

RECOMENDACIÓN T.5

BÚSQUEDA Y SÍNTESIS DE EVIDENCIA DE EFECTOS DESEABLES E INDESEABLES

Guía de Práctica Clínica Trastorno Bipolar en personas de 15 años y más - 2018

A. PREGUNTA CLÍNICA

En personas con trastorno bipolar, cursando episodio maníaco ¿Se debe usar antipsicóticos atípicos como monoterapia en comparación a usar otro estabilizador del ánimo como monoterapia?

Análisis y definición de los componentes de la pregunta en formato PICO

Población: Personas con trastorno bipolar, cursando episodio maníaco.

Intervención: Antipsicóticos atípicos como monoterapia.

Comparación: Otro estabilizador del ánimo como monoterapia.

Desenlace (outcome): Efectividad, efectos adversos.

B. BÚSQUEDA DE EVIDENCIA

Se realizó una búsqueda general de revisiones sistemáticas asociadas al tema de “Bipolar affective disorder”. Las bases de datos utilizadas fueron: Cochrane database of systematic reviews (CDSR); Database of Abstracts of Reviews of Effectiveness (DARE); HTA Database; PubMed; LILACS; CINAHL; PsycINFO; EMBASE; EPPI-Centre Evidence Library; 3ie Systematic Reviews and Policy Briefs Campbell Library; Clinical Evidence; SUPPORT Summaries; WHO institutional Repository for information Sharing; NICE public health guidelines and systematic reviews; ACP Journal Club; Evidencias en Pediatría; y The JBI Database of Systematic Reviews and implementation Reports. No se aplicaron restricciones en base al idioma o estado de publicación. Dos revisores de manera independiente realizaron la selección de los títulos y los resúmenes, la evaluación del texto completo y la extracción de datos. Un investigador experimentado resolvió cualquier discrepancia entre los distintos revisores. En caso de considerarse necesario, se integraron estudios primarios.

Seleccionadas las revisiones sistemáticas o estudios primarios asociadas a la temática, se clasificaron en función de las potenciales preguntas a las que daban respuesta. Al momento de definir la pregunta la evidencia ya se encontraba previamente clasificada según intervenciones comparadas. Los resultados se encuentran alojados en la plataforma Living Overview of the Evidence (L·OVE), sistema que permite la actualización periódica de la evidencia.

C. SÍNTESIS DE EVIDENCIA

Resumen de la evidencia identificada

Se identificaron 14 revisiones sistemáticas que incluyen 110 estudios primarios, de los cuales 109 corresponden a ensayos aleatorizados. Para más detalle ver “*Matriz de evidencia*”¹, en el siguiente enlace: [Intervenciones para la manía aguda en el trastorno bipolar](#).

Tabla 1: Resumen de la evidencia seleccionada

| | |
|----------------------|--|
| Revisión Sistemática | 14 [1-14] |
| Estudios primarios | 109 [15-123] ensayos aleatorizados y 1 observacional [124] |

Estimador del efecto

Se realizó un análisis de la matriz de evidencia. Si bien existen múltiples revisiones sistemáticas analizando la población de interés, solo una de ellas evalúa la comparación específica [13] (antipsicóticos atípicos como grupo versus otros estabilizadores del ánimo como grupo). Se utilizaron sus datos para confeccionar la tabla de resumen de resultados.

Se analizó también una revisión sistemática [14] enviada por el panel de expertos convocado por el Ministerio de Salud, la cual, si bien evalúa mediante la técnica de metanálisis en red una pregunta relacionada con la de este informe, no hace un análisis de la intervención y comparación de interés (antipsicóticos atípicos como grupo versus estabilizadores del ánimo como grupo), además de ser considerablemente más antigua, y no incluir algunos ensayos realizados con posterioridad a su fecha de búsqueda (2010).

Metanálisis

Si bien la revisión sistemática llevó a cabo un metanálisis, no lo presenta gráficamente.

¹ **Matriz de Evidencia**, tabla dinámica que grafica el conjunto de evidencia existente para una pregunta (en este caso, la pregunta del presente informe). Las filas representan las revisiones sistemáticas y las columnas los estudios primarios que estas revisiones han identificado. Los recuadros en verde corresponden a los estudios incluidos en cada revisión. La matriz se actualiza periódicamente, incorporando nuevas revisiones sistemáticas pertinentes y los respectivos estudios primarios.

Tabla de Resumen de Resultados (Summary of Findings)

| ANTIPSIKÓTICOS ATÍPICOS COMPARADO CON OTRO ESTABILIZADOR DEL ÁNIMO PARA BIPOLAR CON EPISODIO MANIACO. | | | | |
|--|---|---|---------------------------------|---|
| Pacientes | Personas con trastorno bipolar, cursando episodio maníaco. | | | |
| Intervención | Antipsicóticos atípicos como monoterapia. | | | |
| Comparación | Otro estabilizador del ánimo como monoterapia. | | | |
| Desenlaces | Efecto relativo (IC 95%) -- Estudios/ pacientes | Efecto | Certeza de la evidencia (GRADE) | Mensajes clave en términos sencillos |
| Efectividad | -- 1 metanálisis en red (network metanálisis) [13] | La efectividad de los antipsicóticos atípicos fue DME: 0,44 (IC 95%: 0,36 a 0,51) y otros estabilizadores del ánimo de 0,39 (IC 95%: 0,28 a 0,49), ambos resultados comparados contra placebo. Esta diferencia se reporta como no estadísticamente significativa. | ⊕⊕○○ ^{1,2} Baja | El uso de antipsicóticos atípicos podría tener efectividad levemente superior que otros estabilizadores del ánimo, pero la certeza de la evidencia es baja. |
| Efectos adversos | El efecto comparativo entre la intervención y comparación de interés sobre el desenlace efectos adversos no fue reportado | | -- | -- |

IC 95%: Intervalo de confianza del 95%.

DME: Diferencia de medias estandarizada.

GRADE: Grados de evidencia Grading of Recommendations Assessment, Development and Evaluation.

* La diferencia de medias estandarizada se utiliza cuando el desenlace ha sido medido en diferentes escalas y es difícil de interpretar clínicamente. Una regla general es que valores menores a 0,2 son de poca relevancia clínica, valores de 0,5 de relevancia moderada y 0,8 relevancia clínica importante.

¹ Se disminuyó un nivel de certeza de evidencia por indirecto, ya que los resultados provienen de un metanálisis en red (network metanálisis).

² Se disminuyó un nivel de certeza de evidencia por imprecisión, ya que cada extremo del intervalo de confianza conlleva una decisión diferente.

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