An Pediatr (Barc). 2016;85(1):34–40

analesdepediatría

www.analesdepediatria.org

ORIGINAL ARTICLE

Comparison of the effectiveness and safety of polyethylene glycol with and without electrolytes in the treatment of chronic constipation☆

Enrique Llerena[a,*], Vicente Varea Calderón[a], Gemma Pujol Muncunill[a], Karina Hernandez Hernandez[a], Franciso Javier Sosa Giraldo[b], Tacya Suarez Fuentes[a], Javier Martín de Carpi[a]

[a] *Sección de Gastroenterología, Hepatología y Nutrición Pediátrica, Hospital Sant Joan de Déu, Esplugues de Llobregat, (Barcelona), Spain*
[b] *Corporación IPS Saludcoop, Medellín, Colombia*

Received 21 April 2015; accepted 19 August 2015
Available online 10 May 2016

KEYWORDS
Constipation;
Laxatives;
Polyethylene glycol;
Treatment of constipation

Abstract
Introduction: To compare the effectiveness and safety of polyethylene glycol with and without electrolytes (EL) over a 12 week period in treatment of chronic constipation in paediatrics.
Material and methods: This was an observational, prospective, longitudinal, parallel group study, including 62 children with chronic constipation according to ROME III criteria and a history of faecal impaction. The children were divided into groups, one group of 30 received polyethylene glycol without EL (PEG) and 32 PEG with EL (PEG + EL) for at least 12 weeks. The main outcomes were the number of bowel movements at 6 and 12 weeks, and the presence of electrolyte disturbances at 6 weeks.
Results: The mean weekly stool frequencies were similar in both groups at 6 and 12 weeks, with 5.4 and 4.6 stools per week in the PEG + EL and PEG groups, respectively at 12 weeks. After 6 weeks of treatment, 83% (25 of 30) of the PEG group had at least one electrolyte disturbance compared with 56% (18 of 32) in the PEG + EL group ($P = .02$). Hyponatraemia was found in 15% (5 of 32) vs. 36% (11 of 30) of PEG + EL and PEG groups, respectively ($P = .05$). None of the laboratory abnormalities were clinically relevant.
Conclusions: PEG formulations with or without EL have a quite similar effectiveness, safety and acceptability. PEG without EL produced more electrolyte abnormalities, but none of them were symptomatic.

☆ Please cite this article as: Llerena E, Varea Calderón V, Pujol Muncunill G, Hernandez Hernandez K, Sosa Giraldo FJ, Suarez Fuentes T, et al. Comparación sobre la efectividad y seguridad del polietilenglicol con y sin electrolitos. An Pediatr (Barc). 2016;85:34–40.

* Corresponding author.
E-mail address: kikellerena@gmail.com (E. Llerena).

PALABRAS CLAVE
Estreñimiento;
Laxantes;
Polietilenglicol;
Tratamiento del estreñimiento

Comparación sobre la efectividad y seguridad del polietilenglicol con y sin electrolitos en el tratamiento del estreñimiento funcional

Resumen
Introducción: El objetivo del estudio fue comparar la efectividad y seguridad del polietilenglicol con y sin electrolitos (EL) en el estreñimiento funcional pediátrico a lo largo de 12 semanas.
Material y métodos: Estudio observacional, prospectivo, longitudinal, de grupos paralelos, que incluye a 62 niños diagnosticados de estreñimiento funcional según los criterios de ROMA III con antecedente de impactación fecal. De ellos, 30 niños recibieron polietilenglicol sin EL (PEG) y 32 PEG con EL (PEG + EL) durante al menos 12 semanas. Los resultados principales fueron determinar el número de deposiciones por semana a las 6 y 12 semanas de tratamiento y la presencia de alteraciones hidroelectrolíticas a las 6 semanas.
Resultados: La media de deposiciones por semana fue similar en ambos grupos a las 6 y a las 12 semanas, siendo en la semana 12 de 5,4 y 4,6 deposiciones por semana en los grupos PEG + EL y PEG respectivamente. Después de 6 semanas de tratamiento, el 83% (25 de 30) del grupo PEG tuvo al menos un parámetro alterado en la analítica, comparado con el 56% (18 de 32) en el grupo PEG + EL (p = 0,02). Se reportó una hiponatremia hasta en un 15% (5 de 32) y un 36% (11 de 30) del grupo PEG + EL y el grupo PEG (p = 0,05). Ninguna de las alteraciones analíticas fue clínicamente relevante.
Conclusiones: Las formulaciones PEG con o sin EL tienen una efectividad, seguridad y aceptabilidad similar. PEG sin EL presentó un mayor número de alteraciones electrolíticas, pero ninguna fue sintomática.

Introduction

Functional constipation in children is a common problem worldwide. Many affected individuals do not seek medical care, so it is difficult to determine its prevalence, but it has been estimated at between 0.7% and 29.6%.[1] In Spain, reported prevalences in adults are as high as 14–20%.[2,3] Constipation significantly impacts quality of life, causing physical as well as emotional distress.[4] It is diagnosed by the Rome III criteria,[5] which are very similar to those established by the PACCT group.[6] The management of functional constipation includes several steps such as education, lifestyle changes, disimpaction and maintenance treatment.[7] Some of the laxatives recommended for its treatment are magnesium hydroxide, lactulose, paraffin and polyethylene glycol (PEG). Compared to its predecessors, now in use for several decades, PEG has become the preferred choice of many practitioners.[8] While the FDA has approved its use only in adults, its use in paediatrics has increased in several countries.[9,10] Several studies have demonstrated its effectiveness and safety in the short term, and two recent systematic reviews[11,12] concluded that PEG may be superior to lactulose and magnesium hydroxide. At present, two formulations of PEG are available in the market, one with and another without electrolytes, and despite their widespread use no studies have been conducted in children to compare their effectiveness and assess their long-term safety. Our study compared the effectiveness of PEG with electrolytes (PEG + EL) and without electrolytes (PEG) and their safety in relation to renal function and electrolyte values as biological markers of absorption over a period of twelve weeks.

Patients and methods

Study design

We conducted an observational and prospective parallel study in two groups of patients that compared the safety and efficacy of a PEG laxative with electrolytes and another without for the treatment of chronic constipation.

The researchers obtained the consent of the patents before starting the period of observation.

Products under study

PEG without electrolytes (Casenlax® powder for oral solution, 4 g and 10 g packets).

Faecal impaction: 1.5–2 g/kg/day in two doses until resolution for a maximum of six days (fixed dose).
Constipation: 0.4–1 g/kg/day in two doses to a maximum of 20 g/day. The duration of treatment was of at least 12 weeks.

PEG with electrolytes (Movicol®, powder for oral solution, 6.9 and 13.9 g packets).

Faecal impaction: 1.5–2 g/kg/day in two doses until resolution for a maximum of six days (fixed dose).
Constipation: 0.4–1 g/kg/day in two doses to a maximum of 27.8 g/day. The duration of treatment was of at least 12 weeks.