pharmacologic management of chronic constipation, found good evidence to support treatment with polyethylene glycol and tegaserod in adults of all ages. Of the 8 RCTs looking at polyethylene glycol, only 1 of the studies—a high-

FAST TRACK

2 RCTs showed no improvement of constipation from exercise in older patients

quality crossover comparison of polyethylene glycol vs placebo with 37 outpatient subjects—included a population with a mean age >60 years (mean age 62, range 42–89 years).

A subgroup analysis[9] of 331 elderly patients enrolled in 2 RCTs of tegaserod found no difference in outcomes between treatment with tegaserod and placebo, although this analysis was limited by inadequate power.

Tegaserod linked to ischemic events. A recent analysis of clinical trials found a statistically significant increase in cardiovascular ischemic events associated with tegaserod. The manufacturer took the product off the market in compliance with an FDA request in March 2007.

Lubiprostone offers promise. Lubiprostone, a chloride channel activator approved by the FDA for the treatment of chronic idiopathic constipation, has been studied in 6 placebo-controlled, double-blind, randomized Phase II and III clinical trials. In 2 unpublished pooled analyses of 3 of the trials, lubiprostone was found to be effective in a total of 220 elderly patients 65 years of age and older.[10,11]

FAST TRACK

There was good evidence to support the use of polyethylene glycol in adults of all ages

Recommendations from others

The American College of Gastroenterology Chronic Constipation Task Force evidence-based guidelines make no reference to age, but state that evidence is best for treatment with psyllium, tegaserod, polyethylene glycol, and lactulose.[12] They found insufficient evidence to support use of stimulants, stool softeners, lubricants, herbal supplements, biofeedback, and alternative treatments.

The American Gastroenterological Association guidelines on constipation are primarily based on expert opinion.[13] Age is not specified in their recommendations. Dietary and exercise modifications are recommended as first-line treatments, followed by laxatives. Laxatives are recommended based on cost, in order from the least to most expensive agents. Suppositories, enemas, biofeedback, and (in refractory cases) surgery are recommended for patients with pelvic floor dysfunction.

The Registered Nurses Association of Ontario guidelines for constipation prevention in the older adult population recommend fluid and dietary fiber, regular exercise, and consistent toileting.[14] ■

References

1. Petticrew M, Watt I, Brand M. What's the "best buy" for treatment of constipation? Results of a systematic review of the efficacy and comparative efficacy of laxatives in the elderly. *Br J Gen Pract* 1999; 49:387–393.
2. Petticrew M, Watt I, Sheldon T. Systematic review of the effectiveness of laxatives in the elderly. *Health Technol Assess* 1997; 1:i–iv,1–52.
3. Kenny KA, Skelly JM. Dietary fiber for constipation in older adults: a systematic review. *Clinical Effectiveness in Nursing* 2001; 5:120–128.
4. Chin APMJ, van Poppel MN, van Mechelen W. Effects of resistance and functional-skills training on habitual activity and constipation among older adults living in long-term care facilities: a randomized controlled trial. *BMC Geriatr* 2006; 6:9.
5. Simmons SF, Schnelle JF. Effects of an exercise and scheduled-toileting intervention on appetite and constipation in nursing home residents. *J Nutr Health Aging* 2004; 8:116–121.
6. Brandt LJ, Prather CM, Quigley EM, Schiller LR, Schoenfeld P, Talley NJ. Systematic review on the management of chronic constipation in North America. *Am J Gastroenterol* 2005; 100 Suppl 1:S5–S21.
7. Mimidis K, Galinsky D, Rimon E, Papadopoulos V, Zicherman Y, Oreopoulos D. Use of a device that applies external kneading-like force on the abdomen for treatment of constipation. *World J Gastroenterol* 2005; 11:1971–1975.
8. Ramkumar D, Rao SS. Efficacy and safety of traditional medical therapies for chronic constipation: systematic review. *Am J Gastroenterol* 2005; 100:936–971.
9. Baun RF, Levy HB. Tegaserod for treating chronic constipation in elderly patients. *Ann Pharmacother* 2007; 41:309–313.
10. Ueno R, Joswick TR, Wahle A, et al. Efficacy and safety of lubiprostone for the treatment of chronic constipation in elderly vs non-elderly subjects. *Gastroenterology* 2006; 130(Suppl 2):A189.
11. Ueno R, Panas R, Wahle A, et al. Long-term safety and efficacy of lubiprostone for the treatment of chronic constipation in elderly subjects. *Gastroenterology* 2006; 130(Suppl 2):A188.
12. American College of Gastroenterology Chronic Constipation Task Force.An evidence-based approach to the management of chronic constipation in North America. *Am J Gastroenterol* 2005; 100 Suppl 1:S1–S4.
13. Locke GR, 3rd, Pemberton JH, Phillips SF. American Gastroenterological Association Medical Position Statement: guidelines on constipation. *Gastroenterology* 2000; 119:1761–1766.
14. Registered Nurses Association of Ontario (RNAO). Prevention of constipation in the older adult population. Toronto, Ontario: RNAO; 2005. Available at: www.guideline.gov/summary/summary.aspx?ss=15&doc_id=7004&nbr=4213. Accessed on November 8, 2007.