



REVISTA DE
GASTROENTEROLOGÍA
DE MÉXICO

www.elsevier.es/rgmx



REVIEW ARTICLE

Effect of antispasmodic agents, alone or in combination, in the treatment of Irritable Bowel Syndrome: Systematic review and meta-analysis

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Received 22 October 2011; accepted 28 April 2012

Available online 5 June 2012

KEYWORDS

Irritable Bowel Syndrome;
Antispasmodics;
Global Improvement;
Abdominal Pain;
Abdominal Distension;
Alverine/Simethicone;
Otilonium;
Pinaverium/Simethicone;
Mexico

Abstract

Introduction: Irritable bowel syndrome (IBS) is characterized by recurrent abdominal pain, bloating, and changes in bowel habit.

Aims: To determine the clinical effectiveness of the antispasmodic agents available in Mexico for the treatment of IBS.

Methods: We carried out a systematic review and meta-analysis of randomized controlled clinical trials on antispasmodic agents for IBS treatment. Clinical trials identified from January 1960 to May 2011 were searched for in MEDLINE, the Cochrane Library, and in the Clinical-Trials.gov registry. Treatment response was evaluated by global improvement of symptoms or abdominal pain, abdominal distention/bloating, and frequency of adverse events. The effect of antispasmodics vs placebo was expressed in OR and 95% CI.

Results: Twenty-seven studies were identified, 23 of which fulfilled inclusion criteria. The studied agents were pinaverium bromide, mebeverine, otilonium, trimebutine, alverine, hyoscine, alverine/simethicone, pinaverium/simethicone, fenoverine, and dicyclomine. A total of 2585 patients were included in the meta-analysis. Global improvement was 1.55 (CI 95%: 1.33 to 1.83). Otilonium and the alverine/simethicone combination produced significant values in global improvement while the pinaverium/simethicone combination showed improvement in bloating. As for pain, 2394 patients were included with an OR of 1.52 (IC 95%: 1.28 a 1.80), favoring antispasmodics.

Conclusions: Antispasmodics were more effective than placebo in IBS, without any significant adverse events. The addition of simethicone improved the properties of the antispasmodic agents, as seen with the alverine/simethicone and pinaverium/simethicone combinations.

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PALABRAS CLAVE

Síndrome de Intestino Irritable;
Antiespasmódicos;
Mejoría Global;
Dolor Abdominal;
Distensión Abdominal;
Alverina/Simeticona;
Otilonio;
Pinaverio/Simeticona;
México

Efecto de los antiespasmódicos solos o combinados en el tratamiento del Síndrome de Intestino Irritable: revisión sistemática y meta-análisis

Resumen

Introducción: El Síndrome de Intestino Irritable (SII) se caracteriza por distensión y dolor abdominal recurrentes, además de cambios en el patrón defecatorio.

Objetivo: Definir la utilidad clínica de los antiespasmódicos disponibles en México para el tratamiento del SII.

Métodos: Se realizó una revisión sistemática y meta-análisis de ensayos clínicos controlados aleatorios de fármacos antiespasmódicos para el tratamiento del SII. Se identificaron los ensayos de enero 1960 a mayo de 2011, para esto se realizó una búsqueda bibliográfica en MEDLINE, the Cochrane Library y en el sitio de registro clinicaltrials.gov. Se tomaron como puntos a evaluar: evaluación global, mejoría de los síntomas, como dolor y distensión abdominal, así como los efectos adversos del tratamiento. El efecto de los fármacos antiespasmódicos vs placebo se expresó como RM e IC 95%.

Resultados: Veintisiete estudios fueron identificados, de los cuales 23 cumplieron los criterios de inclusión. Los medicamentos estudiados fueron pinaverio, mebeverina, otilonio, trimebutina, alverina, hioscina, alverina/simeticona, pinaverio/simeticona, fenoverina y dicyclomina. Un total de 2585 pacientes fueron incluidos en el meta-análisis. La mejoría global fue de 1,55 (IC 95%: 1,33 a 1,83). Otilonio y alverina/simeticona tienen resultados que favorecen la mejoría global, la combinación de pinaverio/simeticona mostró mejoría en el alivio de la distensión. Respecto a mejoría del dolor, se incluyeron 2.394 con un OR de 1,52 (IC 95%: 1,28 a 1,80) a favor de los antiespasmódicos en general.

Conclusiones: Los antiespasmódicos son más eficaces que el placebo en el SII, sin efectos secundarios significativos. La adición de simeticona parece que mejora las propiedades de los antiespasmódicos, tal es el caso de las combinaciones de alverina/simeticona y pinaverio/simeticona.

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Introduction

Irritable bowel syndrome (IBS) is a frequent gastrointestinal functional disorder in the western world and Mexico is not an exception.¹ It is characterized by recurrent abdominal pain, bloating, and defecation disorders.^{2,3} The pathophysiology of IBS is not yet fully understood^{4,5}; but increased pain sensitivity and altered small bowel and colon motility are main factors contributing to IBS symptoms. When compared with healthy controls, IBS patients demonstrate both visceral hypersensitivity and hyper-reactive motility.⁶

Antispasmodic agents are believed to reduce pain associated with IBS through the inhibition of contractile pathways in the gut wall and to improve bowel habits by increasing colonic transit time, therefore reducing stool passage frequency. Previous meta-analyses^{7,8} have proven the usefulness of antispasmodics alone in the treatment of IBS. Nonetheless, antispasmodic availability differs among countries. In the United States, the American College of Gastroenterology review concluded that data were insufficient for making a recommendation as to the effectiveness of the available antispasmodic agents.⁹ In Europe for example, the utility of the available antispasmodics has been evaluated,¹⁰ however, there is no information regarding the effectiveness of those available in Latin America. Therefore, we conducted a systematic review of antispasmodic agents, both alone and in combination, for the treatment of IBS, and carried out a meta-analysis of the data obtained. This was

done to determine the clinical effectiveness of the available antispasmodic agents as sole formulations or in combination with simethicone, and to update the current information on IBS treatment in Mexico.

Methods

To determine the antispasmodic agents that are available in Mexico, we reviewed the therapeutic index of the Dictionary of Medical Specialties (*Diccionario de Especialidades Médicas*), PLM®, Mexico-2011. We focused the search on section A3 of the index that lists all the agents for functional gastrointestinal disorders. The identified antispasmodics were further searched for in a systematic review conducted in MEDLINE, Cochrane Library, and ClinicalTrials.gov from January 1960 to May 2011 and in abstracts presented at the Digestive Disease Week (DDW) and the Mexican Disease Week (*Semana Nacional de Gastroenterología*) from 2010-2011. The agents listed in Table 1 were analyzed. Accordingly, the search terms were Irritable Bowel Syndrome and the following antispasmodics: pinaverium bromide, mebeverine, otilonium, trimebutine, alverine, hyoscine, alverine/simethicone, pinaverium bromide/simethicone, alverine/simethicone, fenoverine, and dicyclomine. Two physicians conducted the search, then reviewed the results and resolved the existing discrepancies. Figure 1 explains the selection process for including papers in the meta-analysis. Articles selected

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