

Safety of Polyethylene Glycol 3350 for the Treatment of Chronic Constipation in Children

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Abstract:

OBJECTIVE:

To assess the clinical and biochemical safety profile of long term use of polyethylene glycol 3350(PEG) therapy in children with chronic constipation.

METHODS:

It is a prospective observational study. 83 children (44 children with chronic constipation and 39 children with constipation and encopresis) receiving PEG therapy for more than 3 months.

Clinical adverse effects, serum electrolytes level, serum albumin level, liver and renal function test were measured.

RESULTS:

At the time of evaluation the mean duration of PEG therapy was 8.7 months and mean PEG dose was 0.75 g/kg/day. There were no major clinical adverse effects except for transient minimal alanine aminotransferase (ALT) increase in 9 patients but was unrelated to therapy.

CONCLUSION:

Long term PEG therapy is safe and well accepted in children with chronic constipation with and without encopresis.

Keywords: Polyethylene glycol, PEG.

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I. Introduction

Constipation is a common problem in paediatric age group. This symptom account for 3% of outpatient visit. Treatment regimes vary widely and includes dietary and behavioural modifications and use of laxatives and stool softeners. Polyethylene glycol 3350 (PEG) is a new osmotic laxative. It is a component of PEG electrolyte lavage solution that has been used in large volume to cleanse the GIT for diagnostic and surgical procedures in children.

Polyethylene glycol 3350 is nontoxic and highly soluble compound that is minimally absorbed in GI tract. Polyethylene glycol 3350 without electrolytes is supplied as powder that is palatable and dissolved in water or juice or any other beverage. PEG increases the faecal water content.

Polyethylene glycol is widely used in clinical practice for children with constipation but to our knowledge there is little data on long term safety profile of this new laxative. The aim of this study was to assess the biochemical and clinical safety profile of long term PEG use.

II. Methods

All children older than 2 years with chronic constipation who were treated daily with PEG for more than 3 months were included in this study. The diagnosis of chronic constipation was based on symptoms of at least 3 months duration including at least 2 of the following symptoms hard stools, painful defecation, encopresis or fewer than 3 bowel movements per week.

Patients with congenital malformation and systemic illness were excluded.

Following diagnosis, PEG therapy at the dose of 0.8 g/kg/day was started and other laxatives treatment were stopped. Patient were instructed to dissolve 17 gm. of PEG powder in 240 ml of beverage like water or juice and give it in two divided doses. Overtime, parents were instructed to gradually decrease the dose of PEG if symptoms improved.

At the time of evaluation parents were asked about the dose of PEG given, beverage used and ease of mixing, any side effects like excessive loose stools, abdominal pain, flatulence, bloating, and nausea.

4 ml of blood was drawn and level of haemoglobin, haematocrit, serum electrolytes, BUN, serum creatinine, serum albumin, liver function test (ALT, AST) were measured. If tests were abnormal, blood test were repeated within 8 weeks while patient continued to receive therapy.

III. Results

A total of 83 children, out of which 44 children with constipation and 39 children with constipation and encopresis were enrolled in this study.

Clinical adverse effects of PEG therapy were minor over mean duration of 8.7 months (3- 30 months of PEG therapy. 8 patients out of 83 children (10%) reported frequent watery stools sometimes during therapy. The diarrhoea disappeared when dose was reduced. Other side effects like flatulence in 5 children (6%) and abdominal pain in 2 children (2%). Thirst, fatigue, nausea was reported in 1 patient (1%). The general examination were normal. The laboratory results included haemoglobin, haematocrit, BUN, serum creatinine, serum albumin were normal. 9 patients (11%) had slightly increased ALT (alanine aminotransferase) < 1.5 times the upper limit ; normal range 31 – 45U/ lt. 8 out of these patients had ALT level remeasured within 8 weeks, 7 of these 8 patients had values in reference range while 1 had slightly elevated ALT level < 1.2 times normal; range 28 U/lt.

3 patient (4%) had elevated AST level < 1.5 times normal; range 42 – 52 U/lt and all had normal values when remeasured while still using PEG therapy.

Polyethylene glycol was mixed in any beverage. 49 children used fruit juice (59%), 13 children used cow's milk (15.66%), 11 children used water (13.25%), 10 children used fruit punch (12.04%).

PEG solution was liked by 78 children (93.97%). 78 out of 83 children (93.97%) reported definite improvement in bowel problem.

IV. Conclusion:

Constipation with or without encopresis is often a chronic problem. Adequate dose of laxative and treatment compliance are important factor for resolution of chronic constipation. Long term treatment is required and relapse is common after discontinuation of laxative. Therefore an ideal laxative that is safe, effective and acceptable to children is needed.

In our study long term PEG therapy did not have any clinical adverse effects. The most common adverse effect was excessively loose or frequent stools that reduced by decreasing the dose. Polyethylene glycol does not ferment by colonic bacterial flora and does not cause flatulence and bloating.

Patient receiving long term PEG therapy did not have any adverse effect on renal function, serum electrolyte level, serum albumin level. 9 patient had minor elevation in ALT level, 3 had minor elevation in AST level. The elevation was only few points above and completely resolved in all but 1 when remeasured while still receiving therapy. No signs and symptoms of liver disease were present, due to these reasons we believe that transiently abnormal ALT level were clinically insignificant and unrelated to PEG treatment.

PEG seems to be a safe medication for long term treatment of constipation in children. It should be considered a favourable option for long term therapy for children.

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