

Daily polyethylene glycol over 6 months was effective for chronic constipation

DiPalma JA, Cleveland MV, McGowan J, Herrera JL. A randomized, multicenter, placebo-controlled trial of polyethylene glycol laxative for chronic treatment of chronic constipation. *Am J Gastroenterol.* 2007;102:1436-41.

Clinical impact ratings: GIM/FP/GP ★★★★★☆ Gastroenterology ★★★★★☆☆

QUESTION

In adults with chronic constipation, is daily use of polyethylene glycol (PEG) for 6 months effective and safe?

METHODS

Design: Randomized placebo-controlled trial.

Allocation: Unclear allocation concealment.*
Blinding: Blinded (unclear which groups were blinded).*

Follow-up period: 6 months.

Setting: 50 centers in the United States.

Patients: 306 patients with chronic constipation over the past 3 months (< 3 satisfactory stools per wk without laxative use and ≥ 1 of the following Rome criteria: straining, lumpy or hard stools, or sensation of incomplete evacuation in > 25% of defecations) and during a 14-day observation period (< 3 satisfactory bowel movements per wk). Exclusion criteria were prior or current treatment with or sensitivity to study medication; use of medications affecting bowel function; the irritable bowel syndrome; pregnancy or lactation; past gastrointestinal (GI) surgery; known or suspected GI obstruction; ileus; ascites; or chronic bowel, liver, or cardiopulmonary disorders.

Intervention: PEG, 17 g ($n = 204$), or placebo ($n = 100$) to be mixed in 8 oz of juice or other beverage and taken daily.

Outcomes: Overall treatment success ($\geq 50\%$ of treatment weeks with ≥ 3 satisfactory stools, no use of rescue laxatives, and ≤ 1 of the following in > 25% of defecations: straining, lumpy or hard stools, or sensation of incomplete evacuation). Secondary outcomes included "super efficacy," defined as 1 week with no constipation symptoms (Rome criteria) and no use of rescue laxatives; and adverse events.

Patient follow-up: 99% (mean age 53 y, 85% women) were included in the intention-to-treat analysis. 170 patients completed all 6 months of the study.

MAIN RESULTS

More patients in the PEG group than in the placebo group had overall treatment success

(Table). The mean number of weeks that patients met the criteria for treatment success and for super efficacy was higher in the PEG group (12 vs 3.4 wk and 9.2 vs 2.2 wk, respectively, $P < 0.001$ for both). GI complaints were more common with PEG (40% vs 25%, $P = 0.015$); groups did not differ for other adverse effects.

CONCLUSION

In adults with chronic constipation, daily polyethylene glycol over 6 months reduced constipation more than placebo.

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*See Glossary.

Polyethylene glycol (PEG) vs placebo for patients with chronic constipation†

Outcomes over 6 mo	PEG	Placebo	RBI (95% CI)	NNT (CI)
Overall treatment success‡	52%	11%	372% (174 to 742)	3 (3 to 4)

†Abbreviations defined in Glossary. RBI, NNT, and CI calculated from data in article.

‡ $\geq 50\%$ of treatment weeks with ≥ 3 satisfactory stools, no use of rescue laxatives, and ≤ 1 of the following Rome criteria in > 25% of defecations: straining, lumpy or hard stools, or sensation of incomplete evacuation.

COMMENTARY

The study by DiPalma and colleagues provides good evidence that PEG can safely relieve chronic constipation in a select group of adults. The authors compared PEG with placebo, rather than other forms of constipation treatment, and required that study patients refrain from taking extra fiber, a commonly recommended intervention. The study confirms that long-term use of PEG will not affect serum electrolytes, and the side effect profile appears acceptable.

The findings may not extrapolate, however, to other types of patients. The average duration of constipation was > 23 years for the study population, and the study excluded people with such common, chronic illnesses as the irritable bowel syndrome or cardiopulmonary disease. Also excluded were patients taking narcotics, such as those who

required palliative care. A recent Cochrane review (1) of constipation treatment in patients receiving palliative care found insufficient data from randomized controlled trials, with too few comparisons of laxatives.

The study by DiPalma and colleagues provides excellent evidence that PEG is safe and effective compared with placebo. Head-to-head comparisons with other regimens would be welcome.

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Reference

1. Miles CL, Fellowes D, Goodman ML, Wilkinson S. Laxatives for the management of constipation in palliative care patients. *Cochrane Database Syst Rev.* 2006(4):CD003448.